

# PARTICIPATE

VOLUME NO 19

AUTUMN/WINTER 2015



**National Institute for Health Research**

Clinical Research Network  
West Midlands



**WARWICK**

WARWICK MEDICAL SCHOOL

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University of Warwick

## The Unsung Heroes of Research

Research in its broadest sense can be defined as investigation carried out to ascertain facts, to test or revise an existing theory, or as an attempt to find practical applications based on previously observed discoveries. Achieving these aims requires the co-operation of a large number of people, together providing the skills needed to bring about a successful outcome.

### Practice nurses – thank you

The staff who support undertaking research in the field, such as the practice-based teams whose involvement and support is essential to so much primary care research, receive insufficient recognition. In this edition of Participate we celebrate the contributions of practice nurses, without whom much research would be difficult or impossible to carry out.



Practice nurses throughout West Midlands South, working with our local research nurses, have extended the reach of research, opening studies to many more patients who otherwise might not have had such opportunities, broadened their access to the latest treatments and as a collateral benefit, in some cases facilitated quicker access to diagnosis of previously unrecognised conditions.

### In this edition we feature articles on:

- **TOSCA** (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 (see page 2)
- **TIME** (Treatment In Morning vs Evening) 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 (see page 6)
- **Co-Creating Education and Research: Solutions to Primary Care Problems**, the re-establishment of a group of academics in Warwick Medical School established to work with you to help improve primary care through education and research (see page 14)
- **Hope Over Fear: iHOPE for Cancer Survivors, a 6 week web-based, self- management programme (SMP)** underpinned by positive psychology theory and practice (see page 7)

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

### POINTS OF INTEREST

- New Study – TOSCA
- Current Study – FAST Gout
- Practice Nurse Special
- Relaunch of WMS Primary Care

### CONTENTS

New Studies	2-3
Current Studies	4-6
Local Research	7
Practice Nurses	8-9
CRN	10-11
Study Results	12-13
Local News	14-15
CPD	16



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

# New Studies



**ALL HEART (Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease) is a major multi-centre trial of allopurinol 600mg daily versus no treatment added to usual therapy in patients aged 60 years and over with ischaemic heart disease. The aim is to establish whether allopurinol improves cardiovascular outcomes in this population.**

Suitable patients are identified in primary care by their GPs; those that respond favourably attend an appointment with a research nurse. Patients will be randomised to either allopurinol or no drug to be given in addition to their usual medications. Allopurinol will be started at 100mg daily for two weeks, then titrated to 300mg daily for two weeks, then titrated to 600mg daily if tolerated. Patients will then be followed up for a period of around four years to count the number of heart attacks, strokes and cardiovascular deaths that occur.

**Recruitment will start soon in the West Midlands. Would your practice be interested in helping us with this important study?**

Participating practices will receive a fee for completing the database search, in addition to per patient payments.

So far, more than 200 practices are taking part in the East Midlands and Scotland. The Trial Manager is Jen Dumbleton, and her contact details are as follows: [jennifer.dumbleton@nottingham.ac.uk](mailto:jennifer.dumbleton@nottingham.ac.uk), 0115 823 1053.

Further details can also be found on the trial website: <http://allheartstudy.org>



**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>

**TOSCA  
is now taking place in  
IAPT services across,  
North Warwickshire,  
South Warwickshire,  
Rugby, Coventry  
and Solihull.**

If you would like more information please contact Mariah Vorajee, Coventry & Warwickshire Partnership Trust, Research & Innovation, 2 Manor Court Avenue, Nuneaton, CV11 5HX, phone: 02476 322746, email: [Mariah.Vorajee@covwarkpt.nhs.uk](mailto:Mariah.Vorajee@covwarkpt.nhs.uk)





## Helping to connect volunteers to research studies

### What dementia research is going on in the West Midlands?

Join Dementia Research ([www.joindementiaresearch.nihr.ac.uk](http://www.joindementiaresearch.nihr.ac.uk)) is a nationwide online and telephone service where you can register your interest in participating in dementia research. Anyone 18 or over, with or without dementia, can register as a volunteer or sign-up for someone else, providing that you have their consent.

#### Some dementia research studies currently taking place in the West Midlands:

The **MADE (Minocycline in Alzheimer's Disease Efficacy)** trial aims to determine whether the antibiotic drug Minocycline is effective in reducing the rate of cognitive and functional decline over a 2-year period for people with very mild Alzheimer's Disease.

The **IDEAL study** is investigating what helps people to live well with dementia. What the researchers find out will be used to guide policy and practice for helping people living with dementia.

The **use of home adaptation by people with dementia study** is looking to improve knowledge regarding how people with dementia and their carers access and respond to information and advice about adapting their homes. This understanding will hopefully lead to improved information and education for people living with dementia on how they can make adaptations which enable them to stay at home for longer. The study is based at the University of Warwick.

The Birmingham Cognitive Screen (BCoS) is a paper and pencil assessment used to assess aspects of memory in people with cognitive impairment. It helps indicate whether a person might

have difficulty in memory, communication, attention, decision making, planning or carrying out everyday tasks.

The Assessing the cognitive profiles of different types of dementia study aims to compare performance on the BCoS in different groups of younger patients (under 75) with mild dementia. BCoS will also be compared with an existing assessment, the ACE-3, used routinely for dementia assessment, on how well BCoS reflects the full range of abilities within individuals.

You can see if you are eligible for any of these studies – and others around the nation by **logging into your Join Dementia Research account**. If you haven't yet registered with Join Dementia Research, **why not sign up today?**



## CANDID

CANcer Diaqnosis Decision rules

### Recruitment update

Continued thanks to those practices recruiting to the CANDID study which is set to continue until the 30th September 2016. Congratulations to our top ten recruiting practices:

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



- Hazelwood Group Practice
- Atherstone Surgery
- Priors Gate Medical Centre
- Rother House Medical Centre
- Whitestone Surgery

We would also like to extend a warm welcome to the practices who have recently joined the study:

- Bennfield Surgery
- Westwood Medical Centre
- Shipston Medical Centre
- Croft Medical Centre
- Alcester Health Centre
- Lapworth Medical Centre

### Can we help you with recruitment?

We hope to be in touch shortly with those practices yet to recruit to this study to offer further support in recruiting patient number one and beyond. A range of promotional material for this study is available – waiting room posters and leaflets and also a screen message. Please let us know if these would be helpful.

For those practices yet to recruit to CANDID please consider installation of the CANDID pop up onto the clinical system to act as a reminder of the study should a potentially eligible patient present in surgery.

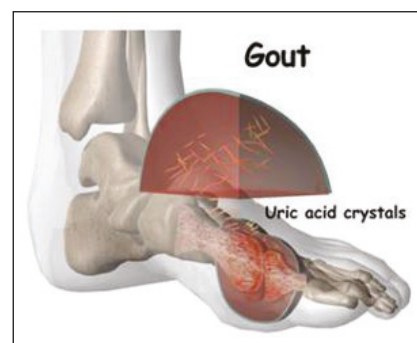
If you would like further information re the installation of the CANDID pop up please contact [Jennifer.lee@warwick.ac.uk](mailto:Jennifer.lee@warwick.ac.uk) or telephone 024 76575919

Our CANDID co-ordinating centre is now via the study team at Southampton University and the new contacts for any queries are: Sue Broomfield, Study Manager or Karen Middleton, Research Administrator, University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST phone: 023 8024 1081, email: [candid@soton.ac.uk](mailto:candid@soton.ac.uk)

## FAST

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). This is a very simple study, with a very low workload for participating practices.

So far, more than 50 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.



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

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.

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



Keele  
University

## 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.

**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](mailto:j.a.prior@keele.ac.uk)

UNIVERSITY OF  
BIRMINGHAM



## Helicobacter Eradication Aspirin Trial

### Helicobacter eradication to prevent ulcer bleeding in aspirin users: a large simple randomised controlled trial

**Principal Investigator Birmingham Region:** Prof Richard Hobbs

**Locations:** ~400 GP practices in Birmingham and Black Country, Worcestershire, Coventry and Warwickshire, Shropshire, Staffordshire, Herefordshire, Stoke, Telford and Wrekin, Wolverhampton, Sussex & Surrey, Nottingham, Durham, Southampton, and Oxford.

**Enrolment Period:** 2012 – June 2016

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

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

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

**Intervention and Clinic:** Suitable patients will be identified by their surgery, using an automated search, and then asked to attend an appointment with a University Research Nurse or Practice Nurse (relevant training will be provided) to consent to the trial and take a H. pylori breath test. Those with a positive result will be randomised to receive a one week course of either eradication treatment or placebo, supplied by the trial centre. No follow-up visits for the patients are required, but any hospital admissions for ulcer bleeding will be recorded over a period of 2-3 years by the trial centre.

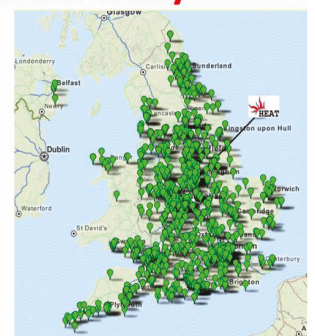
### HEAT – a national study

INVITATION LETTERS SENT = **124,548** (73% of target of 170,000)

POSITIVE RESPONSES RECEIVED FROM PATIENTS = **24,339** (20% positive response rate)

PATIENTS CONSENTED = **19,153** (58% of target of 33,000)

PATIENTS RANDOMISED = **3,349** (17% of those breath tested, 51% of target of 6,600)



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



# TIME STUDY

## Antihypertensive Study

### TIME: Continues to recruit in the UK

**TIME: Continues to recruit in the UK (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.

#### GP practice recruitment

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.

A Docmail account is available to mail patients, reducing costs and administration time for practices. The West Midlands is the lead region for the study in England. Other regions have now also started recruiting with new practices continuing to register their interest.

#### Involvement of hospital clinics

Patient recruitment from hospital clinics is also possible; 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.

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

#### Progress

Recruitment to the study is going well with nearly 9000 people already randomised. It is anticipated that recruitment will continue into 2016.

**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.**

#### 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 over 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 online with patients registering and consenting through the study website 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.



are you taking  
blood pressure tablets?  
morning vs evening  
which is best  
help us find out  
[www.TimeStudy.co.uk](http://www.TimeStudy.co.uk)

Patients register for the study at [www.timestudy.co.uk](http://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.



## Hope Over Fear: iHOPE for Cancer Survivors



Cancer survivors face a number of challenges following primary treatment. Many struggle with unmet needs including fear of cancer recurrence (FCR) cancer related fatigue (CRF), depression and anxiety. Coventry University and Macmillan Cancer Support have recently delivered the iHOPE programme to over 50 cancer survivors.

iHOPE is a six week web-based, self-management programme (SMP) underpinned by positive psychology theory and practice. Cancer survivors reported statistically significant improvements with

RCR, CRF, depression, anxiety, positive mental wellbeing, hope and gratitude.

Participants described the powerful impact of identifying with other cancer survivors, which helped them adopt a more hopeful and inspiring approach to many aspects of cancer survivorship. Weekly goal setting, mindfulness, identifying personal strengths and keeping a gratitude diary were valued activities. Website usability ratings were

high. Participants valued the flexibility a web-based course offered, fitting it around work schedules and hospital appointments. We believe that due to the growing burden of cancer survivors in the UK, a large scale development of this programme could be particularly beneficial to support the health and wellbeing of large numbers of the UK population living with and beyond cancer.

For more information please contact Dr Andy Turner email: [a.turner@coventry.ac.uk](mailto:a.turner@coventry.ac.uk)

## Research Involvement: a Patient's Story

by Colin Tysall

### Background

When I worked in industry I was involved in research, both in developing new products and in finding out what went wrong with failures. After 30 years of working in heavy industry had worn me down, ending with a breakdown, I decided to try and understand my health better, set up self-help groups to pass on my experience, and gain more understanding that could help us deal with our problems.

### Opportunities to help

As soon as opportunities arose to pass on my knowledge to students at the Universities of Coventry and Warwick, I took them. At first it was simply telling my story and answering their questions, but over a number of years, patient participation in health developed, and now we are fully engaged.

The first projects I was involved in were to do with mental health and patient participation research. More recently I have been a co-applicant on many research projects including lower back pain treatments and other long term

conditions. I am now accepted as an 'expert by experience' in my conditions and work with academics and health professionals on an equal footing.

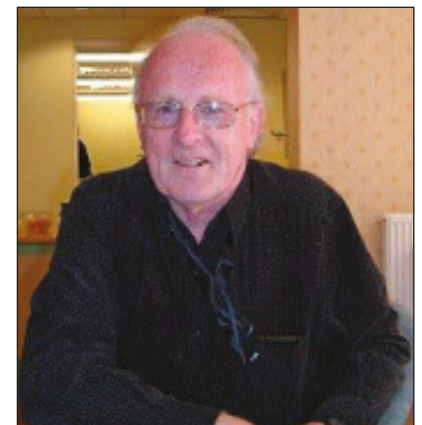
In recent years, funders and university authorities have insisted that true service user and carer involvement takes place in their courses or research projects.

### How involvement in research helped me

After struggling against pain, depression and undiagnosed diabetes, I once more feel a useful part of society, having learned how to manage my condition.

For example, when I was first in constant pain, doctors used NICE guidelines and recommended bed rest, which resulted in me progressively losing the use of my legs. By going for walks with fellow mental health sufferers, I regained strength in my legs and other problems started to recede. This demonstrates the type of practice that eventually led to NICE recommending exercise and a healthy lifestyle.

I am now a part of a research group at Coventry University looking at various aspects of the research programme, such



as ethics, analysis and literature reviews. Researchers come for our opinions of their proposals and to gain our help with their projects.

At Warwick University, UNTRAP: a user, care and teaching organisation, trains lay people who wish to become involved in research.

### A message of hope

*To those who have been struck down by a long term condition, don't vegetate and lose the will to live; get involved with self-help groups and research organisations and get your life back. GPs, hospitals and universities engage in research and need you to help them in improving everybody's health and wellbeing.*



## A Practice Nurse's First Experience of Research: HEAT Study

By Michelle Wheate, RGN/DipHE Practice Nurse, Churchfields Surgery

Even though I had assisted with other studies at the surgery, this was the first research I had ever undertaken on my own.

I was initially a little worried about the study and the paperwork involved; however it was not as much as I feared and the support given by Elaine, our CRN research nurse, and Rachel from the HEAT study team, was fantastic, they answered any question or concern no matter how trivial.

The study was done in my own time at the surgery and involved an initial 45-60 minute appointment with the patient, asking some questions to ensure they

matched the study criteria, obtaining a breath sample and following it up with some observations: BMI, blood pressure etc.

This was all documented and also added to the 'HEAT tool kit' so the team could access the results. The patient and I both received notification of the breath test result and, if positive, I followed up by calling the patient to see if they had started the treatment and whether they were experiencing any side effects or problems. This information was then forwarded to Rachel.

I found it to be really good 'starter' research, the knowledge gained was of



great value and, as incidental benefits, the extra money helps and it looks good on your CV!

The experience of participating in this research study, together with receiving study specific training, has boosted my confidence in being able to tackle further research projects, and I now look forward to the next one.

## Practice or Research? Nurses Working Together to Improve Healthcare Outcomes

By Claire Talbot

A crucial aspect of my role as a research nurse with the Clinical Research Network: West Midlands, based at a host practice in Kenilworth and working at other practices within South Warwickshire, is to promote research by engaging people to participate.

Research is fundamental to the work of the NHS as it influences changes in our practice, improves the quality and outcomes of patient care, and subsequently the health and wellbeing of the nation.

In May 2014 the NIHR published '*Promoting a research active nation*' which encouraged public engagement and participation in health research via a strategic five year plan.

### The role of practice nurses

Practice nurses can play a key role in bringing research to their patients. They have an ideal opportunity, and are in a

fortunate position, from which they can promote, engage, involve, and facilitate a patient's journey through the research process. They can use their knowledge of the person involved to assess and understand their willingness, or reluctance, to take part.

Research is an integral part of our everyday working lives but with ever increasing workloads and time constraints many healthcare practitioners feel that they have little or no time to participate. As research nurses we can help by making their involvement as simple as possible. I have been lucky enough to be part of one practice nurse's journey through the research process: Linda Sanins, at the New Dispensary Surgery in Warwick, agreed to take an active role in running the Four Fold (FAST) Asthma study at her practice with my support. She decided to take part not only because it is interesting, but she



could also see how it would benefit her patients practically. Engaging fellow health professionals in this way contributes to the development of evidence based clinical practice and a research culture in health care.



## What Research in Primary Care means to me: a Practice Nurse's Perspective

By Kam Johal RGN,  
Nurse Practitioner,  
CoventryGP.com



### My research journey

As a nurse working within the primary care setting I have been involved in health research for the last 15 years, starting when I was employed by the University of Warwick to coordinate the United Kingdom Asian Diabetes Study (UKADS). This large study, based in Birmingham and Coventry, was my first insight in to how such research can affect the care we deliver and how it impacts on our patients.

When we consider research generally it will be in terms of trials and outcomes. However, even though I already had some understanding of the nature and scope of the work involved, I was still taken back by the many different roles and varied skill sets needed to successfully steer a research project from inception to conclusion.

### The effects of research at practice level

When Eleanor the research nurse came into Broad Street to carry out clinical trials, this heralded an exciting new initiative which has enabled us to further develop our best practice and work towards improving health outcomes for patients in the future.

Being part of a practice that is research active is very rewarding, knowing that the outcomes of successful research projects have been shared, that this ever-increasing knowledge base contributes to a unified health outcome, and that this leads to the gold standard of

### *"Good Research Based Care"*

To be part of clinical trials can pose a major challenge as it can be difficult for some groups of patients to understand either the importance of research or the long term impact it could have on their health needs. It is by explaining the advantages that we empower our patients to participate and potentially have a very positive effect on their health care outcomes. I feel very privileged to have undertaken such studies and be part of the bigger research picture in general practice today.

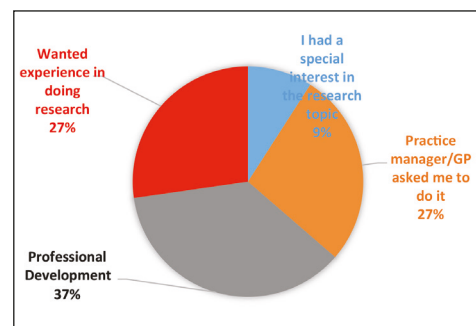
### The lighter side of research

One of my 'smiley' moments was when a lady called and left a voice mail message about the UKADS study (which involved taking blood samples for genetic analysis). She said she was concerned that the blood sample taken from her husband could be cloned to make another one of him and she wouldn't be able cope with two like him!

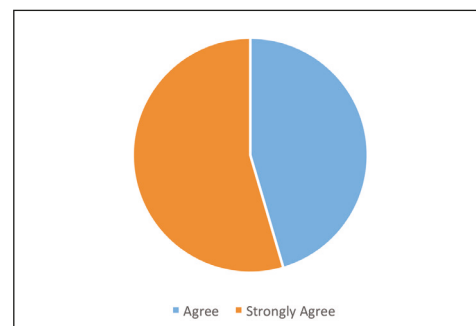
## Results of a Practice Nurse Survey

We surveyed a group of practice nurses based in the West Midlands south area about their attitudes to practice based research. The results were overwhelmingly positive, with an evident strong interest and willingness to participate in research. Thank you to all who completed a questionnaire.

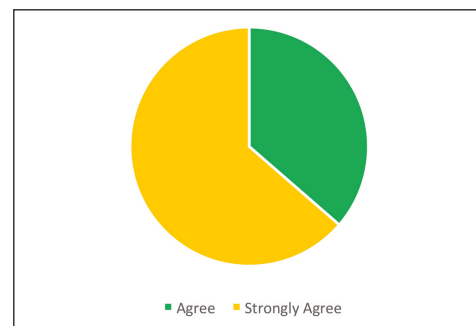
### What made you want to participate in a research study at your practice?



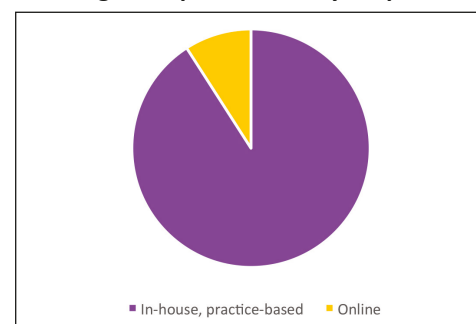
### Thinking about the last study that you helped with did you feel adequately trained to deliver the study?



### Did you feel adequately supported by the CRN (Clinical Research Network) nursing team?



### When considering future training provided by the CRN research nursing team please tell us your preferred format





**CRN: WM Research Academy**

For all training enquiries, please contact  
[TrainingCRNWM\\_generic@uhb.nhs.uk](mailto:TrainingCRNWM_generic@uhb.nhs.uk)

**National Institute for  
 Health Research**

**Clinical Research Network  
 West Midlands**

INTRODUCTION TO VALID INFORMED CONSENT			
DATE	EVENT	TIME	LOCATION
19/1/16	An Introduction to the Valid Informed Consent Process	09.30-12.30	CRN: West Midlands Offices, Unit 9, 1st Floor, Frank Foley Way, Greyfriars Business Park, Stafford ST16 2ST
2/2/16	Principles of Valid Informed Consent	10.00-12.00	Seminar Room, NIHR/Wellcome Trust CRF, old Queen Elizabeth Hospital, Birmingham B15 2TH
10/2/16	Paediatric Communications & Consent	09.30-16.00	Seminar Room, MIDRU, Birmingham Heartlands Hospital, Bordesley Green East, Birmingham B9 5SS
3/5/16	An Introduction to the Valid Informed Consent Process	09.30-12.30	CRN: West Midlands Offices, Unit 9, 1st Floor, Frank Foley Way, Greyfriars Business Park, Stafford ST16 2ST
6/5/16	Principles of Valid Informed Consent	09.30-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
8/9/16	Principles of Valid Informed Consent	09.30-11.30	Ann Gibson Committee Room, City Hospital, Dudley Rd, Birmingham B18
6/12/16	Principles of Valid Informed Consent	10.00-12.00	Seminar Room, NIHR/Wellcome Trust CRF, old Queen Elizabeth Hospital, Birmingham B15 2TH

BUSINESS DELIVERY			
DATE	EVENT	TIME	LOCATION
12/1/16	What did the Monitors, Auditors and Inspectors find in 2015?	09.30-11.30	Seminar Room, NIHR/Wellcome Trust CRF, old Queen Elizabeth Hospital, Birmingham B15 2TH
18/1/16	Monitoring –how to make it pain free (well almost!)	13.00-16.00	Seminar Room, ARC Building, Robert Jones & Agnes Hunt Orthopaedic Hospital, Oswestry SY10 7AG
26/1/16	Site File Management & Delegation of Duties	14.00-16.00	Seminar Room, MIDRU, Birmingham Heartlands Hospital, Bordesley Green East, Birmingham B9 5SS
28/1/15	Data management and case Report Form (CRF) design, development & completion	09.30-11.30	Seminar Room, NIHR/Wellcome Trust CRF, old Queen Elizabeth Hospital, Birmingham B15 2TH
16/2/16	Introduction to Clinical Genetics & Research Overview	09.30-11.30	Education Resource Centre, Birmingham Women’s Hospital, Middlesohn Way, Birmingham B15 2TG
1/3/16	Introduction to Medical Terminology for Research Staff	14.00-16.00	Seminar Room, NIHR/Wellcome Trust CRF, old Queen Elizabeth Hospital, Birmingham B15 2TH
11/5/16	Site File Management & Delegation of Duties	09.30-11.30	Seminar Room, NIHR/Wellcome Trust CRF, old Queen Elizabeth Hospital, Birmingham B15 2TH
11/5/16	Introduction to Clinical Research	09.00-16.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
7/7/16	Site File Management & Delegation of Duties	14.00-16.00	Education Centre, Birmingham Children’s Hospital, Steelhouse Lane, Birmingham B4 6NH
13/9/16	Site File Management & Delegation of Duties	09.30-11.30	Seminar Room, MIDRU, Birmingham Heartlands Hospital, Bordesley Green East, Birmingham B9 5SS
5/10/16	Introduction to Medical Terminology for Research Staff	14.00-16.00	Ann Gibson Committee Room, City Hospital, Dudley Road, Birmingham B18
12/10/16	Introduction to Clinical Research	09.00-16.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
10/11/16	Site File Management & Delegation of Duties	09.30-11.30	Seminar Room, NIHR/Wellcome Trust CRF, old Queen Elizabeth Hospital, Birmingham B15 2TH

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

STUDY SUPPORT SERVICES			
DATE	EVENT	TIME	LOCATION
18/1/16	Cost Attribution	10.00-12.00	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
20/1/16	Making IRAS work for your research amendments	10.00-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
9/2/16	An Introduction to IRAS and Research Management in the NHS	09.30-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
25/2/16	Cost Attribution	10.00-12.00	Coventry –t.b.c.
8/3/16	Cost Attribution Training	10.00-12.00	Guy Hilton Research Centre, Thornburrow Dr, Hartshill, Stoke-on-Trent ST4 7QB
22/3/16	An Introduction to IRAS and Research Management in the NHS	10.00-12.00	Guy Hilton Research Centre, Thornburrow Dr, Hartshill, Stoke-on-Trent ST4 7QB
19/4/16	Making IRAS work for your research amendments	10.00-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
16/5/16	Cost Attribution Training	10.00-12.00	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
17/5/16	An Introduction to IRAS and Research Management in the NHS	09.30-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
5/7/16	Making IRAS work for your research amendments	10.00-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
11/7/16	Cost Attribution Training	10.00-12.00	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, Birmingham B15 2SQ
14/9/16	An Introduction to IRAS and Research Management in the NHS	09.30-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
28/9/16	Cost Attribution Training	10.00-12.00	Coventry –t.b.c.
4/10/16	Making IRAS work for your research amendments	10.00-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
11/10/16	Making IRAS work for your research amendments	10.00-11.30	Guy Hilton Research Centre, Thornburrow Dr, Hartshill, Stoke-on-Trent ST4 7QB
19/10/16	Cost Attribution Training	10.00-12.00	CRN: West Midlands Offices, Unit 9, 1st Floor, Frank Foley Way, Greyfriars Business Park, Stafford ST16 2ST
28/11/16	Cost Attribution Training	10.00-12.00	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ
29/11/16	An Introduction to IRAS and Research Management in the NHS	09.30-11.30	Board Room, CRN: WM Offices, West Wing, Birmingham Research Park, Vincent Dr, B15 2SQ

A variety of training courses are delivered across NIHR Clinical Research Network: West Midlands which have been designed to provide you with the knowledge and skills you need to deliver high quality research.

**Introduction to Good Clinical Practice, Introduction to GCP in Primary Care and Introduction to GCP in a Paediatric Setting:**

These courses are designed to provide a basic introduction to Good Clinical Practice (GCP) and the EU Directives, UK Regulations and Research Governance Framework requirements covering clinical trials and other NIHR Portfolio studies conducted within the NHS. Participants can expect to gain a demonstrable understanding of the background and practical implications of GCP. Sessions specific to the Primary Care and Paediatric studies are available. For further details visit: <http://www.crn.nihr.ac.uk/learning-development/good-clinical-practice/>

**Good Clinical Practice Refresher:** An update on the key changes to the UK Medicinal Products (Clinical Trials) Regulations since their publication in 2004 and a refresher on Good Clinical Practice (GCP) and the Research Governance Framework (RGF). The session is designed to develop participants' previous knowledge and experience of translating principles into

practice. For further details visit: <http://www.crn.nihr.ac.uk/wp-content/uploads/Learning%20and%20development/GCP%20Refresher.pdf>

**Good Clinical Practice Online:** The online course can be taken as an introductory GCP course or a refresher update. The session will provide an introduction to Good Clinical Practice, the EU Directives, UK Regulations and Research Governance Framework requirements covering clinical trials and other NIHR Portfolio studies conducted within the NHS. There is a practical focus, with the key aim that participants know what to do to practice excellent GCP when they return to the workplace. For further details visit: Go to the eLearning courses on CRN Learn

**Essential Principles of Good Clinical Practice for Pharmacy Staff:** This study day is designed to provide a basic introduction to Good Clinical Practice (GCP) for Pharmacy staff who are new to clinical trials conducted within the NHS. Participants can expect to gain understanding of Clinical Trial design & phases; Roles & responsibilities of the Research & Pharmacy Teams; Good Clinical Practice, ICH E6, EU Directives; Quality Cycle; Good Manufacturing Practice v GCP; Monitoring, Audit, Inspection, CAPA; Annex 13, SOPs; Documentation & Record Keeping.





# PRIMIT

Protect yourself and others against cold and flu

## PRIMary Care Infection Control Website Trial (PRIMIT)

### Summary of results

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

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

Across three winters from January 2011 to March 2013, in the midst of the season for flu and other respiratory infections, 20066 adult patients aged 18 years and older took part from 344 general practices across the UK. Volunteers were randomly assigned access to the PRIMIT website or no intervention. Participants were followed for 16 weeks and questionnaires were used to measure episodes of respiratory infections, duration of symptoms, and to check whether other household members had a similar illness.

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

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

This study was funded by the Medical Research Council.



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## Research Design Service (RDS)



If you would like any further information, please contact us on [rds@warwick.ac.uk](mailto:rds@warwick.ac.uk) or via [www.rds-wm.nihr.ac.uk](http://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

## Retaining the General Practitioner Workforce in England

### What Matters to GPs?

*“Currently still very much enjoying the clinical contact with patients but very dispirited due to overwhelming workload as work is passed out to Primary Care from Secondary Care with no funding to employ staff to do it. Obviously patients can no longer get normal GP appointments as a large number of our appointments are now used up doing hospital outpatient duties”*

### Background

The general practice (GP) workforce in England is in crisis, reflected in increasing rates of early retirement and intentions to reduce hours of working. This study aimed to investigate underlying factors and how these might be mitigated.

GPs in central England were invited to participate in an on-line survey exploring career plans and views and experiences of work-related pressures.

### Results

Of 1,192 GPs who participated, 978 (82.0 %) stated that they intend to leave general practice, take a career break and/or reduce clinical hours of work within the next five years. This included 488 (41.9 %) who intend to leave practice, and almost a quarter (279; 23.2 %) intending to take a career break. Only 67 (5.6 %) planned to increase their hours of clinical work.

For participants planning to leave practice, the issues that most influenced intentions were volume and intensity of workload, time spent on “unimportant tasks”, introduction of seven-day working and lack of job satisfaction.

Reducing workload intensity, workload volume, administrative activities, with increased time for patient care, no out-of-hour commitments, more flexible working conditions and greater clinical autonomy were identified as the most important requirements to address the workforce crisis. In addition, incentive payments, increased pay and protected time for education and training were also rated as important.

### Conclusions

New models of professionalism and organisational arrangements may be needed to address the

issues described here. Without urgent action, the GP workforce crisis in England seems set to worsen.

Jeremy Dale, Rachel Potter, Katherine Owen, Nicholas Parsons, Alba Realpe and Jonathan Leach

**Table 1 Participants’ intentions to remain in GP Workforce (% relates to number answering each question)**

Intentions	Frequency (percent)
<b>Work plans for the next five years</b>	<b>537 (45.1%)</b>
Reduce hours of clinical work	67 (5.6%)
Increase hours of clinical work	216 (18.1%)
Reduce management responsibilities	201 (16.9%)
Increase management responsibilities	150 (12.6%)
Reduce teaching/training/research responsibilities	206 (17.3%)
Increase teaching/training/research responsibilities	161 (13.5%)
No plans to change	113 (9.5%)
<b>Intention to remain in general practice beyond next five years</b>	
Yes	676 (58.1%)
No	488 (41.9%)
<b>Intention to work after retirement</b>	
Full-time	11 (3.0%)
Part-time	102 (27.6%)
Will not work after retirement	152 (41.1%)
Unsure	105 (28.4%)
<b>Intention to take a career break from general practice within next 5 years</b>	
Yes	267 (23.2%)
No	883 (76.8%)
<b>Reasons for taking a career break</b>	
Starting a family/young children	46 (17.2%)
Looking after older children	12 (4.5%)
Caring for someone	7 (2.6%)
Travel/work abroad	125 (46.8%)
Study or research	20 (7.5%)
Other	57 (21.3%)
<b>Length of planned career break</b>	
Less than one year	90 (36.1%)
Between 1-2 years	50 (20.1%)
More than 2 years	27 (10.8%)
Unsure	82 (32.9%)

Full text: <http://www.biomedcentral.com/content/pdf/s12875-015-0363-1.pdf>

## Co-Creating Education and Research: Solutions to Primary Care Problems

### Warwick Primary Care

We are delighted to be sending a warm hello from us all at Warwick Medical School (WMS).

Warwick Primary Care is the newly re-forming group of academics here at WMS. Our group has been established to work with you to help improve primary care through education and research. Professor Jeremy Dale still leads our team, with other familiar faces including Professors Frances Griffiths and Martin Underwood, Drs Kate Owen and Anne Slowther, who all continue to lead undergraduate and postgraduate education programmes, along with cutting edge research supporting the advancement of primary care.



We are particularly pleased to have welcomed some new members to our group.



Our newest team member, **Assistant Professor Helen Atherton** is a primary healthcare scientist who has just joined us from Oxford. Helen is a leading expert in the use of information and communication technologies as tools for delivering primary care to patients. Helen was recently awarded the Yvonne Carter prize for outstanding new researcher in recognition of her work in this area. Helen's arrival is certainly very timely in light of the emphasis on these forms of working in Professor Martin Roland's recent Primary Care Workforce Commission report:

**Dr Sarah Mitchell** is an established GP who has led innovative work locally in developing local primary care palliative care services, particularly for children and young people. Sarah has now been awarded a prestigious NIHR doctoral fellowship to undertake her PhD with us here at Warwick.



*"The future of primary care - Creating teams for tomorrow"*



**Associate Professor Joanne Reeve** joined us from Liverpool earlier this year. Joanne's work focuses on developing and evaluating expert generalist solutions for many of the complex challenges facing today's primary care community. She leads work in the areas of multimorbidity, problematic polypharmacy, difficult mental health problems, and acute care.



We are fortunate to have **Associate Professor Stefan Hjörleifsson** visiting us from Bergen, Norway. Stefan's work focuses on over-diagnosis and the ethics of 'too much medicine'. He is with us for twelve months, and we are making the most of his visiting expertise.

This means we have a growing team of clinical and non-clinical academics with a range of skills and experience in tackling the problems facing today's primary health care.

### What we do

The focus for our work is on supporting the redesign of primary care to meet today's challenges. Our work is grouped under four themes:

- i) Complex Illness and the expert generalist
- ii) Building a general practice and primary care workforce
- iii) Innovative solutions to workload capacity issues
- iv) Co-production of practice based evidence driving quality improvement

We will be introducing each area of work in more detail in forthcoming Participate articles.

All of us working in primary care face significant challenges at the moment. But our current difficulties are also stimulating some exciting innovation across our clinical and academic communities. We are looking forward to continuing to share our experience, skills and ideas with you as we work together to drive improvement in primary care.

If you would like more information please go to our website: <http://www2.warwick.ac.uk/fac/med/about/centres/wpc/> or contact Associate Professor Joanne Reeve, email: [j.reeve.1@warwick.ac.uk](mailto:j.reeve.1@warwick.ac.uk)





## South Warwickshire GP Federation and Clinical Practice Research Datalink (CPRD) Collaboration – Success Story

Over the last eight months South Warwickshire GP Federation and CCG have been working with the NIHR Clinical Research Network, West Midlands (NIHR CRN: WM) inviting ALL practices to sign up to CPRD helping to clarify some of the perceived barriers and simplify the key messages.

**We are very pleased to announce that 31 out of 35 practices within South Warwickshire Federation have signed up to CPRD and we would very much like to thank practices for their support with this initiative.**

Research using CPRD data has resulted in over 1,500 publications which have led to improvements in drug safety, best practice and clinical guidelines. Examples include:

- confirming safety of MMR vaccine
- informing NICE cancer guidance
- safeguarding use of pertussis vaccine in pregnancy
- influencing the management of hypertension in diabetics

CPRD is now also using primary care data in clinical trials. Examples include a real world diabetes studies comparing a new therapy to standard of care, and randomised controlled trials on myocardial infarction and COPD patients.

We hope that the remaining practices will realise the benefits and also **take advantage of the £100 joining fee** by completing the form sent previously.



For additional copies of the form or for more information please contact Dr Rebecca Harrison email: [r.l.harrison@warwick.ac.uk](mailto:r.l.harrison@warwick.ac.uk) phone: 02476 575853. Completed forms should also be sent to this email address. CPRD can also be contacted direct email: [kc@cprd.com](mailto:kc@cprd.com) or phone: 020 3080 6383

## News from our Practices: Achievements Over and Above



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

### NEW TO RESEARCH – WELCOME ON BOARD

Congratulations to go to these practices in South Warwickshire for joining us in research:

- Cape Road Surgery
- Brookside Surgery
- Spa Medical Centre

*Welcome!*

Following Professor Jeremy Dale's presentation at the Godiva locality meeting three further Coventry practices have expressed an interest in participating in research:

- Park Leys Medical Practice
- Central Surgery
- Willenhall Primary Care Centre – Dr Sharma

We are delighted to welcome these practices and look forward to working together on a range of studies.

### STUDY RECRUITMENT

Thanks go to:

**Westside Medical Centre** for their hard work on the TASMINH4 study



**Bennfield Surgery** for their recruitment to the HEAT study



And finally, a very special thank you to all the **GP practices in Rugby** for their great recruitment to the TIME study.





Masters and Continuing  
Professional Development

THE UNIVERSITY OF  
**WARWICK**

WARWICK MEDICAL  
**SCHOOL**



## Public Health

Postgraduate Study: Certificate/Diploma/Masters (MPH)



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.

### 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.



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

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.

### 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](mailto:cpdenquiries@warwick.ac.uk)

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