

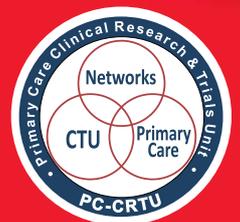
# In Contact

Winter 2015

**NHS**

**National Institute for  
Health Research**

Clinical Research Network  
West Midlands



## Working Together for Better Health

Patient Identification Centre (PIC) Studies

Top Recruiting Practices

**Delivering research to make patients, and the NHS, better**

**NHS**  
National Institute for  
Health Research

Clinical Research Network  
West Midlands



Max Feltham

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# Welcome

Dear Colleagues,

In this latest edition of In Contact we feature all the latest research being conducted across Birmingham and The Black Country. Additionally, there are features on findings from national studies which involved local patients recruited through our network of research active GP practices. We are also pleased to announce that the CRN: West Midlands are delivering courses on an introduction to Good Clinical Practice (GCP), specifically aimed at Primary Care. These courses are held throughout the year and are available online or face-to-face. Furthermore, these courses now have CPD points associated with them, so it is an excellent opportunity to bolster your appraisal.

Firstly, however, I would like to take this opportunity on behalf of the CRN: Primary Care to congratulate Dr. Clare Taylor on being awarded an MBE for services to General Practice. Dr. Taylor is an academic GP at the University of Birmingham and leads research on patient experiences of the clinical pathway for diagnosis of heart failure in Primary Care. It is for her work in establishing the RCGP's First5 programme, that she received the award in the Queen's

Birthday Honours. The programme supports new GPs through the formative years of independent practice. We hope that this additional support will encourage more graduates from medical school into General Practice and maintain GPs in the workforce. Furthermore, Dr. Taylor is an inspiration for trainee and junior doctors to engage with Primary Care research, because it is vital to ensure that good practice is evidence based.

Congratulations also go to our three top recruiting GP practices in Birmingham and The Black Country. We announced in the previous issue of In Contact that Hobs Moat Medical Practice, Three Villages Medical Practice and Greenridge Surgery recruited over 400 patients between them to secure the top spots. We have visited the surgeries in Solihull, Dudley and Birmingham and South Central CCGs to award them with their trophies. It should be noted, however, that the strength of Primary Care is that we are diverse and you and your surgery can contribute towards an array of research ranging from the large cancer, chronic kidney disease or blood pressure monitoring trials to the relatively smaller trials investigating GP views on rheumatoid arthritis, management of heavy



Greenridge Surgery receiving their plaque as a top recruiting practice.



Three Villages Medical Practice receiving their plaque as a top recruiting practice.



Hobs Moat Medical Centre receiving their plaque as a top recruiting practice.

menstrual bleeding or folic acid supplementation in the management of menopausal symptoms. If you are interested in being involved in research we can help you find a study that is beneficial to your practice and patients. Please visit us on: [www.birmingham.ac.uk/crn-wm](http://www.birmingham.ac.uk/crn-wm)

The CRN: Primary Care is in the process of appointing a Senior Research Nurse for Primary Care. They will lead our team of six Research Nurses who are embedded across Birmingham and The Black Country. This group of Research Nurses are able to support you at your practice with the delivery of clinical trials. Their experience and expertise are a vital resource to the CRN: Primary Care and we encourage your practice nurse to contact us, if they need guidance on research activity. One CCG in our area has taken an innovative step to appoint a Nurse Advocate for the Birmingham Cross City area. Maki Chermahini offers sessions to provide practical advice to practice nurses on how they can facilitate research in their GP practices. We hope that these new developments will encourage more practice nurses to support their patients enrolling into research studies. The role of practice nurse is an essential part of delivering research in Primary Care and we can offer studies that need input from this profession, such as the CANDID, FAST-Gout and HEAT study.

Our community pharmacies have been involved in clinical research over the last 6 months. Ten community pharmacies in our region were involved in an over the counter cough medicine. The study team had opened 30% of their sites in

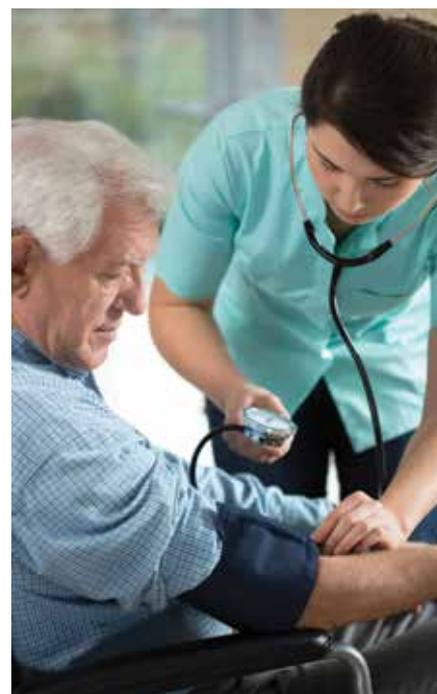
the West Midlands and they contributed to 50% of the national recruitment. Furthermore, three sites are recruiting to a study exploring pharmacy management of acne and dermatitis. This is in addition to their contribution of raising awareness of research studies being delivered in secondary care, such as EVRA and LASER and the Join Dementia Research. This is a new national initiative which allows people to register their interest in participating in dementia research and be matched to suitable studies. For further information please visit the website: [www.joindementiaresearch.nihr.ac.uk/](http://www.joindementiaresearch.nihr.ac.uk/)

We have been attending a number of large and small PLT events across the region to promote research. For instance, we were at the Walsall CCG PLT event this Summer held at Bescot Stadium and we attended meetings held by Dudley, Birmingham South and Central and Sandwell and West Birmingham CCGs. Forthcoming events will include an Industry Showcase event and our annual Research Site Initiative event. Please look out for the invites to these events.

Finally, I would like to finish by saying a sincere 'thank you' to all the Primary Healthcare professionals, who continue to actively engage in Primary Care research. Your enthusiasm and professionalism drives us forward to make patients, and the NHS, better.

**Dr Max Feltham**

Research Manager – Primary Care  
NIHR Clinical Research Network: West Midlands



# New Studies - Site Studies

## e-coachER



e-coachER is a multicentre RCT of an augmented exercise referral scheme (ERS) using web-based behavioural support in individuals with metabolic, musculo-skeletal and mental health conditions.

The study is funded by National Institute for Health Research Health Technology Assessment Programme (NIHR HTA) and is sponsored by University of Plymouth. The Principal Investigator for the study is Professor Kate Jolly (Professor of Public Health and Primary Care).

The study wants to determine whether the addition of a web-based support package (e-coachER) to usual ERS (intervention arm) increases physical activity at twelve months, compared with ERS alone (control arm), and whether such an intervention is cost-effective.

The study considers that, for patients with chronic medical conditions, providing additional support may help them overcome initial and

on-going barriers to maintaining a more physically active lifestyle, however it is unclear if current Exercise Referral Schemes (ERS) alone can provide this support. e-coachER study hypothesise that the additional support provided by e-coachER will improve the level of access to initial ERS support, improve the level of motivational support, and improve adherence to the ERS over a longer period of time than usual ERS, and thereby result in improved levels of sustained physical activity.

The study aims to recruit 180 patients in the pilot phase and 1220 during the full trial. The target population is Individuals living in Birmingham; Individuals registered at Birmingham General Practices.

Practices can take part either by PRO-ACTIVE SEARCH (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. Practice Nurse or GP to check interested participant's details and provide their approval before recruitment. Finally to liaise with CRN Facilitator or e-coachER Research Assistant who will visit the practice for study recruitment) or through REACTIVE RECRUITMENT by referring the ERS patient to the e-coachER research team.

### Learn More

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## 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  $\leq 3$ mmHg 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-out of a study invitation letter
- Receipt of monitors (frontline staff)
- Room hire

### Learn More

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# New Studies - PIC Studies



## eGFR-C

**Accuracy of glomerular filtration rate (GFR) estimation using creatinine and cystatin C and albuminuria for monitoring disease progression in patients with stage 3 chronic kidney disease (CKD): prospective longitudinal study in a multi-ethnic population**

There is major uncertainty about the accuracy of creatinine based equations (to provide estimated glomerular filtration rate (eGFR)) for kidney function testing in patients with stage 3 CKD. Stage 3 CKD affects around 3 million people in the UK; the large majority of these are managed in primary care.

This shortfall in the current laboratory test is of profound importance, as eGFR is used in national guidelines as the basis for recommended pathways for the investigation and monitoring of patients with CKD.

There is evidence that cystatin C is a more accurate molecule for kidney function testing in patients with stage 3 CKD. The NIHR invited applications for a study to provide evidence to

substantiate this and the eGFR-C study was subsequently funded. The eGFR-C investigator group includes clinical chemists, primary care physicians and nephrologists. The study is recruiting patients from primary and secondary care and includes stratification by ethnic group and the presence or absence of diabetes as a comorbidity.

The aim of the study is to assess the accuracy of GFR estimating equations in people with CKD stage 3 using creatinine and/or cystatin C for kidney function testing in patients with stage 3 CKD and to establish the accuracy of cystatin C. The study has recruited over 600 patients to date across 6 centres; the study needs 1300 patients to complete recruitment and is likely to provide practical outcomes that will improve the accuracy of kidney function estimation for patients with stage 3 CKD and help clinicians and their patients in primary and secondary care.

### Practices will be asked to

- Identify eligible patients from the CKD register
- GP to check the list for suitability in accordance with study inclusion/exclusion criteria

- Mail out to eligible patients. Pre-paid study packs will be provided by the study team

As a Participant Identification Centre (PIC), your involvement begins and ends with the identification of participants that meet the study inclusion criteria. Interested participants will then contact the eGFR-C study team at University Hospitals Birmingham NHS Foundation Trust.

### Practice Remuneration

Each practice will receive service support costs of £215.00 for initial set up, database search, list checking and mail out (payable on a pro rata basis dependent on patient numbers). In addition a recruitment incentive of £25 per patient recruited from within primary care has been included in the study grant.

### Learn More

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## Vitiligo Trial



Vitiligo affects around 0.5-1% of the world's population. Current clinical guidelines recommend the use of potent or super potent topical corticosteroids (TCS), topical calcineurin inhibitors, or narrowband UVB light therapy (NB-UVB) for the first line treatment of vitiligo. A Cochrane systematic review of 'Interventions for vitiligo' was last updated in 2010; one of the main conclusions of the update was that combination treatments seem to be more effective than mono-therapies in treating vitiligo but the trial evidence supporting their use is currently limited.

The trial objectives are to assess the effectiveness of TCS and home based NB-UVB therapy for the treatment of patients with early or limited non-segmental vitiligo, used as mono-therapy and in combination for up to 9 months.

- a) To assess whether NB-UVB light therapy is better than potent TCS for the treatment of early and limited non-segmental vitiligo.
- b) To assess whether combination of NB-UVB light therapy with potent TCS is better than either treatment used alone for the treatment of early and limited non-segmental vitiligo.

The sponsor of the study is University of Nottingham, the study is funded by NIHR Health Technology Assessment Ref 12/24/02 and the Chief Investigator is Dr Jonathan Batchelor, Consultant Dermatologist, University of Nottingham.

The HI-Light trial is a multi-centre double-blind, 3-arm randomised controlled trial (RCT) comparing potent topical corticosteroids to home based light therapy using hand-held devices, and to a combination of the two treatments.

Participants will receive up to 9 months of treatment. There will be 2 initial assessments at the hospital on consecutive days, then a 3, 6 and 9 month assessment at the hospital – which will be mainly answering questions, then follow up questionnaires at 12,15,18 & 21 months.

All the research activities are taking place in Royal Wolverhampton Hospital NHS Trust (Adults), Birmingham Children's Hospital (Children) and Solihull Hospital (Adult and Children) Patients choose the research site based on their convenience.

### Learn More

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# Current studies - Site Studies

## CAP

### Cluster randomised triAl of PSA testing for Prostate cancer

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

#### Practice involvement

Your practice might be contacted if a registered patient has been identified as having Prostate Cancer by the study team based in

Bristol through the Cancer Registries. The study team will seek your permission to contact your 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 team will compensate your practice for the additional GP or nurse time according to Clinical Research Network nationally agreed fees.



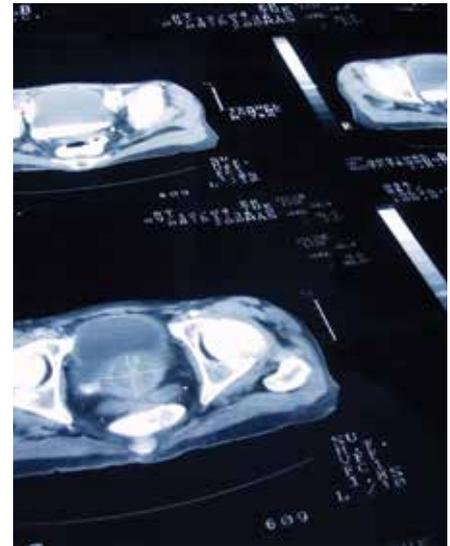
#### Learn More

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## 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

- Nominate 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

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# Current Studies - Site Studies

## Global Anticoagulant Registry in the FIELD (GARFIELD-AF)



GARFIELD-AF is an ongoing observational, multicentre, international registry of newly diagnosed atrial fibrillation patients with at least one additional, investigator determined risk factor for stroke. The aim of the study is to evaluate the management and outcomes of patients with newly diagnosed non-valvular AF at risk of stroke. The registry aims to enrol 55,000 patients at more than 1000 sites in 50 countries. Enrolment is taking place in five independent, sequential cohorts and patients are followed up for a minimum of two years. UK participants are recruited in primary care with the University of Birmingham as the recruiting centre.

GARFIELD-AF is now recruiting to the fifth and final cohort and recruitment is expected to end in July 2016. The UK continues to be a leading recruiter to GARFIELD-AF with 3047 UK participants enrolled to date.

Thank you to all the practices that are participating in GARFIELD-AF.

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

### Enrolment Period

2012 – June 2016

### Participants

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

### Other Information

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

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

### Intervention and Clinic

Suitable patients will be identified by their surgery, using an automated search, and then asked to attend an appointment with a University Research Nurse or Practice Nurse (relevant training will be provided) to consent to the trial and take a *H. pylori* breath test. Those with a positive result will be randomised to

receive a one week course of either eradication treatment or placebo, supplied by the trial centre. No follow-up visits for the patients are required, but any hospital admissions for ulcer bleeding will be recorded over a period of 2–3 years by the trial centre.

### Learn More

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

**Rachel Iles**

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# Current studies - Site Studies

## 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

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

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

Learn more

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**Trial Co-Ordinator**

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## Validation of home blood pressure monitors in patients with atrial fibrillation

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

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

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

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

We are looking to recruit up to 10 practices, 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 mail-out of study invitation letter

Learn More

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# Current studies - Site Studies

## TIME

### Treatment In Morning versus Evening (TIME) Study

The Treatment In Morning versus Evening (TIME) Study is funded by the British Heart Foundation. The main objective is to determine whether anti-hypertensive therapy taken in the evening has improved cardiovascular outcome compared with more conventional morning dosing. The study is trying to recruit approximately 10,000 patients from across the UK in order to find an answer to this clinically important

question. Patients diagnosed and treated for hypertension (all forms) with at least one antihypertensive drug, aged  $\geq 18$  and having a valid email address are randomised into two groups with one group taking the treatment in the morning and the other group in the evening. Moreover, the study also regularly monitors and records number of heart-attacks, strokes and vascular death from each group.

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

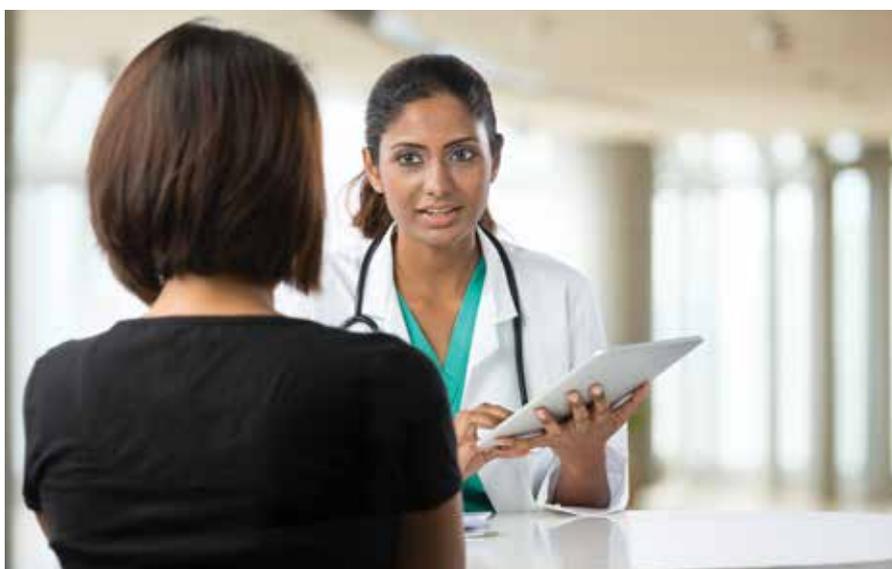
#### Learn More

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## 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  $\geq 140$  (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

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# Current studies - PIC Studies

## Brains in Transition Study



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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or

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## EAST

### Early treatment of Atrial fibrillation for Stroke Trial



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

This is a Patient Identification Centre (PIC) study so we are simply inviting you to identify potential patients who can be invited to take part in the study. In Birmingham, the study is based around 2 secondary care sites; City Hospital and University Hospital Birmingham. Professor Paulus Kirchhof, 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 2016.

**Practices will be remunerated for their involvement in the study.**

Learn More

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# Current studies - PIC Studies

## EVRA



### Early Venous Reflux Ablation Ulcer Trial

Simple study – ideal for novice practices!

#### Background

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

#### Recruitment

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

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

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

#### Practice Involvement

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

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

- Heart of England NHS Trust (Heartlands, Solihull & Good Hope hospitals)
- University Hospital Birmingham NHS Trust
- The Dudley Group NHS Trust (Corbett, Guest & Russells Hall hospitals)

#### Learn More

##### Sarah Campbell

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## 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

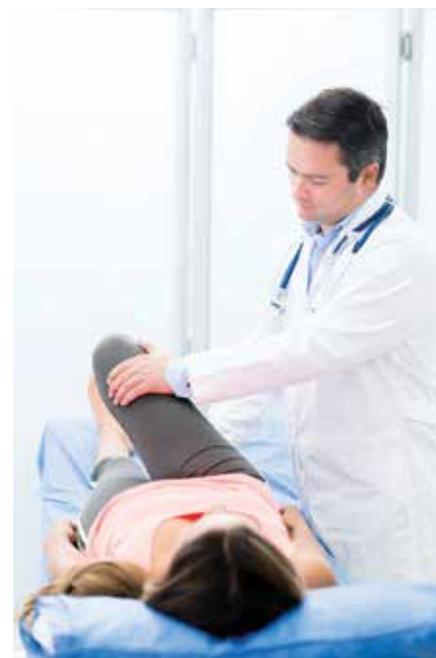
With BACK PAIN due to osteoporosis who have had at least one vertebral (bone in the spine) fracture.

Willing to be treated by either 'Hands on' physiotherapy OR Exercise physiotherapy OR Usual care (a computer will randomly choose treatment type).

#### Learn More

##### Saif Uddin

Research Facilitator, CRN: Primary Care  
Tel: 0121 414 8614  
Email: s.uddin@bham.ac.uk



## Current studies - PIC Studies

### Rehabilitation Enablement in Chronic Heart Failure: REACH-HF



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

The HF Manual comprises a self-help manual which patients will work through by a specially trained facilitator over a period of 12 weeks. The topics covered include a structured exercise programme, monitoring for fluid build-up, stress management, medication management and monitoring and managing heart failure. If the patient has identified a family

member or friend who provides unpaid support that they couldn't manage without (ie, a caregiver) and they consent to take part, they will receive the 'caregiver resource element' of the HF manual.

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

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

**Sheila Bailey**

Research Facilitator, CRN: Primary Care

Tel: (0121) 414 7956

Fax: (0121) 414 6571

Email: s.m.bailey.20@bham.ac.uk

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

### 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.

We would be very grateful for your support and involvement in this study.

Learn More

**Anu Krishna**

Research Facilitator, CRN: Primary Care

Tel: (0121) 414 6643

Email: a.t.krishna@bham.ac.uk



# Current studies

## CPRD



### Major new national research programme – Your participation invited

The CRN: West Midlands 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 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:WM 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: West Midlands can be at the forefront of research in primary care and joining CPRD can help do that.

#### Further Information and sign up

For more information go to:

<http://www.cprd.com/researchpractice/researchgppractice.asp#researchgppractice>



# In follow up

## ExACT



### Extended anticoagulation treatment for VTE: a randomised trial

Funded as part of an NIHR programme grant

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

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

#### Background to trial

Venous thromboembolism (VTE) is common with an incidence of approximately 1 per 1,000 per annum. It is associated with significant mortality and morbidity, including post-thrombotic syndrome (PTS). The annual recurrence rate following a first VTE is approximately 10% per annum irrespective of the duration of anticoagulation therapy.

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

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

#### Trial Intervention

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

#### For those of you who are already involved

We will be in contact as usual to organise rooms for follow up visits.

Please contact the study team on 0121 414 3354 if an ExACT patient experiences any adverse events.

#### There is a reimbursement for these services.

#### Learn More

Sheriden Bevan

Tel: (0121) 414 3354

Email: s.bevan@bham.ac.uk

# Study findings

## PRIMIT – Summary of Results



Because most of the population catches coughs, colds, sore throats and other respiratory infections, the spread of these viruses in the general population results in widespread illness. It also causes pressure on NHS services during the winter months, and this pressure is much worse in a pandemic flu year.

The PRIMIT study examined the real-world effectiveness of PRIMIT, a free-access, interactive, web-based programme, which aimed to reduce the transmission of the viruses causing respiratory infections by encouraging more frequent handwashing. The programme has four weekly sessions which explain medical evidence, encourage users to learn simple techniques to avoid catching and passing on viruses, monitor handwashing behaviour, and provide tailored feedback.

Across three winters from January 2011 to March 2013, in the midst of the season for flu and other respiratory infections, 20066 adult

patients aged 18 years and older took part from 344 general practices across the UK. Volunteers were randomly assigned access to the PRIMIT website or no intervention. Participants were followed for 16 weeks and questionnaires were used to measure episodes of respiratory infections, duration of symptoms, and to check whether other household members had a similar illness.

At 16 weeks, 4242 individuals (51%) in the PRIMIT group reported at least one respiratory infection compared with 5135 individuals (59%) in the control group, equivalent to a 14% reduction in risk. There was a similar reduction in transmission of viruses to family members. The risk of catching a flu-like illness was about 20% lower in the PRIMIT group compared to the control group, as was the risk of getting a gastrointestinal infection (diarrhoea, or diarrhoea and vomiting). The need for primary care consultations and antibiotic prescriptions were also reduced by 10-15%.

Most UK households now have access to the internet, and it has become a central source of health information in a pandemic, so PRIMIT could play an important role in reducing the spread of respiratory viruses (including flu). This could reduce the strain on the NHS not just in a normal winter but also during a pandemic – and at very little cost to the health service. This is a very important finding, as this is the first study worldwide to show that hand-washing can reduce respiratory infections within the home – not only for the person who washes their hands but also for all the other family members.

This study was funded by the Medical Research Council.

# Study Findings

## Efficacy of water preloading before main meals as a strategy for weight loss in primary care patients with obesity: RCT

A bottle of water before each meal could help in weight reduction, researchers say

Researchers from the University of Birmingham have shown that drinking 500ml of water half an hour before eating main meals may help obese adults to lose weight. They believe that the simple intervention could be hugely beneficial, and be easily promoted by healthcare professionals and through public health campaigns.

Obese adult participants were recruited from general practices and monitored over a 12 week period.

Each of the participants, all adults with obesity, were given a weight management consultation, where they were advised on how to adapt their lifestyle and improve their diet and levels of physical activity. 41 of those recruited were asked to preload with water, and 43 were advised to imagine that they had a full stomach before eating.

Those in the group who were instructed to 'preload' with water lost, on average, 1.3kg (2.87lbs) more than those in the control group.

Those who reported preloading before all three main meals in the day reported a loss of 4.3kg (9.48lbs) over the 12 weeks, whereas those who only preloaded once, or not at all, only lost an average of 0.8kg (1.76lbs).

Dr Helen Parretti, NIHR Clinical Lecturer at the University of Birmingham, explained, 'The beauty of these findings is in the simplicity. Just drinking a pint of water, three times a day, before your main meals may help reduce your weight.'

'When combined with brief instructions on how to increase your amount of physical activity and on a healthy diet, this seems to help people to achieve some extra weight loss – at a moderate and healthy rate. It's something that doesn't take much work to integrate into our busy everyday lives.'

Participants were encouraged to drink tap water. Sparkling water, sodas or sweetened drinks were not allowed as part of the study.

The study, published in the journal *Obesity*, showed encouraging initial results for the trial, and the team hope that the findings will inform further research into the benefits of water preloading before meals. They hope to receive backing for a trial with a larger number of participants and over a longer period of time in order to confirm the findings.

Dr Parretti added, 'Losing a few extra pounds over the course of a year can be significant to an individual, and this could be an easy way to help with that weight loss. It's a simple message that has the potential to make a real contribution to public health.'

For interview requests, a copy of the full paper or for more information, please contact Luke Harrison, Media Relations Manager, University of Birmingham on +44 (0)121 414 5134.

To read the full paper online; visit <http://onlinelibrary.wiley.com/doi/10.1002/oby.21167/abstract>



# Courses

## Patient Recorded Outcomes Measures in Clinical Trials

The University of Birmingham is pleased to introduce two new courses, running next March, designed specifically for those working with Patient Recorded Outcome Measures (PROMs) in clinical trials.

The first 'Collecting PROMs for clinical trials' is designed for research nurses, data managers and study coordinators and will run on Wednesday 16th March 2016. It will cover the different kinds of PROMs and how and when they should be administered, how to assist patients completing PROMs, how to prevent and subsequently manage data and scoring errors, how to support patients in answering sensitive questions, how to manage patient distress and how to collect PROMs in a variety of patient groups and settings.

The second 'Successfully incorporating PROMs in clinical trials' is suitable for chief and principal investigators, trial managers, clinical researchers and academics and will run on Thursday 17th March 2016. This will look additionally at understanding key design issues, what information should appear in the trial protocol and staff training, understanding PROM data analysis and reporting PROM results using the CONSORT PRO extension.

Both courses are taught by expert faculty, including Professor Melanie Calvert, Professor of Outcomes Methodology at the University of Birmingham and cost £150 per day. For more information or to book please get in touch with Jessica Dalton (CPD Administrator) on 0121 414 3281 or [j.a.dalton@bham.ac.uk](mailto:j.a.dalton@bham.ac.uk).



## NIHR CRN Online Learning Good Clinical Practice Training

The NIHR has recently made changes to Good Clinical Practice (GCP) training which is now specific to researchers working within primary care. The Introduction to Good Clinical Practice eLearning (Primary Care) now attracts 4 CPD points. Face to face training attracts 6 CPD points. This training is free of charge and available to all healthcare professionals involved in primary care research.

If you would like to register for this training please follow the link: <http://learn.nihr.ac.uk/login/index.php>

If you would like to know more, please contact us on:  
Tel: 0800 085 4229  
Email: [crn-wm@contacts.bham.ac.uk](mailto:crn-wm@contacts.bham.ac.uk)



## University Accredited Courses 2016

For more information on these courses, please contact Amy Partleton at [a.partleton@bham.ac.uk](mailto:a.partleton@bham.ac.uk)

25–28 January

### Treatment of Heart Failure in Primary Care

This course offers a systematic understanding of heart failure and an understanding of how to apply this knowledge to practice; a critical awareness of current management issues and new insights into the management of heart failure. The course will also provide skills to enable autonomous practice in dealing with more complex problems and unpredictable situations and the ability to critically evaluate current research in the heart failure arena. The course can be taken as standalone CPD or, on the completion of coursework, credited with 10 or 20 university credits at Masters level.

Cost: £500 plus £200 bench fee for credits.

8–10 February

### Treatment and Management of Hypertension in Primary Care

This course equips you with the ability to deal with complex issues underpinning hypertension management in primary care, critically evaluate the prevention of long term complications according to current guidelines, understand the roles of the multidisciplinary team in hypertension care and review the requirements of clinical governance for hypertension management. The course can be taken as standalone CPD or, on the completion of coursework, credited with 10 or 20 university credits at Masters level.

Cost: £500 plus £200 bench fee for credits.

7–9 March

### Stroke Management and Atrial Fibrillation in Primary Care

This course will provide theoretical and practical knowledge of the condition of Atrial Fibrillation. Diagnosis will be examined, treatment (both medical and surgical) explained and evidence based management to include anticoagulation for stroke prevention. The course can be taken as standalone CPD or, on the completion of coursework, credited with 10 or 20 university credits at Masters level.

Cost: £500 plus £200 bench fee for credits.

18–20th April

### Gynaecology in the Community

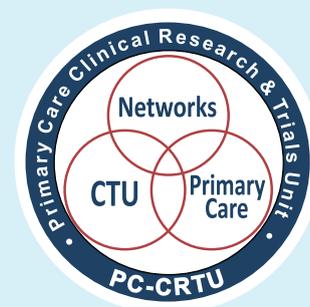
This module is aimed at general practitioners and practice nurses working in the community required to develop competencies in the management of gynaecological disorders to an advanced level. It looks at the theory and practice underpinning complex and common gynaecological conditions, referral pathways and the roles of the interdisciplinary team. The course can be taken as standalone CPD or, on the completion of coursework, credited with 10 or 20 university credits at Masters level.

Cost: £500 plus £200 bench fee for credits.





# Keep In Contact



Interested in taking part in research? We'd like to hear from you.

- You will always be able to choose your practice's level of involvement.
- You will be remunerated for practice time spent on research.

## Contact details:

Name:

Job title:

Practice address:

Postcode:

Practice code:

Email:

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

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

You can:

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

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

### **Primary Care Clinical Sciences**

University of Birmingham  
Primary Care Clinical Sciences Building  
Edgbaston, Birmingham B15 2TT

Visit our website

[www.birmingham.ac.uk/crn-wm](http://www.birmingham.ac.uk/crn-wm)

### **General Enquiries**

Tel: 0121 414 8843

Fax: 0121 414 2282

### **Randomisation Service**

We now offer a telephone  
randomisation service for studies.  
Contact us for further details  
on 0121 414 8532

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