

Clinical Research Network
West Midlands



*National Institute for
Health Research*

In Contact

Spring 2017

Working Together for Better Health

Launch of new Clinical Research Network West Midlands Website

Patient stories



Delivering research to make patients, and the NHS, better

Introduction

Hello,

My name is Louise Jones and I would like to introduce myself as the Research Manager for Primary Care covering Birmingham and the Black Country. I have worked for the NHS since January 2005 in various research related roles, spanning both primary and secondary care settings. I joined the Clinical Research Network in 2009 as a Research Management and Governance Manager working in the South of the region, and commenced in my current post in June 2016.

During my time with the NHS, I have been a Research Manager working on behalf of five PCTs and three CCGs under the terms of Service Level Agreements; I have also visited many GP Practices to deliver Good Clinical Practice (GCP) training.

Working with these organisations, I have seen the increasing pressures and an ever changing and challenging landscape; however, by working collaboratively, I am confident that my team and I can continue to support our research partners and primary care colleagues to maintain the successful delivery of high-quality portfolio research across the patch.

Best wishes,

Louise

Research Manager – Primary Care
Birmingham and Black Country



Louise Jones

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How can the Primary Care Research Network support your practice in research activity?

Dear colleagues,

I recently became the Clinical Lead for the Clinical Research Network (CRN) Primary Care in Birmingham and the Black Country and I am pleased to have this opportunity to introduce myself and explain to you about the different ways the CRN Team can facilitate your engagement with research activity.

As a Birmingham graduate I am familiar with many of the practices across our patch, and as a practising GP in Dudley I am well aware of the many pressures that surgeries are currently facing, that may hinder them from taking part in research activity. Surgeries that are involved in research generally find the activity very enjoyable, quite straightforward, and often provides excellent Quality Improvement evidence for Continuous Professional Development (CPD) activity and also for Care Quality Commission (CQC) inspections, noting that many of the practices which achieve 'outstanding' are highly 'Research Active'. I would urge practices to keep engaging in research so that we can continue to provide the best data to make evidence-based improvements in care.

We have a number of different studies on offer which you can read about over the following pages. The CRN will provide support, funding and infrastructure for GP practices to engage in research, and we can help you select studies that are right for you and your practice.

We have a team of facilitators, research nurses and GP Champions that can advise you on the feasibility of hosting research in your practice. We can also provide you with the essential training to support your research activity, including access to 'Good Clinical Practice' (GCP) training, and even the Royal College of General Practitioners (RCGP) Research Ready Toolkit.

We are currently adapting our established Research Site Initiatives (RSI) scheme which rewards practices financially depending on the number of studies undertaken and recruits made and details about this scheme will be made available in due course.

Finally, you can always be assured that any invitations you receive from us to participate in research will have been reviewed to ensure they meet the highest standards of research governance and patient safety, and you are always welcome to contact our team if you require any clarification about this, or any further information.

Thank you for your help and ongoing support for Primary Care research.

Best wishes,

David

Dr David Shukla MRCGP
Primary Care Clinical Research Specialty Lead,
Clinical Research Network, West Midlands



David Shukla

Why we need patients to tell us their stories of taking part in research

News

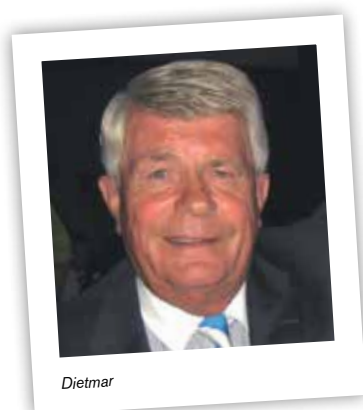
Patient and public involvement is key to the design and implementation of clinical research, and by raising the profile of the contribution they make, we can encourage others to take part.

By telling patient stories, we aim to capture the human element behind the research we deliver. The Network's Patient and Public Involvement and Engagement Team helps provide a platform for patients to tell us about their experience of taking part in research – how they were approached, how they felt about it, what their motives were, what was involved and how it impacted on them.

We can use patient stories to raise the profile of research by promoting them to patients, carers and the general public, with a view to encouraging them to consider participation. We do this online, in the media (including social media) and face to face at events.

A pack is available to help clinical staff capture these stories – please contact Mary-Anne Darby, Head of Patient and Public Involvement and Engagement: mary-anne.darby@nihr.ac.uk

You can read some of our patient stories on the CRN WM website: www.crn.nihr.ac.uk/west-midlands/casestudies and also see videos of patients talking about their experience.



CANDID
CANcer Diagnosis Decision rules

Dietmar's Story

This study aims to help doctors diagnose cancer quickly so that potential high risk patients are detected sooner and unnecessary examinations are minimised for those patients that are low risk. The research is about finding what symptoms and examinations are best for predicting lung and bowel cancer.

Did you know anything about research before taking part?

Nothing at all, the advantages of taking part in research were pointed out to me by my doctor when I visited him for my constant coughing for over three weeks.

Why did you consult your doctor?

My cough came on suddenly, I thought I was going to get a cold so wasn't too concerned, although it did get progressively worse and then I happened to see an article in a national newspaper advising anyone not to ignore a consistent cough that has lasted more than three weeks, but to see their GP and get checked out. As an ex-professional footballer for Coventry City, I am accustomed to having very regular medical attention and check-ups so the thought of seeing my GP held no fears.

I would advise all young and old men not to be afraid . . . go and get checked out . . . thinking it will be alright and will go away could be fatal.

Sadly, three people very close to me thought the problem would go away, and I lost all three, including my wife, Maureen who was only 51 when she passed away with leukaemia. She was constantly tired and lacking energy but thought it was because she was working hard and that it would be OK soon.

I insisted she seek help and took her to see her GP. She received excellent attention from the NHS, a first class organisation; she had blood tests and x-rays that confirmed she had leukaemia, and her therapy started immediately. Three months later she passed away.

Why I joined the study

From my experience, there were no downsides to participation in research. As anticipated, I was tested, x-rayed and was generally well looked-after; I also had the advantage that I would find out more about my body and learn more about my condition.

Fortunately, my outcome was good. I would most certainly recommend it . . . it makes you feel good to know and understand.

I would certainly be prepared to take part in another study: the more you know about yourself the better, such knowledge could be very important. Participation in research is something that I would wholeheartedly recommend to family and friends. My own health is important to me, I always try to make sure I keep myself fit by doing exercises, swimming, healthy eating and keeping my weight down.

Health research means so much to me, it shows how much the NHS is trying to help by making us aware of the importance of keeping healthy and fit [and by] giving us good advice.

As told to Eleanor Hoverd, Research Nurse, February 2017.

News



Helen Stokes-Lampard and David Shukla

West Midlands GP Practices Help to Recruit One Million Patients to Clinical Research

New figures published by the National Institute for Health Research (NIHR) have confirmed that one million patients have now taken part in research via their local GP practices, pharmacies and dentists in England, through the NIHR Clinical Research Network (CRN).

CRN West Midlands' Clinical Director Professor Jeremy Kirk commented: 'It is a fantastic reflection of the commitment of GPs and other Primary Care researchers that more than 175,000 patients in our region have been given the opportunity to take part in high quality studies through their GP practices, contributing to this one million total. We are proud of our contribution, here in the West Midlands area, with 43% of our local GP Practices involved in research.'

Professor Helen Stokes-Lampard, Chair of the Royal College of GPs, whose practice is in Staffordshire, called it 'an amazing achievement' and thanked GPs and their practices for making it happen.

The NIHR is the research arm of the NHS, and this research is delivered and supported by 15 local Networks. Ultimately, clinical research means patients get access to new treatments, interventions and medicines, and investment in research means better, more cost-effective patient care.

See Coventry City legend Dietmar Bruck's Story of taking part in research on page three.

Learn more:

Claire Hall

Communications Lead
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www.crn.nihr.ac.uk/westmidlands

The Clinical Research Ambassador Group – Valuing Patient and Public involvement in research

Improved care and better outcomes are strongly associated with research active organisations. At the Heart of England NHS Foundation Trust (HEFT), we have a commitment to ensure research is an integral part of the clinical care that is provided to our patients. As part of this commitment, we have a research Patient and Public Involvement (PPI) group called The Clinical Research Ambassador Group (CRAG) in order to engage with patients, carers and members of the public to enable them to voice their opinions and offer their perspective on the research we do at HEFT.

Public involvement in research is essential to enable us to gather a different perspective and outlook on the research we do within the Trust.

It allows us to draw on others personal knowledge and experiences to provide an alternative perspective on the array of research topics we are involved with in the Trust. This can ensure the research methods and outcomes are important and relevant to the public and patient's needs.

CRAG was formed in 2012 for people who have an interest in research to meet, through meetings and events held at the trust, to discuss, inform and update on research within the Trust. Membership of the group is open to anyone within the HEFT catchment area and the level of involvement is up to the individual. This can vary from being involved with designing research projects to ensuring research questions being asked are understandable and relevant to the public.

Learn more:

Teresa Melody

CRAG
Tel: 0121 424 2966
Email: teresa.melody@heartofengland.nhs.uk
Twitter: @CRAGHEFT



New Studies – Site Study

The CEDAR Randomised Controlled Trial

The CEDAR trial aims to discover if painkilling ear drops can reduce antibiotic consumption in children aged 12 months to ten years presenting to primary care with acute otitis media (AOM), by directly treating the ear pain caused by the infection. The trial has three arms: (1) active ear drops (Auralgan) administered with usual care; (2) placebo ear drops and usual care; and (3) usual care only. Usual care is as per NICE guidelines, ie, advice about the use of rescue analgesia for symptom management, with or without a delayed antibiotic prescription.

Why is this trial important to the NHS?

AOM is common in children under ten and causes pain and distress to children and their families. Despite good evidence that most children will not benefit clinically from antibiotics, they are still prescribed for most children with AOM. Antibiotics don't treat the child's pain, in most cases do not help to treat the infection (because many ear infections have a viral origin), but can cause side effects (such as diarrhoea) and contribute to the problem of antibiotic resistance.

We want to find out if pain-killing ear drops can help to reduce ear pain in children with ear infections, if they could help children feel better more quickly and reduce unnecessary antibiotic use. If we show the drops work, clinicians will have a better treatment to offer children in the future, and the drops could even become available over-the-counter at pharmacies.

The CEDAR intervention

The ear drops are Auralgan, which contain benzocaine (a pain killer) and phenazone (an anti-inflammatory drug). They are manufactured by Pfizer Consumer Healthcare and currently available as an over-the-counter medicine in Australia, New Zealand and other countries. They are not available in the UK. Auralgan ear drops have a robust safety profile and are known to be as safe as other commonly prescribed medicines for children, such as antibiotics.

Which children are eligible for this trial?

Children aged between 12 months and ten years with ear pain within the last 24 hours, if the clinician's working diagnosis is otitis media and if they do not require a same-day antibiotic under NICE guidelines.

What is involved for children and their parents?

Parents/guardians of participating children will be asked to complete a daily (paper or online) Symptom and Recovery Questionnaire about their child's symptoms, on the same day as recruitment and over the next seven days. If the child has been randomised to receive ear drops, the parent will be asked to give them the ear drops, every 1–2 hours and up to 12 times per day, until the child's pain is relieved. A small number of parents will be invited to take part in a longer qualitative interview. After three months, parents will be asked to complete a brief postal or online questionnaire about their child's quality of life.



What is involved for recruiting primary care sites?

Sites will opportunistically identify and recruit to a target of six children, explaining the research to parents and taking informed consent and assent as required. Clinicians will complete the baseline Case Report Form and enter the data online. Practice staff will explain to parents of children allocated to one of the ear drops arms how to give the ear drops and tell them what is involved in follow-up. After three months, sites will be asked to complete a review of the child's primary care medical notes. Additional database searches are optional. Sites will be appropriately reimbursed for all CEDAR activities through a combination of research costs and approved NHS support and treatment costs.

For further information or to register your interest please contact the CEDAR study team at cedar-trial@bristol.ac.uk, or email: anuradha.krishna@nihr.ac.uk

The CEDAR trial is a National Institute for Health Research (NIHR) portfolio study funded by the Health Technology Assessment (HTA) Programme (ref 18/33/18).

** Due to a delay in the manufacture of the placebo, CEDAR will start as a two arm pilot trial of active drops against usual care only, and introduce the 3rd placebo arm from November 2016.*



New Studies – PIC Study

RAte control Therapy Evaluation in permanent Atrial Fibrillation (RATE-AF) trial

Atrial Fibrillation is increasingly common and an important cause of poor quality of life and heart failure in older patients.

The RATE-AF trial is designed to evaluate the use of rate control therapy to benefit patient-reported quality of life and improve heart function.

The trial is recruiting permanent AF patients newly in need of rate control therapy, with current symptoms of breathlessness aged 60 years or older. RATE-AF is funded by the NIHR and will assess patients over a one-year period, based at the Queen Elizabeth Hospital and the University of Birmingham:

www.birmingham.ac.uk/rateaf

What is involved for patients?

- Randomisation to digoxin or bisoprolol for rate control, with Consultant Cardiologist-led study visits at baseline, two weeks, six months and 12 months.
- Questionnaires on quality of life, heart function assessment with ultrasound, heart rate recorder and walking test.
- Taxi fares to the hospital paid for all visits.

What is the benefit for GPs?

Direct access to the AF team, with patient appointments usually within 48–72 hours. Includes all components of clinical care that would usually require referral (consultations, echocardiography, ambulatory ECG and follow-up).

Learn more:

Karina Bunting (NIHR research assistant) /

Dr Dipak Kotecha (Consultant Cardiologist)

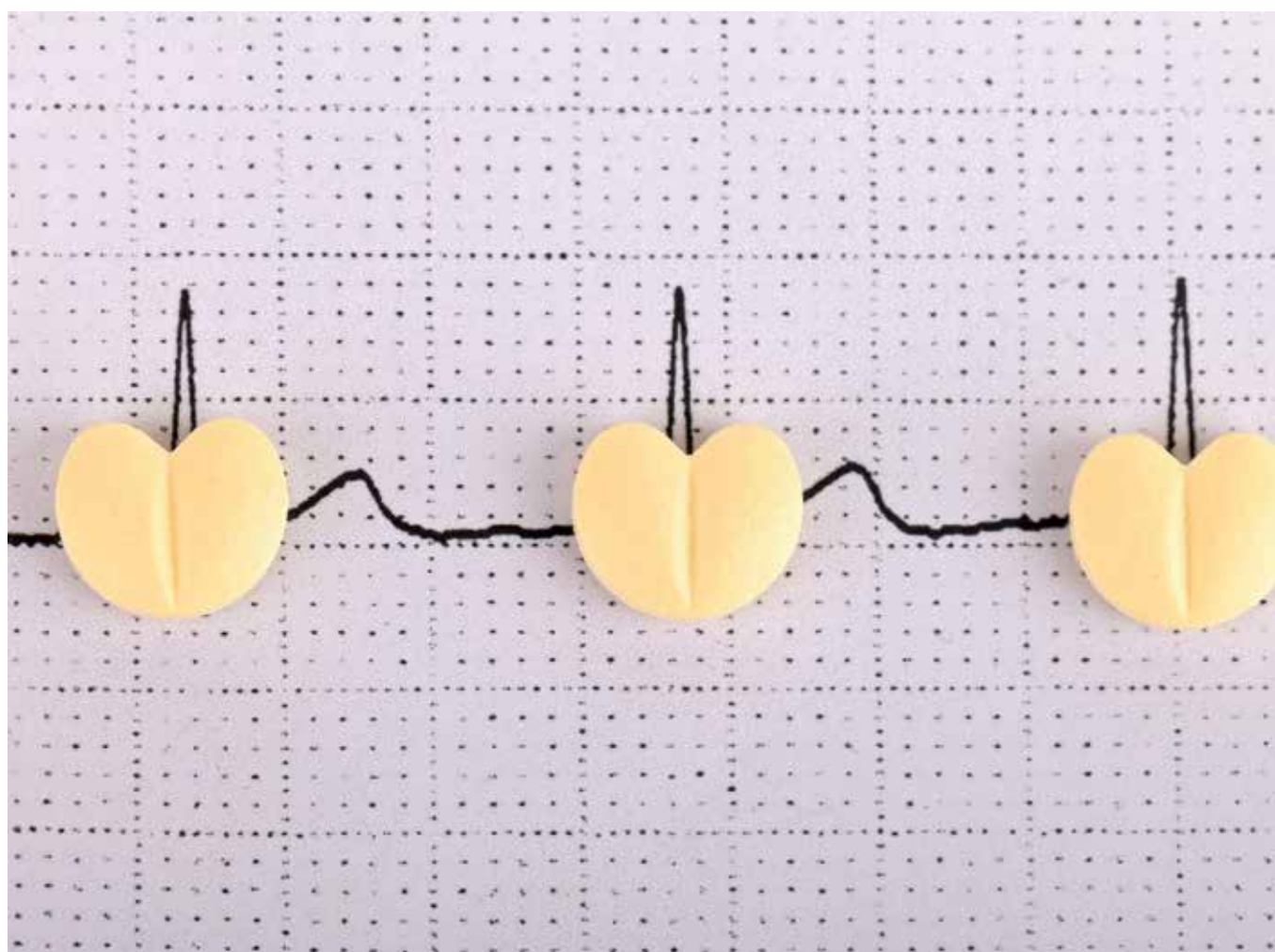
Tel: 07867 551957

Email: karina.bunting@nhs.net

YouTube video: search for "rate af"



**National Institute for
Health Research**



New Studies – PIC Study

Supporting Primary Care with Challenging Behaviour in Dementia: MEDREV

The National Dementia Strategy introduced a target of reducing the prescribing of antipsychotics. Aston University, in conjunction with a number of other organisations, is running a research project entitled MEDREV.

MEDREV aims to test the feasibility of staff training (for care home staff and GPs) and medication review (by specialist pharmacists) to limit the inappropriate prescribing of psychotropics for BPSD (Behavioural and Psychological Symptoms of Dementia) in people with dementia in care homes.

Key points:

- The medication review includes all psychotropics for BPSD (there is increasing evidence that focusing on anti-psychotics has simply driven prescribing to other potentially inappropriate medicines).
- By training care home staff and providing them with other 'tools' to help them manage BPSD we aim to reduce their reliance on medication.
- The input from secondary care specialists is designed to support primary care with managing this complex area.
- The medication review is collaborative and responsibility for implementation will continue to rest with the GP; the GP is under no obligation to implement the review.

What is involved for practices?

- Receive training.
- Collaborate with the medication review process.

Ethics and governance:

The research is funded by the NIHR and has full ethical and governance approval. Service support costs for practices are fully funded. It has the full support of the local Clinical Research Network, the CCGs in greater Birmingham and is closely aligned to the Birmingham Dementia Strategy.

The benefits:

Potential benefits for primary care and people with dementia:

- Support from expert secondary care pharmacists with managing BPSD.
- Enhance practice achievement on QOF and contributes to individual revalidation / appraisal portfolios.
- Training on up to date evidence for managing BPSD including case discussions.
- Formal written evidence of active engagement in research for CQC purposes.

The team:

This research is conducted by an inter-disciplinary team of academics and clinicians, including GPs, Health Psychologists, Pharmacists and Psychiatrists.

The chief investigator is Dr Ian Maidment, Senior Lecturer in Clinical Pharmacy, at Aston University who has worked in the field of dementia care, both as a clinician and researcher, for over 20 years. Rachel Shaw, a Reader in Health Psychology at Aston, leads on the training aspects. Steve Iliffe, Emeritus Professor of Primary care for Older People, University College London is a co-applicant and Dr Elizabeth Bates, NIHR Academic Clinical Lecturer in Primary Care at the University of Birmingham and Practising GP is providing local support.

Full details of the study are available at www.aston.ac.uk/medrev

The protocol is published in BMJ Open: <http://bmjopen.bmj.com/content/6/3/e010279.full>

If you have any further questions or would like to be involved, please do not hesitate to contact us.

Learn more:

Dr Ian Maidment

MEDREV Chief Investigator, Senior Lecturer in Clinical Pharmacy, Aston University, Email: i.maidment@aston.ac.uk





Medicines & Healthcare
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New Studies – PIC Studies

DECIDE: Real-world type 2 diabetes study

DECIDE is a pioneering real-world pragmatic trial investigating the effectiveness of dapagliflozin compared to Standard of Care for second line treatment. The study is looking at Patient Population of Type 2 Diabetes Mellitus; Uncontrolled on first-line metformin treatment.

Interested Practices (EMIS or VISION) need to first join CPRD using online link: www.cprd.com/generalpractitioner/ and send an expression of interest to pragmatics@cpdr.com.

Next they need to:

1. Sign and return Investigator Agreement, protocol signature page, CV and online Site Specific Information (using IRAS account).
2. Complete a short e-learning module (GCP and Protocol training) on CPRD study platform after activation.
3. Store and maintain the supplied Site Investigator File.

Patient recruitment will be during their standard appointment. Investigator's (either GP or Nurse Prescriber) need to identify potential participants (using a list provided by CPRD), consent and randomise using online CPRD platform.

Reimbursement will be £200/patient enrolled (Vision), £300 (EMIS), £250 Site set-up and management and additional drug reimbursement per patient per month is provided.

Learn more:

Anu Krishna

Research Facilitator

Tel: 0121 414 6643

Email: anuradha.krishna@nihr.ac.uk



An exploration of parents' perceptions and experiences of using e-cigarettes in homes with children (PPEC Study)

(This study is considered a Patient Identification Centre (PIC) study but will contribute towards meeting the Research Site Initiative (RSI) scheme criteria.)

The study aims to explore parents' perceptions and experiences of using e-cigarettes in homes with children.

GP Practices will be asked to:

- Display posters advertising the study
- GP, Nurse and/or Receptionist to identify potential participants and hand out a brief study information leaflet

Study duration: 12 months
(1 May 2016 to 30 April 2017)

Learn more:

Marie Crook

Research Facilitator

CRN West Midlands

Tel: 0121 414 6270

Email: marie.crook@nihr.ac.uk



Current Studies

Mixed Methods Multimorbidity Study (MiMMS)

Overview:

MiMMS seeks to highlight the challenges faced by healthcare professionals when treating patients with multiple chronic conditions. We are working with the School of Computer Science at The University of Birmingham to form a new software-based tool to help support clinicians treating patients with more than one condition. To ensure this tool is useful for you and your practice, the MiMMS research is gathering evidence on the challenges faced by primary care in treating and managing patients with multimorbidity.

Design:

MiMMS has two phases: The first phase consists of a series of short, semi-structured interviews with clinicians around the challenges of treating patients with multiple conditions. In particular, we are interested in issues that arise from following multiple sets of guidelines, the influences that shape decisions on

medications, and how new national guidance or policies are incorporated. In the second phase, anonymous data is extracted from practices' clinical management system (at this point the software is only compatible with EMIS) to help us understand the number and variety of medications prescribed for patients with a minimum of two out of six common conditions; COPD, Type 2 Diabetes, Depression, Ischaemic Heart disease, Osteoarthritis and Hypertension.

Current progress:

We have reached our site recruitment target and Phase One data collection is nearly complete. Phase Two is about to start and once completed we can analyse individually and collectively the audit data of prescriptions issued in the last 12 months for patients with at least two of the target conditions.



Future plans:

Whilst recruitment for this study has closed, there will be an opportunity to take part in the wider grant as we begin user testing the software prototype later in the year. If you are interested in the final phase and contributing to the final design and functionality of the software please contact Ruth Backman for further information. In the meantime our thanks go to all of the participating primary and secondary care centres in the West Midlands for their ongoing support of this study.

Learn more:

Ruth Backman

Research Fellow, University of Birmingham

Tel: 0121 414 3761

Email: r.backman@bham.ac.uk

Join Dementia Research (JDR)

Join Dementia Research enables, empowers and encourages people to become involved in dementia research. As well as supporting people with dementia and their carers they can participate in research that might benefit them and/or others in the future, it also helps researchers and the NHS find new ways to care, treat, fight and beat dementia.

To do this we want to contribute to increasing the numbers of people with dementia and their carers participating in research, with the aim that 25% of people diagnosed with dementia will register as a volunteer on Join Dementia Research and 10% will be participating in research, up from the current baseline of 4.5%.



Currently there are more healthy controls than people with dementia registered. Although this is great that people are willing to contribute to research, we do need to better support people with dementia and their carers in accessing research through Join Dementia Research. For more information please go to the website address. If you have any specific queries about JDR please contact the National Institute for Health Research Clinical Research Network West Midlands office on 0121 301 4325 or email jennifer.swain-boateng@nihr.ac.uk who will direct your query to a member of the team.

Please help us by displaying a poster and leaflets in your practice and talking to people with dementia and their family members about the JDR service. To obtain the promotional materials please contact Sarah Hinton using the contact details below.

For more information:

www.joindementiaresearch.nihr.ac.uk

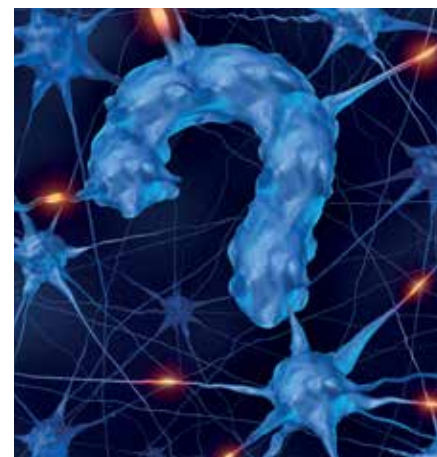
Learn more:

Lucy Hughes

Research Facilitator CRN Primary Care

Tel: 0121 515 8740

Email: lucy.hughes@nihr.ac.uk



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

Learn more:

Brains in Transition (BrIT) team

Tel: 07934 996686 / 0121 414 4937

Email: brit@contacts.bham.ac.uk

or

Anu Krishna

Research Facilitator, CRN: Primary Care

Tel: 0121 414 6643

Email: anuradha.krishna@nihr.ac.uk



UCON Study

Ulipristal acetate versus conventional management of heavy menstrual bleeding (HMB; including uterine fibroids): a randomised controlled trial and exploration of mechanism of action.

Previous research has shown that a hormone releasing coil, which is fitted inside the womb, is effective in reducing the impact and symptoms of heavy menstrual bleeding. Other medical treatments, including the contraceptive pill and non-hormonal treatments also reduce bleeding, but not as well as the coil. Ulipristal has been found to quickly reduce bleeding in women with large, non-cancerous growths in the womb, known as fibroids.

It is not known whether this drug is effective in reducing the impact of heavy menstrual bleeding in women who do not have fibroids, or have small insignificant fibroids. It is also unclear how ulipristal stops menstrual bleeding and its effect on the womb lining.

The aim of the study is to test the hypothesis that ulipristal acetate (UPA; Esmya®), is more effective than the levonorgestrel releasing intrauterine system (LNG-IUS, Mirena®) for the long-term treatment of HMB. Furthermore, we aim to understand the mechanism of action UPA on the endometrium and its effects upon the vasculature and structure of the uterus. The study will be looking to recruit females aged 18 years or over who perceive their bleeding to be heavy or troublesome.

What is involved for practices?

- Search GP database in accordance with inclusion/exclusion criteria as defined in the study protocol, GP to check the list
- Mail out to potentially eligible patients using DOCMAIL

Practice Remuneration:

Service support costs: £56.97 (database search and list checking)

Research costs:

£12.44 per patient mailing using DOCMAIL

The above costs are pro-rata based on a mailing of 41 patients.

This is PIC activity and recruitment and consent will be undertaken by the study team located at Birmingham Women's hospital.

We are looking to recruit ten practices within this locality.

UCON is funded by Medical Research Council (MRC) and National Institute for Health Research (NIHR) Efficacy and Mechanism Evaluation (EME) programme (Ref 12/206/52)

Learn more:

Anu Krishna

Research Facilitator, CRN Primary Care

Tel: 0121 414 6643

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

Current Studies – SITE Studies

REACT: RETirement in ACTion study

An opportunity for your practice to be involved in a major study to help older people stay fitter and live independently for longer.

REACT (REtirement in ACTion) is a new intervention study aimed at preventing lower limb disability in older people using an exercise-based rehabilitation programme. It has been shown to be effective in a clinical trial in the US and we now have funding to ascertain whether or not the REACT intervention is useful and good value for money as a means of increasing physical function in older adults in a UK setting.

REACT will recruit sedentary, community living, older persons aged 65 and over, with functional limitations (ie, who are at risk of major mobility limitations), but who are still ambulatory. The aim is to target a non-disabled, but at-risk population. REACT intervention is a 12-month programme with a strong social element. It starts as a centre-based exercise programme, but adds support for gradually 'translating' exercise and physical activity into participants' day-to-day lives. It will be delivered in community centres and fitness/health clubs when low-cost daytime capacity is available.

Sessions will be organised as group activities (15 per group) with individually tailored elements, and will include cardiovascular, strength, co-ordination and flexibility/balance exercises. Increased daily walking will also be encouraged and social engagement and enjoyment will be prioritised.

What is involved for practices?

- Search GP database
- GP to check the list
- Mail out to eligible patients

Patients will respond directly to the study team based at the University of Birmingham.

Remuneration:

£601.53 – traditional mailout or
£440.63 – docmail option

(The above figures are pro-rata based on the GP checking a list of 579 patients from a database search).

The target number of participants is 768 across all the trial centres (Bath, Bristol, Birmingham and Devon) with the aim of recruiting around 32 patients per practice (dependent on list size).

Learn more:

Sheila Bailey/Marie Crook
Research Facilitator, CRN Primary Care
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Fax: 0121 414 6571
Email: sheila.bailey@nihr.ac.uk
marie.crook@nihr.ac.uk

REACT is funded by the National Institute for Health Research Public Health Research Programme.



Current Studies – SITE Studies

ALL-HEART

ALL-HEART is a multi-centre, controlled, randomised open-label blinded trial of allopurinol 600mg daily versus no treatment added to usual therapy in patients aged 60 years and over with ischaemic heart disease (IHD).

The aim is to establish whether allopurinol improves cardiovascular (CV) outcomes in this population. Allopurinol has several positive effects on the cardiovascular system, is inexpensive and is already widely used in patients with gout.

The results of this study could have major benefits for patients and result in significant cost savings for the NHS if allopurinol is found to be effective, as it would be inexpensive and easy to introduce quickly to patient care within the UK.

Practices will be asked to:

- Identify potentially eligible patients by carrying out a search, check and mailout
- Provide a room for a research nurse to undertake screening visits and any follow-up blood tests
- GP to act as Study Site Coordinator (SSC) and report serious adverse events

Learn more:

Saif Uddin

Research Facilitator, CRN Primary Care

Tel: 0121 414 8614

Fax: 0121 414 6571

Email: saif.uddin@nhr.ac.uk



Febuxostat versus Allopurinol Streamlined Trial (FAST)

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 three years. The trial aims to recruit 5,706 patients by December 2017.

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 six patients per practice.

Practice Remuneration:

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

Learn more:

Beth Hinks

Research Facilitator, CRN Primary Care

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FAST



In Follow Up

TASMINH4

Recruitment to the TASMINH4 trial has now finished and, in total, 1,181 patients were recruited to the study nationally. Patient follow-up ended February 2017.

The study team would like to say a huge 'Thank You' to staff at all the 28 practices in our region that have helped to recruit patients and made the study such a success. Currently our follow-up response to six-month follow-up clinics averages 83%. This response rate represents a lot of hard work from all the surgeries and researchers involved in the study and we would like to extend our sincere thanks and gratitude. We really do appreciate the efforts that colleagues are taking to see participants and keep them engaged with the study.

What is the TASMINH4 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.

Learn more:

Dr James Hodgkinson

Tel: 0121 414 8842

Fax: 0121 414 8616

Email: j.a.Hodgkinson@bham.ac.uk



Study Findings

CHANGE

The University of Birmingham **CHANGE** study (Child weight mANAgement for Ethnically diverse communities) has been working with the NHS community healthcare trust to test a culturally adapted child weight management programme for primary school children. It is a feasibility study funded by the NIHR.

A multifaceted approach was applied to assist the programme adaptation: (i) qualitative interviewing and focus groups with Bangladeshi and Pakistani families who had experience of the programme (ii) current literature, (iii) the behaviour change wheel (iv) typology of cultural adaptation of health promotion programmes.

The developed intervention was six weeks in duration and focused on encouraging peer and social support within the groups, emphasising sustainable lifestyle changes, and tailoring of messages to allow for different cultural interpretation.

Between September 2015 and April 2016, 24 weight management courses were delivered across Birmingham, 16 of which were the adapted courses. Results showed more families (76%) are completing the adapted programme, compared to the original (58%) during the intervention year. Feedback from the facilitators and the participants was positive.

Full data analysis is underway and the findings are due to be completed in 2017 but the preliminary findings suggest the adapted programme, underpinned by theoretical models and evidence from the Bangladeshi and Pakistani communities of Birmingham, has helped to improve the number of families completing the programme.

CHANGE study team:

Miranda Pallan (PI), Tania Griffin (Study Coordinator), Kiya Hurley (Research Associate), Laura Ocansey (Study Administrator)



**National Institute for
Health Research**

Study Updates

Community Pharmacies and Research

Over the last two years the CRN West Midlands have developed a strong working relationship with over 50 Community Pharmacies in the West Midlands region.

Community Pharmacies are increasingly being used as PIC sites for research studies and displaying posters within the Pharmacies has proved to be a valuable tool in patient recruitment. Some of the studies that have been promoted within Community Pharmacy are listed below.

The TIME study had a very successful poster campaign within Pharmacies and in their final report cited that in the North Staffs and Stoke CCG, 38 participants (16% of recruits) came from within five miles of a participating pharmacy without being directly recruited from a GP practice.

Preloading (stop smoking trial) was also very successful in pharmacies with 46 participants recruited through pharmacies during their poster campaign.

BrIT (Brains in Transition), recruited 75 participants with the study teams reporting that a strong proportion of those recruited, originated within Pharmacies.

The PRIM/Rococo study was a commercial cough study where there were 163 participants recruited in England with a number of West Midlands pharmacies taking part in the study. In this instance, pharmacies were not only used as PIC sites but were actively involved in the recruitment of participants by obtaining informed consent.

Why not think about utilising Community Pharmacy when designing your study?

Learn more:

Tina Sexty

Research Facilitator, CRN Primary Care

Tel: 0121 415 8730

Email: christina.sexy@nihr.ac.uk



CANcer Diagnosis Decision rules (CANDID)

CANDID
CANCER Diagnosis Decision rules

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

Notice for all GPs/Practices currently taking part in the CANDID study.

We will continue recruiting participants until 30 September 2017 and require your ongoing support with identifying new participants.

Reminders:

- Research Nurse Support is available to run clinic visits, take consent, complete the non-examination section of the CRFs and take samples.
- Clinicians don't need to have a very high suspicion that the patient has cancer for them to be included in the CANDID study (a 1 in 100 risk).

Thank you for your continued support.

If you have any questions or queries, please do not hesitate to contact me.

Learn more:

Marie Crook

Research Facilitator, CRN Primary Care

Tel: +44 (0)121 414 6270

Email: marie.crook@nihr.ac.uk



Study Updates

Update from Community-based Prevention of Diabetes (ComPoD) trial

ComPoD (www.isrctn.com/ISRCTN70221670) is a randomised, waiting list controlled trial of an existing community-based programme delivered by voluntary sector providers to assess its effectiveness in modifying diabetes risk factors in adults with 'pre-diabetes'. Across two UK sites (Exeter and Birmingham) adults with pre-diabetes were recruited via GP practices and were randomised to receive the Living Well Taking Control (LWTC) programme immediately (intervention) or after six months (waiting list control).

The study recently completed follow-up of participants initially recruited from eight GP practices in Birmingham (Alpha Medical, College Road, Gate Medical, Hall Green, Laurie Pike, Nechells, Omnia and Tower Hill). Locally, it achieved an outstanding 93% follow-up rate and recruitment of 49% of participants from ethnic minority groups.

Changes from baseline to six months in participants' objectively-measured weight, physical activity, blood glucose, and self-reported diet, health and well-being are currently being compared between the intervention and control groups. Maintenance of changes up to 12 months is also being examined in intervention group participants.

Trial findings are eagerly anticipated in light of the roll out of the NHS Diabetes Prevention Programme commencing in Birmingham and 26 other areas across England. The voluntary sector organisation involved in the ComPoD study (Health Exchange in Birmingham, www.healthexchange.org.uk) are one of four providers chosen to lead delivery of the programme. We will provide GP practices with information on the final results of the study later in the year.

The ComPoD researchers would like to take this opportunity to thank the GP practices for their help and support with the trial.



ExACT

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 three–six 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



Research Design Service West Midlands

What is RDS WM?

RDS WM exists to provide help to people preparing research proposals for submission to peer-reviewed funding competitions for applied health or social care research. RDS WM 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 RDS WM is funded by the NIHR for this purpose, such help is provided free of charge.

Who can use the RDS?

We support a broad range of people, including:

- Doctors, nurses and allied health professionals
- Patients and service users
- Academics and NHS and social care managers

For more information on RDS WM please contact
Karen Biddle on 0121 414 6774
or rds.wm@nihr.ac.uk
www.wm-rds.bham.ac.uk

How can RDS WM help me?

RDS WM can advise on all aspects of the preparing grant applications, eg,

- Formulating research questions
- Building an appropriate research team
- How to apply for our public involvement fund scheme
- 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 WM 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.



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:	<input type="text"/>
Job title:	<input type="text"/>
Practice address:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Postcode:	<input type="text"/>
Practice code:	<input type="text"/>
Email:	<input type="text"/>

Your email address will only be used to send you details of studies being undertaken by the CRN Primary Care.

Clinical Research Network: Primary Care is part of the National Institute for Health Research (NIHR). Only studies which have been independently peer-reviewed and funded through national competition; and commercial research asking relevant questions will be adopted onto the NIHR Portfolio of studies.

You can:

Fax back this form to **0121 414 2282** or

Email the details above to crn-wm@contacts.bham.ac.uk or

Phone us on **0800 085 4229** for further information.

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

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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 0800 694 6943



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