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WARWICKSHIRE

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WEST MIDLANDS SOUTH PRIMARY CARE RESEARCH UPDATE

# PARTICIPATE

VOLUME NO 17

SPRING 2015

## POINTS OF INTEREST

- Current Study -TIME
- Local Research Boundaries for Life
- HotTopic Research
   Incentive Scheme 2015-16

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# What has Research Ever Done for You?

Primary care research is sometimes perceived as an elitist 'ivory tower' activity where esoteric questions are posed and answered for the benefit of the research community without meaningful changes arising in the way conditions are diagnosed or managed.

Challenging this perception requires a concerted joint effort from researchers, study facilitators, GPs and other health professionals. In addition, local patient participation groups can also play an important role in helping the wider public understand how improvements can be made to their care and management through the answering of key questions in primary care research.



"Image courtesy of Stuart Miles at FreeDigitalPhotos.net"

For instance, simple changes in the way a regime is implemented can have far-reaching consequences for the health of the population. Something as simple as changing the time of day medication is taken is potentially a powerful tool in improving the management of a condition, but research is needed to discover whether this occurs.



"Image courtesy of Stuart Miles at FreeDigitalPhotos.net"

Last September a poll of 3,000 people in England was commissioned by the National Institute for Health Research (NIHR) Clinical Research Network, asking for the opinions of patients about research carried out in their own general practice. Two questions, based on this poll, were asked to judge research interest locally. Of those that completed our local survey, 86% felt it was important that the NHS carry out clinical research. Further details can be found on page 13 and detailed analysis will follow in the summer.

#### In this edition, we feature articles on:

- taking once a day blood pressure medication, aiming to establish whether night time dosing is better (or worse) than morning time treatment (page 6)
- health checks at sporting events for the 'hard to reach' (pages 8-9)
- interim results on the long-running Million Women study (page 12)

If you would like to contribute to Participate or for further information please contact Jenny Oskiera email: j.oskiera@warwick.ac.uk

## **CANDID**

**CANcer Dlagnosis Decision rules** 



This study is looking at which symptoms, signs and examinations are best for predicting lung and bowel cancer. It follows on from two preliminary studies investigating cancer symptoms — a Delphi study and a qualitative study, which resulted in a list of symptoms, signs and tests to be assessed by GPs in patients consulting with respiratory or bowel symptoms who are considered to be at risk of cancer.

In total 20,000 people with lung and bowel symptoms will be asked to take part in this research, half with lung and half with bowel symptoms. This is a multi-centre study across eight academic sites led and coordinated from the University of Southampton by a team led by Professor Paul Little and funded by the NIHR NSPCR.



#### Local progress

Within the area covered by West Midlands South, recruitment to CANDID is gathering pace and as of mid-April 2015 we have a total of 165 recruits. Thank you to the Eighteen practices within our area that have recruited so far with a special mention to The New Dispensary surgery who are leading the way. We have a total of 31 practices open to recruitment for this popular study and expressions of interest still being received before recruitment closes on 30th September 2015. Our target for case identification is I-2 participants per month per clinician to help us make a significant contribution to the national target and we will update practices regularly on their progress.



Our top recruiting practice, New Dispensary in Warwick, has an impressive 49 patients entered into the study.

#### Practice involvement and reward

Patients have to be entered into the study within 3 weeks of the initial consultation with a GP. Practices may invite patient with a broad spectrum of lung or bowel symptoms, which is important for developing future guidance that can distinguish between people at very low risk versus increased risk of cancer. For every patient successfully recruited to the study there is a practice payment of approximately £100.

#### How can we help?

For those practices yet to recruit their first patient to this study please consider utilising one of our research nurses to support your team in the initial recruitment of patients via an online system. We also have available study posters and a computerised pop-up alert as a reminder.

Should the practice be interested in hearing more about this study please do let us know and a member of our team would be happy to come out to the practice to explain further. We are here to support and answer any questions you may have.

Please contact Jenny Lee, email: jennifer.lee@warwick.ac.uk

## **Helicobacter Eradication Aspirin Trial**

UNIVERSITY<sup>OF</sup> BIRMINGHAM



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.

Further Information: If you would like to find out more, please contact the Trial Manager for your region, Rachel Iles (riles@bham.ac.uk phone: 0121 414 2691).



# NHS National Institute for Health Research

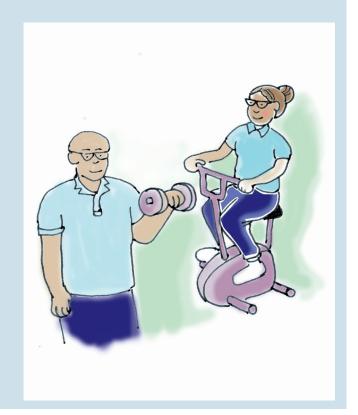
The Dementia And Physical Activity (DAPA) trial, which aims to show whether a programme of exercise can have a beneficial effect on cognition (memory and understanding) as compared to usual care, has been recruiting very successfully in 2015. We expect to achieve the recruitment target of 468 by June 2015.

Recruitment activity within the NIHR - Clinical Research Network West Midlands region has now ended. Our focus now is to complete the exercise classes still being held in some of the local exercise venues and finish follow-up visits.

Since commencing primary care recruitment in March 2014, patients have been randomised as follows:

- 20 patients from 15 Coventry practices
- 9 from 8 Nuneaton practices
- 10 from 7 South Warwickshire practices
- 5 from 11 Birmingham and Black Country practices
- 37 from 18 GP PICs in Worcestershire

On behalf of the trial team, we would like to thank all the various teams within the region who have contributed to DAPA.



For more information, please contact the team quoting 'DAPA' on: phone: 02476 150 955 or email: DAPA.Trial@warwick.ac.uk.



FAST (Febuxostat versus Allopurinol Streamlined Trial) is a major multicentre clinical trial evaluating long term cardiovascular safety of febuxostat in comparison with allopurinol in patients with chronic symptomatic hyperuricaemia (gout).

Suitable patients are identified in primary care by their GPs; those that respond favourably attend an appointment with our research nurse and enter a pre-randomised phase where their urate levels are optimised on allopurinol. Once optimised, patients will be randomised to either allopurinol or febuxostat, and are followed up every two months by our research nurses. Urate levels will be checked annually as part of the trial.

#### Can you help us?

## Would your practice be interested in helping us with this important study?

So far, 26 practices in the West Midlands are taking part, and patient recruitment has commenced. Thank you so much to those of you who are on board, and we look forward to expanding this exciting trial to any other practices who may be interested.

Participating practices will receive a  $\pounds 500$  fee for completing the database search, in addition to  $\pounds 5$  per month per patient for the duration of the trial. All medication will be prescribed by the trial sponsor, and so there will be no prescribing costs to GP practices.



The Trial Manager is Jen Dumbleton, and her contact details are as follows, email: jennifer.dumbleton@nottingham.ac.uk, phone: 0115 823 1053. Further details can also be found on the trial website: www.fast-study.co.uk.



## Four-Fold Asthma (FAST) Study -Can a new approach to managing asthma help to prevent a bad attack?

In a national study led by DrTim Harrison at the University of Nottingham and funded by the National Institute for Health Research, researchers are inviting people with asthma to participate in a clinical trial exploring whether a new approach to managing asthma could prevent an attack.

The researchers aim to find out if advising patients to temporarily quadruple their inhaled corticosteroid treatment when asthma symptoms start to deteriorate may help to prevent a more serious asthma attack from happening. If found to be effective, this advice could be incorporated into standard asthma management guidelines.

#### **Recruiting locally**

This study remains open to practice recruitment until the end of June 2015, with patients able to be recruited to the study until the end of the year. The second phase of recruitment has proved

successful, with a total of seven practices recruiting or in set-up.

Interested practices will receive a training session and can then choose whether the practice asthma nurse supports patients with this study or whether a CRN nurse comes into the surgery to see patients.

Recruitment is via a retrospective search for those asthma patients with one or more exacerbations within the last year, or opportunistically as patients come into the practice for their asthma review.

#### **Trial intervention**

Enrolled participants will be randomised and taught how to use one of two asthma action plans that will contain advice on how to manage asthma. One of the action plans will contain standard advice on how to manage asthma whilst the other will include information on the new approach.

Participants will then be invited to attend at least two follow-up visits at their own GP practice over the next 12 months with an additional visit if their asthma control deteriorates.

This is a multi-centre pragmatic, randomised, normal care-controlled clinical trial, where the primary outcome is 'time to first asthma exacerbation', defined as: the need for systemic corticosteroids and/or unscheduled health care consultation for asthma (i.e. reaching zone 3 or 4 of the Asthma UK self-management plan).



"Image courtesy of Marin at FreeDigitalPhotos.net"

If your practice would like to take part or would like more information, please contact: Linda Field, CRN Research Nurse, email: linda.field@warwick.ac.uk or Jenny Lee, CRN Research Facilitator email: jennifer.lee@warwick.ac.uk





# TASMINH4: Telemonitoring And/or Self-Monitoring IN Hypertension

#### 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. 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 110 PRACTICES NATIONALLY FROM NOW UNTIL AUGUST 2015

#### What is involved for practices?

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

#### Full training will be provided

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





UNIVERSITY<sup>OF</sup> BIRMINGHAM Learn More: If your practice would like to take part or would like more information please contact: Mrs Siobhan Milner, Project Officer phone: 0121 414 2954, fax: 0121 414 8616, email: s.l.milner@bham.ac.uk

## The impact of Giant Cell Arteritis (GCA) study



#### **Principal Investigator:**

Professor Christian Mallen

**Institute:** Keele University

**Recruitment period:** Spring 2015

**Funders:** National Institute for Health Research (NIHR) Research Professorship (Grant No: NIHR-RP-2014-04-026) and Collaborations for Leadership in Applied Health Research and Care (CLAHRCs). Arthritis Research UK (Grant

No: 20202)

#### Study background:

Giant Cell Arteritis (GCA) (also known as Temporal Arteritis) is the commonest form of Large-Vessel Vasculitis (LVV), with inflammation typically affecting the cranial arteries. If left untreated, the most serious outcome is blindness and therefore early diagnosis of GCA by GPs is critical to preventing the vision loss which can occur in 15-20% of cases. Once diagnosis of GCA is determined and corticosteroids are started, vision loss is extremely rare.

However, the diagnosis of GCA in primary care remains difficult, with patients presenting with sometimes vague and varied symptoms. This can cause the GP to consider other conditions prior to GCA, resulting in subsequent delayed diagnosis and treatment.

Research into the impact of GCA on primary care patients is under-researched, in particular reasons behind diagnostic delay. Using a cross-sectional questionnaire, we aim to investigate the

health care processes which may lead to delays in GCA diagnosis and several other health outcomes which may impact on patients.

#### Study methods:

All adults aged 50 years or older, with a diagnosis of GCA in the three years before the baseline questionnaire will be included in the study population. These patients will be recruited from approximately 200 research active general practices from across Staffordshire and the West Midlands, facilitated by the NIHR Clinical Research Network (NIHR CRN): West Midlands.





For further information, please contact: Dr James Prior, Research Associate, email: j.a.prior@keele.ac.uk

## Primr\*se

# Management of cardiovascular risk for people with severe mental illnesses: a cluster randomised controlled trial in primary care.

#### What is the PRIMROSE Study?

The aim of the PRIMROSE study is to test the clinical and cost effectiveness of a primary care led behavioural intervention to reduce cardiovascular disease (CVD) risk in patients with severe mental illnesses. The primary outcome of interest is total cholesterol and secondary outcomes include lipids, HBA I c, blood pressure, BMI, smoking, diet, physical activity, alcohol use and adherence to treatments.

The study is important because people with severe mental illnesses (SMI) are at an increased risk of CVD and are more likely to die from the disease than the general population.

The study is being run by researchers at University College London, Southampton University, Imperial College London, Kings College London and the McPin Foundation in partnership with Camden and Islington NHS Foundation Trust.

We have recruited 130 patients and 46 GP practices across England. We aim to recruit a further 14 GP practices to the study by the end of June 2015 and 6-10 patients within each practice by September 2015.

## What does the study involve for GP practices?

- Carrying out a search for eligible patients
- Sending out study invitation letters to all eligible patients
- Sending out invitations to patients
   with SMI to attend a physical health screening appointment
- Carrying out CVD risk screening including a blood test for total cholesterol, total cholesterol/HDL ratio and HbA1c, blood pressure, smoking status, BMI, diabetes and hypertension status

#### In addition, if your practice is randomly selected to deliver the PRIMROSE intervention:

- Attendance at two training sessions by one practice nurse or healthcare assistant (HCA) with some experience of delivering health behaviour advice
- Intensive case management of CVD risk factors in patients with SMI by the practice nurse/HCA over a six month period

Practices undertaking this study will be eligible to receive payment via service support costs to cover the time spent identifying and screening for eligible patients. PRIMROSE intervention GP practices will receive further payment to cover the practice nurse/HCA time to deliver the intervention.

If your practice would like to take part or would like more information please contact: Alexandra Burton, Programme Manager: phone: 0207 679 9031 email: a.burton@ucl.ac.uk For further information please see our website: www.ucl.ac.uk/primrose or follow PRIMROSE on Twitter: @UCLPrimrose





### TIME Makes Encouraging Start across the UK

TIME (Treatment In Morning vs Evening) is looking at patients taking once a day blood pressure medication, aiming to establish whether night time dosing is better (or worse) than morning time treatment in preventing heart attacks, strokes, and deaths related to diseases of the heart and circulation.

The study is being undertaken by a team based at the University of Dundee led by Professor Tom MacDonald and is backed by a British Heart Foundation research grant. The TIME study is currently recruiting patients across the UK following a successful pilot which has been ongoing since 2011.

#### Who is eligible?

Recruitment to the study is open to anyone in the UK who takes tablets for blood pressure once daily. The aim is to recruit 10,000 participants of as varied demographics as possible and study them over a period of five years. Patients are being invited via GP surgeries and hospitals and by their responding directly to advertising or social media.

Participants are randomly allocated to either take anti-hypertensive medication at night or in the morning, and the study is conducted entirely online with patients registering and consenting online and being followed up by email.

## Participants need to have regular access to the internet, as this study is done entirely through a secure website and all contact is by email.

Although this excludes a certain proportion of patients, for practical and financial reasons it would be difficult to do a study of this size in the conventional way. Previous studies that have used this method found it to yield high quality and cost-effective data. Patients register for the study at <a href="https://www.timestudy.co.uk">www.timestudy.co.uk</a>, where they can read more detailed information. Consent for the study is completed by the patient online and they then input study data.

#### **GP** practice recruitment for the TIME study

An initial mailing in 2014 to GP practices has been followed up by the Research Networks in all UK countries, and local approvals are being granted to allow interested practices to be registered as Patient Identification Centres (PICs) to invite suitable patients.

To facilitate the mailing to patients and minimise the costs to practices, an account has been established for the study on Docmail which can be used to mail patients and so far this has been used in 32 practices in the West Midlands, which has been at the forefront of activity for the study. The West Midlands is the lead region for the study in England. Other regions are now also starting on the recruitment process with new practices continuing to register their interest.

#### Involvement of hospital clinics

Patient recruitment from hospital clinics is also possible and there has been considerable interest from hospital trusts across the UK and several have already been set up as PICs to be able to invite their patients.

#### Study aim

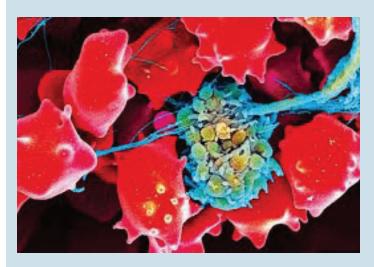
If showing that the time of day patients take their blood pressure medication can have an effect on events such as strokes and heart attacks, this would provide enormous health benefits. Even getting a modest effect within our study could imply an incredible benefit to the population at large.



Anyone who is interested in finding out more about this can contact the co-ordinating centre in Dundee at TIME-study@dundee.ac.uk



## select-d: Anticoagulation Therapy in SELECTeD Cancer Patients at Risk of Recurrence of Venous Thromboembolism A study for cancer patients with venous thromboembolism



**select-d** is a prospective, randomised, open label, multicentre pilot study comparing dalteparin vs. rivoraxaban with a second placebo-controlled randomisation comparing the duration of anticoagulation therapy (6 months vs. I 2 months treatment) in patients with DVT who are Residual Vein Thrombosis [RVT] positive (+ve). All patients presenting with PE will be invited to participate in the second randomisation.

**Treatment:** Dalteparin (Fragmin<sup>®</sup>, Pfizer), a low molecular weight heparin, the only licensed anticoagulant in the UK for the extended treatment and prevention of recurrence of VTE in cancer patients.

Rivaroxaban (Xarelto®, Bayer), an oral direct Factor Xa inhibitor, licensed for the treatment of DVT and the prevention of recurrence of DVT and PE in adult patients.

Chief Investigator: Professor Annie Young

Sponsor: University of Warwick

Funder: Educational grant from Bayer plc (Investigator

Initiated Study)
Sites: 80 sites

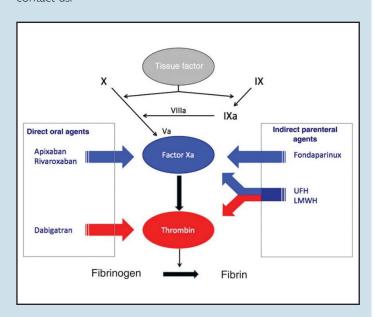
Recruitment target: 530 patients

Recruitment period: September 2013 – September 2015 (extension to December 2016 currently pending)

Eligible patients: Aged > 18 with active cancer and a primary presentation of an objectively confirmed VTE; symptomatic lower extremity proximal DVT or symptomatic or incidental PE

**Update:** It has been 18 months since we welcomed our first site (Queens Hospital, Burton upon Trent) to start recruiting into select-d, and since then a further 43 sites have followed, including the following sites in the Midlands: Hereford County Hospital, Kidderminster Hospital, New Cross Hospital (Wolverhampton), Royal Shrewsbury Hospital, Russells Hall Hospital (Dudley), and University Hospital Coventry. Many thanks also go to Russells Hall Hospital which is currently the highest recruiting select-d site in the Midlands.

We are currently in the process of setting up the following additional sites in the Midlands: Alexandra Hospital (Redditch), Worcestershire Royal Hospital (Worcester) and Queen Elizabeth Hospital Birmingham, and look forward to opening them for recruitment. We are accepting new sites, so if you or your colleagues are interested in participating in select-d, please do contact us.





For further information please contact: Jenny Phillips (Trial Coordinator): email: j.phillips@warwick.ac.uk phone: 024 7657 3315 Or Helen Hancocks (Recruitment Facilitator) email: n.h.hancocks@warwick.ac.uk phone: 024 7652 8046

## Local Research



#### It's Just not Cricket!

### 'Boundaries for Life': lessons learnt from health checks at sporting events

By Dr Chetan Trivedy BDS FDS (RCS) MBBS PhD MCEM MFMLM

NIHR Academic Clinical Lecturer in Emergency Medicine Centre for Applied Health Research Delivery Warwick Medical School

#### **Background**

I was never a huge fan of cricket, nor of seeing my GP, so it was by complete chance I became the crowd doctor at the Kia Oval in 2007. Many a day was spent in our medical room tending to the numerous bumps, bruises, sunburn and occasional near fatal consequences of alcohol toxicity. All in a day's work for the medical team. With the unpredictability of the British weather there would often be long spells of break in play where over 20,000 fans would look for ways to entertain themselves. Although consumption of alcohol was most favoured, many fans would sneak in to see us in the medical room for a bit of advice from the doctor or to have their blood pressure checked. Although this was not our primary remit, we would often oblige.

Cricket has an immense following among the ethnic minorities and at no other sport will you see so many Indian, Pakistani or Sri Lankan fans in one place. Cricket is almost a religion in some of these countries and generations of supporters will pack cricket stadia to see the likes of Sachin Tendulkar occupy the crease.

In addition, unlike other sports like football or rugby

which are over in a matter of hours, a game of cricket can go on for five days allowing fans more opportunity to explore the ground.

Data from Public Health England has suggested that

"each year NHS health check could prevent 1,600 heart attacks and save 650 lives, prevent 4,000 from developing diabetes and detect 20,000 cases of diabetes or kidney disease earlier"

Furthermore, identifying risk factors such as smoking, physical inactivity, alcohol overconsumption, raised cholesterol and high blood pressure could help reduce or prevent diseases such as Type 2 diabetes, coronary heart disease, dementia and strokes. It has been estimated that the cost of treating these conditions in secondary care is £5-11 billion and may add an increased £34 billion burden annually to the tax payer.

Considering the higher prevalence of Type 2 diabetes, coronary heart disease and mouth cancer amongst the ethnic minorities from the cricketing nations, this was an ideal opportunity to develop a health promotion and intervention initiative, especially if young individuals with high risk factors could be identified and signposted to engage with their GPs.

#### 'Boundaries for Life'

In 2010 Boundaries for Life was born and teams of health care professionals volunteered to run checks at the England v Pakistan One Day International at the Kia Oval in London. We were encouraged by the queues of participants who waited patiently to have their free health MOT. Our aim was to offer blood pressure, diabetes, cholesterol, body mass index (obesity), mouth cancer screening, and to raise awareness on dementia.

In the 2013-14 season we performed over 600 health checks in four venues (Edgbaston, The Oval, Old Trafford and Lords) finding that:

- up to 32% of the users were obese having a BMI of more than 30
- 26% had high random cholesterol of more than 5 mmol/L and
- 37% at one venue had high blood pressure (140/90 mm/Hg).



## Local Research



Although some of these users may have been self-selecting as they had a pre-existing illness, many were not previously aware of their abnormal results and were advised to follow up with their doctors. The feedback from the users was exceptional and applying the 'family and friends' test 100% of users stated they would recommend the service.

#### Why do people not visit their GP?

During these checks, some very interesting underlying narratives surfaced.

Firstly, lack of access to similar one-stop NHS services had prompted users to have the checks at the cricket.

Secondly, they did not need to take time off work, plus all checks were free.

Finally, having a health check outside of the traditional medical setting (GP surgery, hospital or pharmacy) gave users greater control and ownership of their health and health information without becoming completely submerged into the medical model.

The first two made sense, given the pace of life these days; the opportunity for a free health check is a potent incentive. However, as a doctor committed to helping my patients I could not appreciate the issues of being part of the medical model until I, too, became a patient.

#### Personal experience

On 18th February 2015 I was diagnosed with a small brainstem stroke, Type 2 diabetes, high blood pressure and high cholesterol. Not having seen a GP for over 15 years, the irony of having a full house of risk factors, given the checks I was performing on others,

was a definite 'do as I say and not as I do', moment.

Attending numerous outpatient clinics has given me a better appreciation of what we put our patients through once we find they have an illness or an abnormal blood test. As health care professionals we have an inherent urge or need to 'fix it' and often without realising we take complete control of the situation. However this often comes with loss of autonomy for the patient on dealing with blood pressure, blood sugar or high cholesterol and this is what had put off many from having checks in more traditional settings, and why a health check at a cricket match where they had complete control over the information given was greatly valued.

#### **Next steps**

Further work is ongoing to explore reasons and barriers related to health behaviour amongst people attending cricket matches and whether cricket can play a role in not just providing entertainment but also in helping to improve the health and wellbeing of supporters.

What makes this initiative unique is the interest and support from sporting venues and governing bodies who have pushed this scheme at grounds across the UK. It is hoped that by 2020 every cricket ground in the UK will run one free health check for its fans and staff annually.

It will be interesting to see what impact this may have on the health of users and whether these initiatives can be more cost-effective than traditional NHS checks. A direct comparison of health check costs at the cricket is not possible as these are done on a voluntary basis with a small budget for consumables

Work is in progress to build a research team interested in looking at the evaluation of this work and we are keen to develop a multi-disciplinary team from across the University.

For further information, please contact Dr Chet Trivedy email: c.trivedy@warwick.ac.uk



## Local Research

## Research Design Service (RDS)



via www.rds-wm.nihr.ac.uk

Do you have a good research idea that you'd like to develop further into a grant application? The RDS can help by providing methodological expertise and advice on all aspects of research design.

The RDS exists to provide help and advice to NHS researchers and others working in partnership with the NHS in preparing research proposals for submission to peer reviewed funding competitions. As the RDS is funded by the NIHR such help is provided free of charge.

Here are some of the ways we can help:

- Formulating research questions
- Building an appropriate research team
- Involving patients and the public
- Designing a study
- Appropriate methodologies for quantitative and qualitative research
- Identifying suitable funding sources
- Regulatory issues
- Writing lay summaries
- Identifying the resources required for a successful project

## 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 through validation studies of different home BP monitors in patients with AF to assess their accuracy in this population, including additional 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.

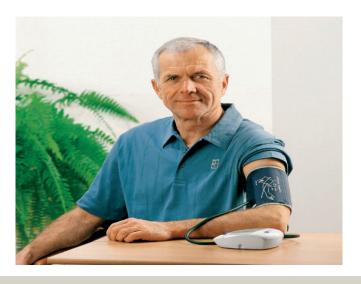
Eligible patients, recorded as having permanent chronic AF, will be invited to participate. The validation studies will follow the standard British Hypertension Society (BHS) and European Society of Hypertension International Protocol (ESH-IP) protocols, and will take place in the NIHR Wellcome Trust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

#### Would you like to be involved?

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
- Mail-out of study invitation letter
- Eligible patients will be seen at the Wellcome Trust Clinical Research Facility in Birmingham



Contact: Dr James Hodgkinson phone: 0121 414 8842 email: j.a.hodgkinson@bham.ac.uk

## **Updates and Events**

# CRN: WM Research Academy - Training Schedule

Date	Event	Time	Location	For More Information
01/06/15	Introduction to Good Clinical Practice	09.00 – 16.30	Royal Orthopaedic Hospital, NHS FT Birmingham	TrainingCRNWM Generic@uhb.nhs.uk
12/06/15	GCP Refresher	08:45-12:30	Hereford County Hospital	TrainingCRNWM Generic@uhb.nhs.uk
15/06/15	Introduction to Good Clinical Practice	09:00-16:30	Burton Hospitals NHS FT	marg.brammeld@northstaffs.nhs.uk
19/06/15	GCP Refresher	08:45-12:30	Birmingham Women's Hospital, Birmingham	TrainingCRNWM Generic@uhb.nhs.uk
30/06/15	Essential Principles of Good Clinical Practice for Pharmacy Staff	09:30-16:30	New Cross Hospital, Wolverhampton	TrainingCRNWM Generic@uhb.nhs.uk
09/06/15	Cost Attribution Training	09:30-11:30	Clinical Sciences Building, UHCW	TrainingCRNWM Generic@uhb.nhs.uk
17/06/15	Commercial Trials Workshop	09:30-12:30	Seminar Room CTCIM156, University Hospital North Stoke	TrainingCRNWM Generic@uhb.nhs.uk
16/06/15	Introduction to Radiotherapy	14:00-16:00	Education Resource Centre, Birmingham Women's Hospital	www.brtc.org.uk

For all other training related queries, please contact any of the following:

## **CRN: WM Research Academy**

#### Suzanne Sumara, Workforce Development Lead

phone: 0121 204 1825 email: Suzanne.Sumara@uhb.nhs.uk

#### Hannah Reay, Workforce Development Lead (GCP Programme Lead)

phone: 0121 627 5883 email: Hannah.Reay@uhb.nhs.net

#### **GCP** Training, Jane Willcocks

phone: 0121 204 1813 email: Training CRNWM Generic@uhb.nhs.uk

#### **Marg Brammeld**

phone: 01785 221368 Ext: 5368 email: Marg.Brammeld@northstaffs.nhs.uk

#### Maggie Hope, Birmingham Research Training Collaborative Training

phone: 0121-121 371 6694 email: Maggie. Hope@uhb.nhs.uk BRTC: brtc@uhb.nhs.uk

## Study Update

## The Million Women Study

We are grateful for the continued support of all our collaborators and study participants. In addition to the funding awarded to the Million Women Study in 2013 from the Medical Research Council, we are pleased to announce continued funding from Cancer Research UK. We now have more than 13 years of follow-up which will allow us to answer many questions about women's health.



## Million Women Study papers published since October 2013

Published papers include studies of organic food consumption in relation to risk of cancer, the link between birth weight and cancer risk in adulthood, and ethnic differences in the risk of breast cancer. We have also looked at risk factors for coronary heart disease, diverticular disease and hospital admissions for different conditions. Summaries of all publications are available on the study website:

#### Hospital admissions and excess weight

We estimated rates of admission to hospital according to body mass index. We found that one in eight of all admissions of women to hospital in the UK are linked to overweight or obesity. Hospital admissions for diabetes, knee-replacement, gallbladder disease and venous thromboembolism were most strongly associated with body mass index.

Reeves GK et al; Hospital admissions in relation to body mass index in UK women: a prospective cohort study. **BMC** Med 2014; 12:45.

#### Organic food and cancer

Organically produced foods are less likely than conventionally produced foods to contain pesticide residues. We found that there was little or no decrease in the risk of developing cancer associated with eating organic food, except possibly for non-Hodgkin lymphoma.

Bradbury KE et al; Organic food consumption and the incidence of cancer in a large prospective study of women in the United Kingdom. **Br J Cancer 2014**; 110:2321-6.

#### **Blood Samples and the disease susceptibility study**

We have been asking more study participants to provide blood samples to help us expand our understanding of the relationship between genetic and biochemical factors and disease susceptibility. The total number of blood samples collected is now 48,559. The lab staff are always delighted to receive the gift of blood from a participant and look forward to reaching the 50,000 milestone next year.

#### Online diet questionnaire

To date, 96,000 online diet questionnaires have been completed.

We're still collecting data and hope to get even more participants involved now that our email list has been updated via the 4th general follow-up questionnaire.

#### 4th General follow-up questionnaires

The mailing of the 4th general follow-up questionnaire was completed in March 2014 and around 600,000 responses have been received.

All of our questionnaires and publications can be viewed on the study website: <a href="https://www.millionwomenstudy.org">www.millionwomenstudy.org</a>

Funded by









Please let us know if you have any comments or suggestions. Contact: Barbara Crossley barbara.crossley@ceu.ox.ac.uk

## Research Awareness



## Holbrooks Health Team and City of Coventry Health Centre Research Awareness Mornings

During the first week of December, the CRN: primary care team held two research awareness mornings at Holbrooks Health Team and City of Coventry Health Centre to engage with patients and the public about clinical research studies.

#### **Holbrooks Health Team**

The first research awareness morning was held on Monday December 1st at Holbrooks Health team, a host practice since 2013 and part of the CRN: primary care research incentive scheme, offering a wide range of clinical research studies to its patients. CRN research nurse, Linda Field, works closely with lead research GP, Ken Holton, to support the whole practice team in clinical research studies that both benefit patients and support existing clinical priorities.

Lead Research GP Ken Holton said:

"I have always been excited by researching our work. Whether it is regular analysis of the running of the practice, or investigation into new ideas and treatments, it is important that every aspect of care is based on knowing that it is likely to be doing good. Since then, we have supported research, investigation and analysis in every aspect of our work in Coventry. Our current deployment of research staff has resulted in this practice being associated with many projects both locally and nationally intended to advance the effectiveness of healthcare in the UK"



#### City of Coventry Health Centre

On Tuesday 2nd
December, City of
Coventry Health
Centre took part in
raising awareness of
clinical research,
with members of
the CRN: primary
care team on hand
to speak to patients
and the public
about clinical trials
and research
studies. City of
Coventry Health

Centre, which opened in 2011, provides a wide variety of community health services to adults and children. Priory Gate Practice, located within the health centre has also recently become research active.

Dr Helen Tyrell, a Priory Gate GP, has supported the practice in becoming research active and said:

"Although I and my practice are relatively new to research, the benefits are obvious. Not only can we gain a broader understanding of disease evolution and management, the research provides evidence of the efficacy of treatments - by being involved we are helping both our own patients, and patients as a whole, because we are better able to tailor and select the most appropriate response to their condition. Patients can also gain confidence that their GPs are at the forefront of primary care knowledge and therefore are receiving the best care available"

#### What do patients think of research in their practice?

Patients were asked two questions which reflect those asked in the recent poll of 3,000 people in England, commissioned by the National Institute for Health Research (NIHR) Clinical Research Network in September 2014. A summary of these results can be found in Table 1, along with total figures of the number of surveys completed at both venues.

#### **Question One:**

How important is it to you that the NHS carries out clinical research?

#### **Question Two:**

If you were diagnosed with a medical condition or disease, how willing would you be to participate in a study?

#### Table I

	Holbrooks Health Te	am	City of Coventry Health Centre	
No. of surveys completed	42		50	
How important is it to you that the NHS carries out clinical research?	Very/fairly important	87%	Very/fairly important	85%
	Not important	0%	Not important	2%
	Don't know	13%	Don't know	13%
If you were diagnosed with a medical condition or disease, how willing would you be to participate in the study?	Very/somewhat willing	76%	Very/somewhat willing	74%
	Not very willing	21%	Not very willing	14%
	Not willing at all	3%	Not willing at all	12%

Further Information: Patients and members of the public also completed a survey to enable evaluation of the impact being made by research and to find out more about how they wish to be involved. Overall, 92 surveys were completed and results will be analysed and published in the next edition of Participate.

## **Local News**

# **Principal Investigators -** Achievements and Awards Ceremony 4th February 2105 at BMA House

Dr Claire Jones

GP Research Champion for South Worcestershire.

I was delighted to have been invited to the NIHR Leading Commercial Principal Investigators (PI) Award Ceremony. This lunch was organised to recognise PI contribution to Industry Research. Out of I 00 present only a handful were from primary care, most others were consultants from secondary care with paid time set aside to participate in research.

My nomination was for 'First commercial study delivered successfully' and was for ELIOT, a trial testing a new inhaler device.

At Spring Gardens we had recruited 24 patients, more

than the 10 set as a target. The highlight was the motivating talk from Dame Sally Davies, Chief Medical Officer, and creator of the NIHR.

It was a wonderful opportunity to meet new researchers

and doctors and to put a foot in BME House. I came away enthused to engage in more industry research.



### West Midlands Research Incentive Scheme 2015-16

The Research Incentive Scheme (RIS) was established in 2010 and, over the years, has proved a very popular initiative. After consultation, a new simplified national framework has been developed to replace the initial scheme and build on previous years' success.

#### What can you gain?

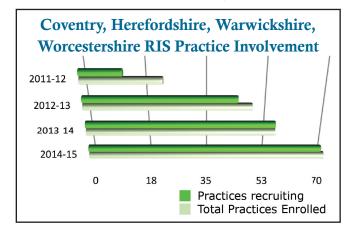
Your local CRN team is on hand to offer advice and assistance. Research facilitators can assist with running practice searches. Our CRN research nurses can assist with some study recruitment clinics; others, with remuneration via service support costs, can be run by your own practice nurse.

Remuneration is on a sliding scale, depending on the level of involvement and number of studies a practice has recruited to.

#### New for 2015-16

Whilst the basic requirements asked of practices e.g. becoming research ready, attending an annual symposium etc., and the level of support and assistance offered by the CRN West Midlands team have not changed, the study recruitment gateways for the RIS levels have been adjusted. The revised framework, now comprises three simplified levels:

**Introductory level:** recruitment to one study **Delivery Site Level 1:** recruitment up to two studies **Delivery Site Level 2:** recruitment up to four studies



This year we are offering places to a total of 75 GP practices. If your practice has not been approached, and you would like either to be considered for inclusion in the RIS scheme at some point, to find out more information about primary care research, or to register your general interest in taking part in research studies, please contact the research facilitator for your area:

#### **Coventry and Herefordshire**

Jenny Lee jenniferlee@warwick.ac.uk phone: 02476 575 919 mob: 07920 531 253

#### South Warwickshire

Becky Harrison<u>r.l.harrison@warwick.ac.uk</u> phone: 02476 575 853 mob: 07788 351 365

#### **Worcestershire and North Warwickshire**

Aman Johal <u>amanpreet.johal@warwick.ac.uk</u> phone: 02476 574 127 mob: 07788 351 364

#### **Pharmacy Involvement**

For the first time, we are seeking outline expressions of interest from pharmacies who might like to know about studies available and to find out more about research in general.



If you would like further information, or for an informal discussion, please contact: Sue Elwell, research manager, s.elwell@warwick.ac.uk or phone 02476 575854

## **Local News**





## A CRN Supported Questionnaire – Can You Help? National Survey of GP Cancer Test Access

Oxford University is surveying GP access to tests for cancer investigation across NHS England as part of a Cancer Research UK funded study. We aim to understand how test access varies between CCGs.

The survey should take you no longer than 10 minutes, and includes questions about your practice, the tests you can request, and access to specialist advice.

If you have any questions or queries about the survey, please contact Dr Brian Nicholson, MRCG, Cancer Research UK Clinical Research Fellow, Nuffield Department of Primary Care Health Sciences, New Radcliffe House, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG email: brian.nicholson@phc.ox.ac.uk

To complete the survey please follow: https://www.surveymonkey.com/s/testaccesssurveyEngland

# **News from Our Practices: Achievements Over and Above**



Well Done! Our thanks and congratulations go to the following:

#### **NEW HOST PRACTICE**

#### **Westside Medical Centre**

For becoming our new host practice. We look forward to continuing our already excellent working relationship with them.

## Welcome!

#### **TOP NEW PRACTICE**

#### **Golden Valley Practice**

New to research, this practice will join the incentive scheme this coming year as an introductory practice. To date they have participated in TIME and GCA and the research process has been very straightforward thanks to the staff responsiveness and efficiency of the practice staff.

## **RESEARCH RESPONSIVENESS Priory Gate Practice**

Only recently becoming research active, this practice hosts an NIHR GP research champion and has already started the following studies:

- HEAT
- TIME
- CANDID
- FAST Gout
- FAST Fourfold Asthma and agreed to GCA

#### RESEARCH AWARENESS Limbrick Wood Surgery

For publishing a monthly news sheet for their patients which highlights the research that is going on within the practice.



#### **Whitestone Surgery**

For holding a research awareness session with patients, in conjunction with their Patient Panel Group, where information was given about research and specifically the DAPA and TIME studies.

#### **Rother House Medical Centre**

For in depth commitment to research throughout the practice, with recruitment being successfully carried out by six different GPs.

#### STUDY RECRUITMENT

For being our latest top five recruiters to CANDID:

# **CANDID**

#### CANcer Diagnosis Decision rules

- The New Dispensary Surgery
- Spring Gardens Medical Group
- Corbett Medical Practice
- St. Stephens Surgery
- Sherbourne Medical Centre

#### **INDUSTRY STUDY**

#### **Spring Gardens Medical Group**

For continuous recruitment to GARFIELD; having recruited around nine patients since last September.

## Continuing Professional Development



Masters and Continuing
Professional Development

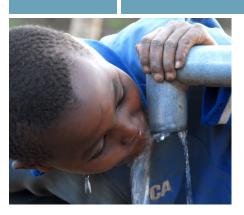
# WARWICK

WARWICK MEDICAL SCHOOL



#### **Public Health**

Postgraduate Study: Certificate/Diploma/Masters (MPH)



Who the course is for

This course is suitable for both UK and international students. It is aimed particularly at people currently involved in the practice of public health, people seeking membership of the UK Faculty of Public Health, people working in health promotion, and those interested in pursuing academic careers within public health.

Imagine if your work helped not only individual patients, but also improved the health of whole communities. The Public Health study programme will enable you to do just that and aims to provide relevant qualifications and skills to meet national and international needs for a skilled public health workforce. As a Public Health student, you will have the opportunity to develop and demonstrate systematic knowledge and understanding, as well as qualities and skills in a wide range of public health areas; optional modules enable you to pursue your own particular health related interests.

WMS pays particular attention to the professional development of practitioners, organising its study programmes to provide a flexible educational pathway taken over a number of years to suit individual requirements and to take account of professional commitments. This is reflected in the structure of the Public Health programme which enables you to progress from Certificate, to Diploma, to Masters degree as you increase in knowledge, skills and confidence. The full Masters qualification (MPH) can be achieved in one year (full-time study), or over two to five years if studied on a part-time basis.

Coming from Nigeria, I appreciated the fact that the modules were structured to accommodate geographical variations, while being delivered by specialists with experience in public health research in low and middle income countries. The members of staff were such wonderful people, and the classes had never a dull moment with students from diverse backgrounds attending the course. I have

such fond memories of my time as an

MPH student at the University.

Dr Chidozie Nduka, MPH with Distinction

The MPH was intellectually stimulating and provided an opportunity to network with other physicians and professionals from around the world... It provided a strong basis for my career in public health medicine.

Dr Daniel Todkill, Speciality Registrar in Public Health Medicine

#### Benefits

This is an interdisciplinary course, drawing on expertise across a wide range of subject areas to explore the complexity of public health issues in the UK and internationally. You will have the advantage of working with experts in the Division of Health Sciences in Warwick Medical School (WMS), which delivers high-calibre, multidisciplinary research that helps to shape policy at home and abroad. Parts of the course will also be taught by guest clinical or academic lecturers.

#### Get in touch to find out more:

T: +44 (0)24 765 72958 E: cpdenquiries@warwick.ac.uk

> Warwick Medical School The University of Warwick, Coventry, CV4 7AL

www.warwick.ac.uk/wms

