COVENTRY
WARWICKSHIRE
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WEST MIDLANDS SOUTH PRIMARY CARE RESEARCH UPDATE

PARTICIPATE

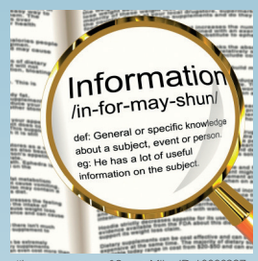
VOLUME NO 16 WINTER 2014

POINTS OF INTEREST

- Current Study – TASMINH 4
- Training – Getting to Hospital at a Stroke
- CPRD

CONTENTS

Stand Up and Be Proud – Celebrating Research Awareness and Involvement



"Image courtesy of Stuart Miles ID-10088297 at FreeDigitalPhotos.net"

All too often research is perceived as the forgotten wing of the NHS.

The amount of high quality research taking place in various health settings is overlooked in the hurly-burly and 'busy-ness' of the everyday delivery of healthcare. However, the data from everyday NHS general practice is increasingly being used to produce data for high quality research that is answering important clinical questions. To make greatest use of the vast amount of data collected on a daily basis within primary care, the Clinical Practice Research Datalink (CPRD), one of the largest databases of longitudinal medical records from primary care in the world, has been established to take forward the work started under the General Practice Research Database (GPRD). The CPRD is an immensely powerful research tool which will become even more potent when allied with the data collected for decades in the secondary care setting.

CPRD recognises the concerns expressed over the use of, and secure storage of, the data gathered within a general practice setting and has in places systems and processes that fully address this. As GPRD, and then as CPRD, data collection has been undertaken for over twenty years from GP practices who have agreed to participate. This includes coded data: diagnoses, treatments, referrals etc., but never includes NHS numbers, names, addresses or post codes so the identities of patients, GPs or practices is never known to researchers. After the initial set-up process, all data extraction is automatic and involves no additional work at the practice. This information can then be used to conduct medical research under licence on studies approved by the Independent Scientific Advisor Committee (ISAC): so far over 1,000 published research papers are available to view at www.cprd.com

Benefits of Participation in CPRD

It is hoped, that many practices in this area will want to join CPRD. Not only do practices contribute to answering important questions by doing this, but they would also benefit by receiving feedback reports about their data quality and prescribing patterns and have the opportunity to take part in further, remunerated, research activity. We strongly commend CPRD to our practices as a valuable research tool and we will be in contact soon with further information.

Research Incentive Practices Local Research Symposiums

The local research symposiums, an annual showcase event for practices, both those already engaged in research and those who may be interested in finding out more are taking place soon; results of past studies, forthcoming studies and details of our research incentive scheme for 2014-15 will be showcased. If you are interested in attending the event held in your area, please contact your local research facilitator.

In this edition we feature articles on:

- the management of hypertension in primary care using self-monitored blood pressure values (page 14)
- a new, free training initiative to help GP receptionists recognise the symptoms of stroke and TIA (transient ischaemic attack) (page 6)
- the role of prescribing in general practice (page 14)

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

Current Studies

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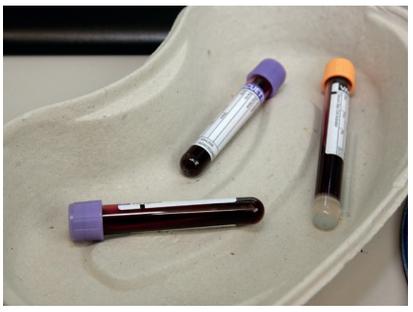

This study is looking at which symptoms, signs and examinations are best for predicting lung and bowel cancer. It follows on from two preliminary studies investigating cancer symptoms – a Delphi study and a qualitative study, which resulted in a list of symptoms, signs and tests to be assessed by GPs 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, as of end of December 2014 we have a total of 80 recruits. Eleven practices within our area are currently recruiting patients and we have a total of 24 practices open to recruitment - with expressions of interest still being received. Our target for case identification is 1-2 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 28 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 Julia Roscoe, email: j.roscoe@warwick.ac.uk or Jenny Lee, email: Jennifer.lee@warwick.ac.uk

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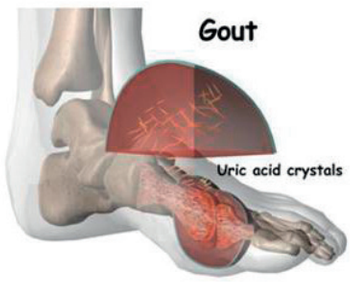
FAST

F A S T *(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). **F A S T *(Febuxostat versus Allopurinol Streamlined Trial)*** is sponsored by the University of Dundee, and is co-adopted by the Primary Care.

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.

Participating practices will receive a £500 fee for completing the database search, in addition to £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.

Would your practice be interested in helping us with this important study? So far, more than 20 practices have expressed an interest in the West Midlands region, and there are already 100 practices signed up in the East Midlands.



The Trial Manager is Jen Dumbleton 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 Dr Tim 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

Recruitment for Four-Fold Asthma started in West Midlands south in September 2014 and we have received a high level of interest from practices to date. We are currently planning a second phase of practice recruitment starting Spring 2015 and are looking for additional GP practices to recruit up to 10 patients per practice.

GPs or nurses are asked to identify patients who have asthma, use an inhaled steroid or combination inhaler and have had at least one asthma attack requiring prednisolone tablets in the last 12 months.

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 ID-100112438 at FreeDigitalPhotos.net"

If your practice would like to take part or would like more information, please contact: Julia Roscoe, CRN Research Facilitator j.roscoe@warwick.ac.uk or Linda Field, CRN Research Nurse linda.field@warwick.ac.uk

Helicobacter Eradication Aspirin Trial

UNIVERSITY OF BIRMINGHAM HEAT

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 2015

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, phone: 0121 414 2691, email: r.iles@bham.ac.uk

Current Studies

The Lipos Study: Liraglutide in PCOS

Lipos

Principal Investigator:
Dr Harpal Randeva

Location: University Hospital Coventry and Warwickshire, with recruitment from UHCW, George Eliot and Warwick Hospitals as well as NHS Community Health Clinics and GP practices within Coventry and Warwickshire.

Enrolment Period:
October 2013 – March 2015

Participants: Women with PCOS

Study details
The Lipos (Liraglutide in PCOS) study has recently begun recruitment in the Coventry and Warwickshire area. Lipos is a prospective, randomised, double blind, placebo controlled study investigating the use of Liraglutide alongside Metformin SR to improve fertility and symptom control in women diagnosed with Polycystic Ovary Syndrome. The study is funded by Novonordisk, sponsored by the University of Warwick and hosted by UHCW.

The study aims to establish whether the combined use of Metformin SR and Liraglutide will improve menstrual regularity amongst women diagnosed with PCOS. Secondary outcome measures include improvements in other symptoms and effects of the condition including hirsutism, metabolic syndrome and difficulty controlling weight and acne.

We aim to enrol 106 participants, who will all receive Metformin SR, with randomisation leading to 50% receiving Liraglutide and 50% receiving a placebo. Participants will need to attend UHCW on a number of occasions (10) over a period of 62 weeks, with multiple data being collected by study clinicians at each visit to measure a wide range of metabolic and cardiovascular parameters. Potential participants should be over 18 and diagnosed with PCOS.

If you would like to be involved, or for more information, please contact Dr Randeva email: harpal.randeva@warwick.ac.uk or the study nurses, Sundeep Deo sundeep.deo@uhcw.nhs.uk or Catherine Casas catherine.casas@uhcw.nhs.uk

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TASMINH4

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.

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

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES
UNIVERSITY OF OXFORD

UNIVERSITY OF BIRMINGHAM

CPRD
MORE DIMENSIONS TO DATA

Clinical Practice Research Datalink: What it means for General Practice and Public Health Improvement

Electronic health databases have been used widely in health research for years, consisting of data derived from routinely collected health records generated by daily clinical practice. Clinical Practice Research Datalink (CPRD) is one of the largest databases of longitudinal medical records from primary care in the world.

CPRD is the evolved GPRD

The original version of CPRD was GPRD (General Practice Research Database) established in 1987. It was renamed in 2012 to take account of both the increasing use of anonymised patient data for clinical trials and links being created with secondary datasets such as those from HES, Cancer, Diabetes, etc. CPRD is continuously collecting anonymised clinical records from millions of individuals and its total data archive currently represents almost 10% of the population of England.

Power and reach

CPRD is an enormously powerful research tool, data from which have been used to produce close to 2,000 research reports, published in peer-reviewed journals, many of which have had a direct impact on public health.

How the data are used

For example, in 2004, CPRD data was used to ascertain whether or not the combined MMR injection was having a detrimental impact upon patients, as had been reported in the national press. The published report concluded that:

"...after adjustment for age at joining the database, the odds ratio for association between MMR and pervasive developmental disorder was 0.86 (95% CI 0.68–1.09). Findings suggest that MMR vaccination is not associated with an increased risk of pervasive developmental disorder..."

Lancet 2004, v364; p963-969.

More recently researchers identified a totally anonymised research frame of over 100k obese persons and of these

"...2167 patients without diabetes who had bariatric surgery were matched according to age, BMI, sex, index year, and HbA1c category with 2167 controls who did not have surgery...".

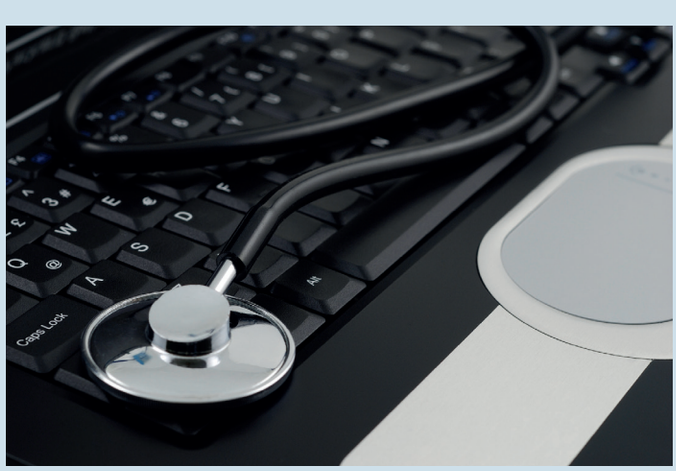
The subsequent research concluded that

"...bariatric surgery used in the prevention of Type 2 diabetes can reduce the incidence of clinical diabetes for up to 7 years after surgery in 80% of those who undergo the procedure".

Incidence of Type 2 diabetes after bariatric surgery: population-based matched cohort study, Lancet Diabetes & Endocrinology, v2, iss12, December 2014, p963–968.

The immediate future

These two examples of CPRD data being used to inform and offer the opportunity to influence public health practice and procedure, demonstrate how essential patient data is to the medium and long-term health and wellbeing of the nation. This said the time is right for a rethink in how CPRD aligns itself and coordinates research activity with CRN and the LCRNs, so that clear benefits for practices, patients and researchers can be achieved through sharing patient data for research purposes. This requires both a dialogue to identify a best-fit collaboration and a continued drive in recruiting practices to CPRD. At the end of the day, what's important to remember is that it doesn't matter how many or how few research platforms GP practices contribute patient data to, as long as practices continue to contribute data.



"Image courtesy of stockimages at FreeDigitalPhotos.net"

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If you would like further information on any aspect of CPRD organisation or sign-up, please contact Keith Hackett, Practice Recruitment Lead
email: keith.hackett@mhra.gsi.gov.uk phone: 0203 080 6699

New Studies

The impact of Giant Cell Arteritis (GCA) study

Keele University

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.

Arthritis Research UK

Providing answers today and tomorrow

NHS National Institute for Health Research

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

west midlands ACADEMIC HEALTH SCIENCE NETWORK

National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care West Midlands

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

A new, free training initiative launches in the New Year to help GP receptionists recognise the symptoms of stroke and TIA (transient ischaemic attack).

The programme, 'Getting to Hospital at a Single Stroke', has been developed in response to a recent study at the University of Birmingham that revealed that 20% of stroke patients called their GP, rather than an ambulance, at the onset of symptoms.

Dr Liz Bates, a GP in Birmingham and NIHR Clinical Lecturer at the university, was involved in the research and is now project lead for the training initiative. She explained:

"From the second the symptoms appear the clock is ticking: to save lives and minimise long-term damage, stroke patients must be diagnosed and treated in just four-and-a-half hours. GP reception staff are on the front line, and we aim to give these staff the confidence to recognise stroke and TIA symptoms as emergencies, and the skills to act quickly and effectively to improve clinical outcomes."

A stroke happens when blood supply to the brain is cut off and cells die; timely treatment with clot-busting drugs restores the blood flow saving lives and minimising damage. Experiencing a TIA (sometimes called a 'mini-stroke') greatly

ToSCA

Trial of Sertraline versus CBT for generalised Anxiety

Generalised Anxiety Disorder (GAD) is common, causes unpleasant symptoms and impairs people's functioning. It is often chronic and may be accompanied by depression and other anxiety disorders. Recent NICE guidelines have outlined the best initial treatments but it isn't clear whether medication or psychological therapy provides better long term outcomes for those not responding to simpler low intensity treatments.

The ToSCA trial (Trial of Sertraline versus CBT in generalised Anxiety) is a randomised trial of the medication sertraline versus Cognitive Behavioural Therapy for people with GAD who have not responded to low intensity psychological treatments.

Participants will be recruited via the Increasing Access to Psychological Therapies (IAPT) service from up to 15 sites in England. Those interested in taking part in the trial will be given an appointment to meet a research team member and will be assessed against trial inclusion and exclusion criteria. They will need to be at least 18 and to meet psychiatric criteria for GAD assessed with a standardised psychiatric instrument. We will also use this to assess if they have depressive symptoms and any other anxiety disorder.

More details can be found via the NIHR HTA web-site (our funders) http://www.nets.nihr.ac.uk/projects/hta/132802

We have recruited sites for our internal pilot which will start in February 2015, but will soon be looking for further sites to be involved in early 2016.

If you may be interested and would like more information please contact
Dr Marta Buszewicz (CI)
m.buszewicz@ucl.ac.uk
or Richard Haslop
(trial co-ordinator)
r.haslop@ucl.ac.uk

increases risk of having a stroke in the days and weeks immediately after the event. Assessing patients and starting treatment on the same day as a TIA reduces this risk by 80%.

'Getting to Hospital at a Single Stroke' offers two complementary and flexible ways to access training: an e-learning module accessed online and a half-day face-to-face training event delivered at venues across the region. The pilot will launch in the Telford and Wrekin CCG area in Shropshire in early 2015 and be rolled out to the wider West Midlands the following month.

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

Prof Ruth Chambers, Clinical Lead for long term conditions at the WMAHSN, said:

"We are delighted to be backing the 'Getting to Hospital in a Single Stroke' initiative. The programme reflects the ethos of the WMAHSN, joining academic research uncovering hitherto little-known statistics to putting that research into practice by supporting practical measures that will have a positive impact on patients, and the health economy as a whole."

"Image courtesy of shutterstock_175511726 at FreeDigitalPhotos.net"

For more information visit http://mymds.bham.ac.uk/eStroke/

TIME STUDY
Antihypertensive Study

Is it TIME for a change?

Could changing the time of day blood pressure medications are taken improve their effectiveness?

High blood pressure (hypertension) affects one in four adults in the UK, and this can significantly increase your risk of cardiovascular disease including heart attack and stroke. This condition poses a significant threat to the health of millions of people but, once diagnosed, can be managed well with medications.

The Treatment In Morning vs Evening (TIME) study is looking to substantiate the findings of an earlier study (the MAPEC study), which showed a reduction of cardiovascular events in patients that took their hypertensive medication in the evening compared with those who took them in the morning. TIME will look 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. Participants will be randomly allocated to either take anti-hypertensive medication at night or in the morning.

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.

Participant recruitment for the TIME study

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 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 www.timestudy.co.uk, where they can read more detailed information. Consent for the study is completed by the patient online and they then input study data.

Data security

The TIME study website, that has been set up for this study and the data, is stored as securely as possible at the University of Dundee. Testing of the system has shown that there are robust security measures in place for the study data. Personal data will be treated with the strictest confidentiality by the staff working on the study.

Involvement of GP practices

A mailing to all GP practices in the UK has recently been completed asking for practices to indicate if they would be interested in taking part in TIME by writing to all of their hypertensive patients currently on once a day medication. If practices are interested then network support is available to help with patient identification and invitation. Practices can register their interest by emailing the study at time-gpregistrations@dundee.ac.uk, registering on the website (www.timestudy.co.uk/GPRegistration.aspx) or returning a freepost response slip. Once patients have been invited then no further input is required from practices.

We are also asking if practices can put up posters in their practices even if they do not want to actively invite patients.

Involvement of hospital clinics

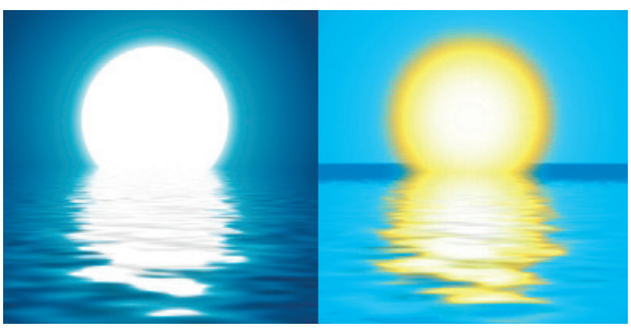
The study is adopted by the British Hypertension Society and members of their network have already been asked if they can directly invite suitable patients from their clinics. We hope that consultants who are not members of the network will also do the same. Anyone who is interested in finding out more about this can contact the co-ordinating centre in Dundee at TIME-study@dundee.ac.uk.

Summary

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

We'd like to thank the BHF who have funded this study and the British Hypertension Society who are coordinating it.

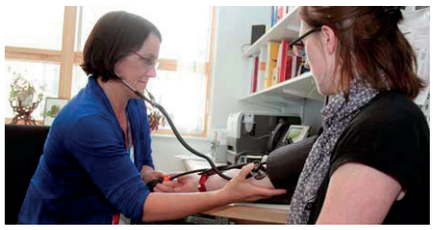
"Image courtesy of Anusorn P nacholID-10072322.jpg at FreeDigitalPhotos.net"



"Image courtesy of Danilo Rizzuti ID-10015601.jpg at FreeDigitalPhotos.net"

Primrose

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, HBA1c, 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 114 patients and 44 GP practices across England. We aim to recruit a further 16 GP practices to the study by the end of March 2015 and 6-10 patients within each practice by June 2016.

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 6 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: Telephone: 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

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EVRA

Early Venous Reflux Ablation Ulcer Trial

Simple study - ideal for novice practices

Background

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

Recruitment

Patients will be randomised from secondary care into one of two treatment arms to either:

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

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

Practice Involvement

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

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

- University Hospital Birmingham NHS Trust
- The Dudley Group NHS Trust (Corbett, Guest & Russells Hall hospitals)

Learn More

If you are interested in taking part, please contact:
Jenny Lee, Research Facilitator phone: 02476 575 919
email: jennifer.lee@warwick.ac.uk

InSpires Awards Evening 21st November 2014

NHS Coventry and Rugby Clinical Commission Group has a locality structure consisting of InSpires, Godiva and Rugby. The InSpires locality annual awards evening 2014, held on the 21st November, recognises achievement and dedication of member practice staff. Some 26 Coventry practices are members of InSpires locality, and the current Chair is Dr Peter O'Brien supported by Jag Tomlinson the Locality Manager

This year a new category was created for the Research in Primary Care Award. This was judged and presented by Professor Jeremy Dale, Professor of Primary Care, Warwick Medical School.

Practices were asked to demonstrate:

- How clinical research has enhanced/changed routine clinical practice over the last 12 months
- An organisation wide approach to research rather than just one individual taking the responsibility
- Participation in a range of research studies
- That the practice has embraced patient involvement in research via activity on their website, on their notice board and the involvement of their patient reference group

Who entered?

Forum Health Centre, Henley Green Medical Centre, Holbrooks Health Team, Walsgrave Health Centre and Coventry GP.com Group of Medical Practices (Jubilee Health Centre & Broad Street Surgery), self-nominated for the award.

All practices are part of the Research Incentive Scheme working with the Clinical Research Network: Primary Care, based at Warwick Medical School. The scheme financially rewards commitment to research delivery and provides appropriate levels of training and support. These incentive payments are in addition to the normal study support costs that practices are paid by study teams.

Joint runners up: Henley Green Medical Centre and Forum Health Centre.

Henley Green Medical Centre has been part of the research incentive scheme for three years. This practice highlights the fact that research can flourish within any size of practice.

The Esteem study in particular helped change clinical practice here, improving patient waiting times. Such perceptible patient benefits prompted further participation in a large number of wide ranging studies (five so far this year) and successful recruitment – this practice was the highest recruiter to the national 3C study in Coventry.

The practice is quick to respond to expressions of interest and helps the CRN: Primary Care team with assessing feasibility of studies.

Forum Health Centre has established a whole-team approach to consideration and delivery of a large number of research studies. Updates from research staff have become a regular item on the weekly practice meeting agenda to discuss eligible studies and recruitment strategies - research being perceived as a core activity. The practice has participated in a wide range of studies (five so far this year), contributing significantly to recruitment numbers and this year a range of staff have also become GCP (Good Clinical Practice) trained. A wide range of staff including GPs, practice nurses, health care assistants and administrative staff have been involved in this work, allowing new skills to be learnt by many members of the practice team. There are plans to extend patient awareness of the research available by information on the plasma screen in the waiting room and on the practice website.

The winner

The award went to CoventryGP.com Group of Medical Practices (Jubilee Health Centre & Broad Street Surgery), Drs Nahl, Sihota and Dosanjh.

Dr. Hergeven Dosanjh, Lead Research GP, accepted the award with research nurse Eleanor Hoverd. The practice has been part of the Research Incentive scheme for two years, acting as a host practice, where a research nurse helps in set-up, delivery and recruitment for clinical trials. Since becoming involved in research in 2012, the sites have taken part in 19 clinical trials (15 of those since becoming a host practice), including commercial work, acting as a PIC (Patient Identification Centre) site and also taking part in a variety of clinical trials covering a broad spectrum of disease and conditions.

As a training practice there are clear opportunities for trainees to experience research delivery at practice level first hand. The practice clearly recognise the potential to further develop, and feel they are now building upon firm foundations.

Research Awareness

To support the raising of patient awareness the practice held research awareness mornings on both branch sites in May of this year to celebrate International Clinical Trials Day – patient opinions gained at these events have helped with some ideas to further enhance recruitment into our studies. Research Nurse Eleanor Hoverd thanked Lead Research GP Dr. Hergeven Dosanjh for his energy, enthusiasm and responsiveness, the Practice staff, in particular the Receptionists at Broad St Surgery and Senior Practice Nurse Kam Johal, who offer great insight into the local population and are very supportive in helping to deliver clinical research in Primary Care.

Eleanor said:

"We have a diverse population here in Coventry - with some creativity and innovation we can engage more with some of our seldom heard patients, who may actually benefit the most from being offered the chance to be involved with health research.

We know taking part in health research improves care and quality, health and wellbeing and can also impact on service and delivery. There's much work to be done in making health research part of our everyday practice but I hope this inspires more practices in Coventry and elsewhere in the West Midlands South to begin to build a research culture in your practices and gives patients and staff the opportunity to be involved with the exciting prospects that health research has to offer".

from left to right: Dr Hergeven Dosanjh, Eleanor Hoverd, Research Nurse, Bally Gidda, Senior Receptionist, Kam Johal, Senior Practice Nurse, CoventryGP.com Group of Medical Practices

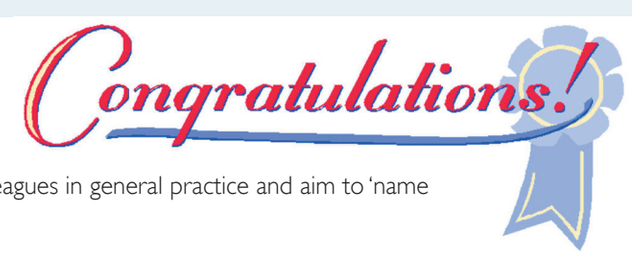
The importance of research as shown in the NHS Constitution:

Research is a core part of the NHS. Research enables the NHS to improve the current and future health of the people it serves.

The NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them. The NHS is therefore putting in place procedures to ensure that patients are notified of opportunities to join in relevant ethically approved research and will be free to choose whether they wish to do so. (Handbook to the NHS Constitution, January 2009).

If you would like more information on how to take part in clinical research, please contact your research facilitator, Jenny Lee, on 02476 575919 or email: jennifer.lee@warwick.ac.uk

News from Our Practices: Achievements Over and Above



In the first of a new series we celebrate the achievements of our colleagues in general practice and aim to 'name and praise', highlighting examples of when things go well.

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

TOP RECRUITERS

Castle Medical Centre:
For recruiting 43 patients to HeLP which is double the number of patients expected/required, which was 19-20 patients per practice.

Dr Singh's practice at Bedworth Health Centre:
For recruiting twice the expected number of patients to the BWEL study.

BWeL
Brief intervention for Weight Loss

New Dispensary:
For their enthusiasm and drive in becoming our top recruiting practice for CANDID.

CANDID
CANcer DIagnosis Decision rules

FIRST RECRUIT TO A NEW STUDY

Holbrooks Health Team:
For the first recruit in West Midlands South to the Four Fold [FAST] asthma study.

FAST

INDUSTRY STUDY RECRUITMENT

Spring Gardens:
ELIOT was their first industry study as a site; target was six patients and they recruited 22, which makes them one of the highest recruiting practices in the country.

Claire Jones and Mike Arnold are fantastic to work with, Mike goes the extra mile and Claire is always pro-active. Recruitment figures are high and it is always a joy to work there.

Many congratulations to Dr Claire Jones on her recognition of being one of the country's leading commercial PIs. She has received a personal invitation from Dame Sally Davies to attend an event recognising NIHR CRN leading commercial PIs. This is fantastic news for her, the team and South Worcestershire and a very well-deserved reward for much hard work.

TOP NEW PRACTICE

Alcester Health Centre:
Recently joined our research incentive scheme; already completed research ready training and are underway with GCP training; took on a PIC study at short notice within one day of the request. They have expressed interest in other studies and have been a pleasure to work with.

Study Update

TArgets and Self-Management for the control of blood pressure IN Stroke and at Risk groups (TASMIN-SR): an unblinded randomised controlled trial

Objective

Our previous trial (TASMINH2) showed that self-monitoring of blood pressure (BP) with self-titration of antihypertensive medication (self-management) resulted in lower BP in patients with hypertension, but there has been no data from patients in high-risk groups.

Our aim with TASMINSR was to determine the effect of self-monitoring with self-titration of antihypertensive medication compared with usual care on systolic BP among patients with stroke, cardiovascular disease, diabetes, or chronic kidney disease.

Design, setting and patients

A primary care based, unblinded, randomised clinical trial involving 552 patients aged at least 35 years with a history of stroke, coronary heart disease, diabetes, or chronic kidney disease and with baseline BP of at least 130/80 mmHg being treated at 59 UK primary care practices. The study was conducted between March 2011 and January 2013.

Interventions, main outcomes and measures

Self-monitoring of BP combined with an individualized self-titration algorithm. During the study period, the office visit BP measurement target was 130/80 mm Hg and the home measurement target was 120/75 mm Hg. Control patients received usual care consisting of seeing their GP for routine BP measurement and adjustment of medication if necessary.

The primary outcome was the difference in systolic BP between intervention and usual care groups at the 12-month office visit.

Results

450 patients (81%) were seen at the 12 month follow up visit. Patients in the self-management group had a mean baseline BP of 143.1/80.5 mmHg, usual care patients had a mean baseline BP of 143.6/79.5 mmHg.

After 12 months mean BP had decreased to 128.2/73.8 mmHg in the self-management group and to 137.8/76.3 mmHg in the usual care group, a difference of 9.2 mmHg for systolic BP and 3.4 mmHg for the diastolic BP. Accounting for missing values using multiple imputations gave similar results.

At 12 months mean BP was 128.6/73.6 mmHg in the self-management group and 138.2/76.4 mmHg in the usual care group, a difference of 8.8 mmHg for systolic BP and 3.1 mmHg for diastolic BP. There were no significant differences in subgroup analysis including age, gender, baseline BP, baseline health condition and level of deprivation. There were no excessive adverse events during the study and no difference in the reporting of adverse events between the self-management and usual care groups.

Conclusions

Among hypertensive patients at high risk of cardiovascular disease, self-management, compared with usual care, resulted in lower systolic BP at 12 months. Patients at high risk of cardiovascular disease whose BP is not optimally controlled could be considered for self-management.

Future work

Results from other UK studies have demonstrated short term reduction of BP with self-monitoring alone but issues remain regarding

a) the impact and necessity of telemonitoring in recording BP readings
b) whether titration by GPs solely on the basis of self-monitoring is effective and
c) whether any effects are maintained for at least 12 months.

Integration of self-management into daily practice is likely to be only relevant for a minority of individuals with hypertension hence the need for self-monitoring with GPs directly titrating on this basis. In order to investigate whether self-monitoring would be feasible in general practice we are starting the TASMINH4 trial which will compare the effect of patients self-monitoring their BP and sending paper based readings to their GP, patients self-monitoring and texting their readings to a specially developed web based system and patients undergoing usual care.

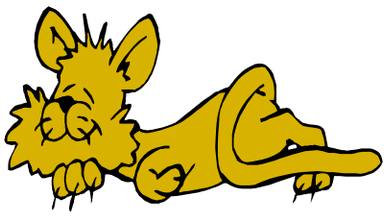
If you are interested please contact us here at the University of Oxford– TASMINH4@phc.ox.ac.uk or your local research network.

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

TASMINH4

UNIVERSITY OF BIRMINGHAM

Medicated Sleep and Wakefulness Study



Feedback Event: Warwick University 5th November 2014

The aims of the study were to compare and contrast GP and patient views on `medicating sleep' in primary care.

Approximately 10 million prescriptions are issued for sleeping pills in the UK each year

The prescription of hypnotics is a politicised issue in the UK with measures in place to monitor and reduce the prescription of hypnotics in primary care. All of the sleeping pills currently available in the UK are only licensed for short term use only – no pharmaceuticals are licensed for long term treatment of insomnia due to lack of evidence for long term efficacy, risk of dependency and other side effects.

Following up on the role of supporting the delivery of patient focus groups and general practice clinician interviews on the above topic, came attendance at the Sleep, Medicines and Society Programme feedback held at the University of Warwick.

Our participating practices were:

- Abbey Medical Centre
- Sherbourne Medical Centre
- Springfield Medical Centre
- Castle Medical Centre
- Jubilee Health Centre
- Henley Green Medical Centre
- Forum Health Centre

Data was drawn from semi-structured interviews with seven GPs and three focus groups with 12 chronic users of hypnotics.

How does your patient view insomnia and its treatment?

Patients hold multiple views about the aetiology of their insomnia and the impact of any pharmaceutical regime adopted. Personal ambivalence is characterised by conflicting wishes which make it difficult to decide how to act. GPs are ambivalent about whether to prescribe hypnotics or not, especially to chronic users; however chronic use of hypnotics was also a source of personal ambivalence for some patients.

The impact of medication on insomnia was of concern to both patients and clinicians and the associated stigma of hypnotics and their addictive properties of primary concern within the patient focus group sessions.

Hypnotics are viewed as a temporary remedy rather than daily therapy and short term use is seen in more positive terms, with long term use associated with the negative aspects of hypnotic drug use. Intermittent chronic use at a stable dose is seen as more acceptable than daily use or escalating doses.

Whilst prescribing nationally for hypnotics is flat-lining and is certainly viewed as much more short term treatment (2-4 weeks) there is an increase in anti-depressant medication. The availability of CBT, or talking therapies, as a viable treatment option is patchy around the country.

COPERS
MANAGING PAIN • LIVING LIFE

Improving the self-management of long term pain

Trial results summary

After six months those who had attended the COPERS course were coping with their pain better, were more self-confident, less depressed and anxious and more socially integrated than those who did not attend the course.

One year after being in the COPERS trial those who had attended the COPERS course were still less depressed and more socially engaged than those who had not attended the course.

The COPERS course did not make any difference to 'function despite pain' or health care utilisation, but it was found that using a group based course that enabled people to discuss their conditions and learn non-drug pain management techniques helped psychological wellbeing. The team are hoping that the course will be introduced into the NHS as it was also found to be cost-effective (based on NHS guidance).

The COPERS team would like to thank all who supported and contributed to the study, your participation has helped further health care in the field of chronic pain.

If you would like further details, please contact Dawn Carnes d.carnes@qmul.ac.uk

The Role of Prescribing in General Practice

Prescribing is an important activity for general practitioners. Patients rely on the medicines that their doctors choose. From a medical perspective, the prescriber should be adequately trained to perform this important clinical task. Although patients demand the best medicines, there is an ongoing tension between choosing the clinically most advantageous products and what the NHS can afford.

Since 1948, successive governments have introduced various policies to control doctor prescribing as a means of controlling Exchequer spending on drugs. However, the history of medicines policy has received little attention in academic and trade journals. Therefore, Professor Darrin Baines, an economist from Coventry University, has embarked on a long-term research project to map out the history of prescribing policy in the NHS. Recently, his work has resulted in a series of articles in the Prescriber magazine.

Although history can be fun to learn, is there anything that can be of any use from the past for doctors and policy makers today?

"Yes", says Professor Baines, ***"history matters"***

By looking into the past, we can see how modern policies evolved. We can see how compromises and choices were made. We can see how today's policy has been shaped by previous events. Therefore, a good knowledge of prescribing policy can better helps policy-makers, CCGs and prescribers to better understand how to control drug costs whilst meeting patient needs.

If you would like to learn more about Professor's Baines work, please visit darrinbaines.net or email him at: darrin.baines@coventry.ac.uk

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.

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 Tel: 0121 414 8842
Email: j.a.hodgkinson@bham.ac.uk

Research Design Service (RDS)

If you would like any further information, please contact us on rds@warwick.ac.uk or 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

Keep in Touch: Your Local Staff and Sub-Team Contact Details

Clinical Lead
Professor Jeremy Dale
jeremy.dale@warwick.ac.uk

GP Research Lead
Dr Tara Al-Salihi
t.al-salihi@warwick.ac.uk 07880 175 386

Research Manager
Sue Elwell
s.elwell@warwick.ac.uk 02476 575 854

Research Facilitator (study specific)
Julia Roscoe
j.roscoe@warwick.ac.uk

Admin Co-ordinator
Jenny Oskiera
j.oskiera@warwick.ac.uk 02476 575 767

Team Secretary
Viv Owen
v.j.owen@warwick.ac.uk 02476 574 698

COVENTRY

Research Facilitator
Jenny Lee 02476 575 919
jennifer.lee@warwick.ac.uk 07920 531 253

Research Nurses
Eleanor Hoverd
e.j.hoverd@warwick.ac.uk 07867 468 560
Linda Field
linda.field@warwick.ac.uk 07880 175 384

HEREFORDSHIRE

Research Facilitator
Jenny Lee 02476 575 919
jennifer.lee@warwick.ac.uk 07920 531 253

Research Nurses
Pauline Darbyshire
p.darbyshire@warwick.ac.uk 07867 468 557
Jon Davies
j.davies.5@warwick.ac.uk 07823 362 149

SOUTH WARWICKSHIRE

Research Facilitator
Becky Harrison
r.l.harrison@warwick.ac.uk 02476 575 853
Becky Harrison 07788 351 365

Research Nurses
Sarah Joshi
sarah.joshi@warwick.ac.uk 07884 733 057
Claire Talbot
c.talbot@warwick.ac.uk 07884 733 058
Susan Zhao
s.zhao@warwick.ac.uk 07823 362 148

WORCESTERSHIRE

Research Facilitator
Aman Johal 02476 574 127
amanpreet.johal@warwick.ac.uk 07788 351 364

Research Nurses
Elaine Butcher
e.butcher@warwick.ac.uk 07867 468 556
Jon Davies
j.davies.5@warwick.ac.uk 07823 362 149

NORTH WARWICKSHIRE

Research Facilitator
Aman Johal
amanpreet.johal@warwick.ac.uk 07788 351 364

Research Nurses
Elaine Butcher
e.butcher@warwick.ac.uk 07867 468 556
Tracey Adcock
t.a.adcock@warwick.ac.uk 07880 175 385

Continuing Professional Development

Masters and Continuing Professional Development

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WARWICK MEDICAL SCHOOL

Medical Education

Postgraduate Study: Certificate/Diploma/Masters (MMedEd)

The Medical Education programme at Warwick Medical School (WMS) is designed for clinicians and health professionals who are involved in the delivery of medical education and training at either undergraduate or postgraduate level. It covers the principles and methods of teaching and learning and their application to healthcare, providing you with the skills needed to plan and deliver successful teaching and learning sessions.

WMS has developed its postgraduate level programmes in response to the changing professional development needs of medical practitioners. They are ideal for busy healthcare professionals who require the flexibility to study at a pace and level that suits their needs and fits around their professional commitments.

The Medical Education programme offers modular learning allowing you to progress from Certificate to Diploma to a full Masters degree (MMedEd). The Masters in Medical Education can be completed on a part-time basis over a period of two to five years.

Taught by experienced clinicians and leading academics in the field of medical education, this programme will enhance your knowledge and skills as an educator and give you the confidence to apply them in your own professional practice.

Elements of the course are accredited by the Higher Education Academy.

Successful completion of the first module, 'Essentials of Clinical Education,' entitles participants to recognition as an Associate of the Higher Education Academy.

Successful completion of the Certificate in Medical Education entitles participants to recognition as a Fellow of the Higher Education Academy.

For further information please contact:

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

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