PARTICIPATE



VOLUME NO 21

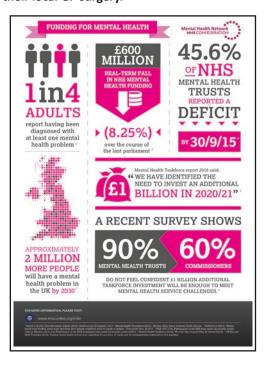
SUMMER 2016

Awareness of mental health

Although attitudes to mental health are changing, there is still a perceived stigma to the diagnosis which affects people's willingness to come forward and seek assistance. The role of the GP in overcoming this barrier to obtaining help is pivotal as the vast majority of people seek assistance in the first instance via their local GP surgery.

This edition highlights the importance of on-going research into mental health to try and inform decisions on improved care and treatment paths. An overview of current attitudes to mental health from DeNDRoN, (Mental health and Neurological Disorders) shows the preponderance and high cost of mental health problems as a proportion of the NHS care budget.

Interest in researching into mental health has never been greater, with studies currently open looking at issues as diverse as mental health within prisons; the increased prevalence of other health problems in those already diagnosed with mental health issues; coping with the transition from the children and adolescents mental health service (CAMHS) to an adult mental health service (AMHS); and the role of Selective Serotonin Reuptake Inhibitors (SSRIs) in treatment of depression.





WARWICK MEDICAL SCHOOL

Supported by the University of Warwick

POINTS OF INTEREST

- New Study TAPS
- Current Study BrIT
- Study Update Past BP
- Local Research GP Registrar's Role

In this edition we feature articles on:

- Brains in Transition (BriT): Linear and non-linear brain changes over the transition to psychosis (page 7)
- Join Dementia Research: members of the public who have memory problems, or those who are family members/cares for those who do, can register to be informed of research opportunities as they arise (page 5)
- Home-BP: assessing whether use of the HOME-BP programme for self-monitoring and self-management of uncontrolled hypertension of patients on medication results in greater control of systolic blood pressure over one year, in comparison to usual care (page 4)
- ALL Heart: looking at whether allopurinol improves cardiovascular outcomes when added to usual therapy in patients aged 60 years and over with ischaemic heart disease (page 6)

CONTENTS

New Studies	2-4
Current Studies	4-7
Mental Health	8-9
CRN	10
Local News & Research	11-13
Study Results	14-15
CPD	16

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



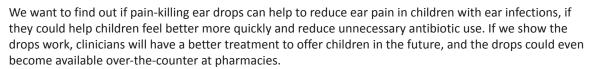
The CEDAR Randomised Controlled Trial

e children's ear bain

The CEDAR trial aims to discover if painkilling ear drops can reduce antibiotic consumption in children aged 12 months to 10 years presenting to primary care with acute otitis media (AOM), by directly treating the ear pain caused by the infection. The trial has three arms: (1) active ear drops (Auralgan) administered with usual care; (2) placebo ear drops and usual care; and (3) usual care only. Usual care is as per NICE guidelines, i.e. advice about the use of rescue analgesia for symptom management, with or without a delayed antibiotic prescription.

Why is this trial important to the NHS?

AOM is common in children under 10 and causes pain and distress to children and their families. Despite good evidence that most children will not benefit clinically from antibiotics, they are still prescribed for most children with AOM. Antibiotics don't treat the child's pain, in most cases do not help to treat the infection (because many ear infections have a viral origin), but can cause side effects (such as diarrhoea) and contribute to the problem of antibiotic resistance.







The CEDAR intervention

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

Which children are eligible for this trial?

Children are eligible for CEDAR if aged between 12 months and 10 years with ear pain within the last 24 hours, if they are generally well, if the clinician's working diagnosis is otitis media and if they do not require a same-day antibiotic under NICE guidelines.

What is involved for children and their parents?

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

What is involved for recruiting primary care sites?

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

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













For further information or to register your interest please contact the CEDAR study team at cedar-trial@bristol.ac.uk, or email the Trial Manager Harriet Downing at harriet.downing@bristol.ac.uk

PACE:

Primary care use of a C-Reactive Protein (CRP)



Point of Care Test (POCT) to help target antibiotic prescribing to patients with Acute Exacerbations of Chronic Obstructive Pulmonary Disease (AECOPD) who are most likely to benefit.

Sponsor: University of Cardiff - Funder: NIHR HTA

Background: PACE is a randomised controlled trial that aims to evaluate whether using a CRP point of care test (POCT) results in better targeting of antibiotic treatment than usual care informed by NICE and GOLD guidelines. The primary outcomes are the overall consumption of antibiotics for COPD and patient-rated clinical recovery from their AECOPD, with the aim being to reduce overall antibiotic use without compromising patient recovery.

Patient Population and recruitment: 650 participants are to be recruited among three centres: Cardiff, Oxford and London.

- Inclusion Criteria: Participants with a diagnosis of COPD in their clinical record, aged 40 years or more, presenting in primary care with a current acute exacerbation.
- Recruitment deadline: 31 January 2017

Practice involvement:

- Mailout: Invitation packs will be sent to all eligible COPD patients to inform them about the study and encourage them to contact the practice before taking any rescue medication.
- Baseline Visit: Eligible patients will be randomised either to management according to best current practice alone or to best current practice with the addition of a CRP POCT to guide decisions about antibiotic treatment. All participants will have a posterior pharynx swab and sputum sample taken at this visit.
- Week 4 Follow-up: Participants will be followed up for 4 weeks following recruitment. At week 4 participants will visit their practice again for their 4-week follow-up appointment during which another posterior pharynx swab sample and sputum sample will be taken.

Diagnostic tests that can be used at the point-of-care to better target antibiotic prescribing for common conditions provide a major opportunity for improving antibiotic stewardship in primary care. C-reactive protein point-of-care testing (CRP-POCT) is a promising tool to help guide antibiotic treatment decisions, but the use of a CRP POCT to safely guide antibiotic treatment decisions for acute exacerbations of chronic obstructive pulmonary disease (AECOPD) in primary care has not been previously evaluated.

The study team has previously led or contributed to two trials evaluating the use of a CRP POCT to help target antibiotic treatment for lower respiratory tract infections in primary care. The antibiotic prescription rates for those with lower respiratory infections were 53% and 68% in the usual care groups. These studies demonstrated that use of the test (with training) resulted in 22% and 29% reductions in antibiotic prescribing, and that CRP is cost effective in reducing antibiotic prescribing for LRTI.

The PACE study will determine whether GP use of a simple, rapid, one-step CRP POCT in addition to clinical assessment leads to improved antibiotic prescribing decisions for AECOPD in general practice, such that fewer antibiotics are prescribed overall without having adverse effects for patients.

For more information: www.pace-study.co.uk. Main contact details: jenny.riga@phc.ox.ac.uk

TAPS:Treatment of Aches and PainS Trial

The study

- The **STarT Back trial** showed that stratified care, based on matching treatment to prognosis (low, medium, or high risk of ongoing problems), was clinically and cost effective
- TAPS is a flagship clinical trial to test if this approach also works for people with neck, shoulder, knee and multi-site pain (& back pain)
- Practices will be randomised to deliver one of two approaches for patients presenting with musculoskeletal pain, either **stratified care** or **usual care**

What does it mean for your practice?

- Agree to be randomised to the control or intervention arms of the trial
- Deliver the trial interventions:
- For intervention arm practices for patients with MSK pain, use of a brief template to assess prognosis & inform treatment decisions
- For control arm practices for patients with MSK pain, use of a brief template to record levels of pain intensity
- Attend study related meetings:
- For intervention arm practices one 1-hour set-up meeting, and two 2-hour training workshops
- For control arm practices one 1-hour set-up meeting
- Provide feedback on delivering the intervention (in intervention practices)

What are the benefits for your practice?

- Fully funded: reimbursements tied to level of involvement
- Revalidation activities: participating in research and training
- Involvement in developing and testing new ways of working

This research is funded by the NIHR Programme Grants for Applied Research programme (Grant reference number: RP-PG-1211-20010). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.







If you are interested in finding out more, please contact TAPS Trial Manager Stephanie Tooth phone: 01782 734835 email: s.j.tooth@keele.ac.uk

New Studies/Current Studies

HOME-BP (Home & Online Management & Evaluation of Blood Pressure Trial)







Study Aims

Blood pressure is a key risk factor for cardiovascular disease, the largest cause of morbidity and mortality worldwide. Increasingly widespread access to the Internet and mobile phones means that digital interventions are accessible to the majority of patients at any time when they need it. The web-based HOME-BP programme has been developed to help patients in management of high blood pressure, incorporating previously identified effective intervention components (self-monitoring, pre-planned medication titrations and behavioural support). The programme also encourages patients to self-monitor and to choose healthy lifestyle modifications. This trial will assess whether use of the HOME-BP programme for self-monitoring and self-management of uncontrolled hypertension of patients on medication results in greater control of systolic blood pressure over one year, in comparison to usual care.

We are looking to recruit patients who have access to the internet and will be able to use and comprehend the website. Patients should have uncontrolled hypertension (mean BP reading of >140 or >90 mmHg) and should be receiving medication for hypertension control.

Recruitment period: May 2016 - June 2017 Recruitment target: 236 patients

The HOME-BP study is recruiting practices for the main trial following a successful pilot study which reached its target in January 2016.

What does the trial involve for the practice?

Suitable patients (identified by electronic searches) will be asked to make an appointment with the practice nurse who will screen them for eligibility. Through the study the nurse will also conduct optional support appointments and can send motivating messages through the website. Participants will complete the baseline questionnaires online and will be automatically randomised into self-monitoring or usual care groups. Participants in both groups will book an appointment with the prescriber (a GP) for a medication review.

Participants in the self-monitoring group will enter their blood pressure readings for a week each month on the website. The prescriber will be informed of patients' readings through the intervention and will be responsible for actioning emails regarding medication change. Six and 12 month follow up assessments will be conducted by an independent study nurse.

USER FRIENDLY WEBSITE AND NO PAPER CRFs SIMPLE SCREENING & PATIENT REGISTRATION, **OPTIONAL PHONE REMINDERS**

If you would like to be a participating practice for the HOME-BP study, then please email: home.pb@phc.ox.ac.uk or call us at 01865 617196.







Lancashire Care Miss **NHS Foundation Trust**



Do you feel DISTRESSED?

Would you like to take part in an ONLINE research study for relatives?

Would you like SUPPORT and information via an online toolkit for relatives?

If the answer to these questions is YES then we'd love to hear from you!

What is REACT?

REACT (Relatives Education And Coping Toolkit) is online peer-supported toolkit for relatives of people with psychosis or bipolar disorder.

The aim of this study is to test the effectiveness of REACT for reducing relatives' distress and explore the costs involved in delivering this intervention.

Is this research for you?

Participants must be aged 16 years old or over, have access to the internet, and be able to understand written and verbal English. Participants must not be currently taking part in another research study.

Who are we?

We are a team of researchers from Lancaster University, Lancashire Care NHS Foundation Trust, Liverpool University and University College London. This project is funded by the National Institute for Health Research Health Technology Assessment (ref 14/49/34).

For more information or to register your interest for the study please visit www.reacttoolkit.co.uk or contact the REACT Team on react@lancaster.ac.uk

Current Studies



Join Dementia Research (www.joindementiaresearch.nihr.ac.uk) was launched nationally in February 2015 as part of the prime minister's dementia challenge. As part of this the prime minister wants to ensure that the public can find out about important research they can participate in.

This initiative means members of the public who have memory problems, or those who are family members/cares for those who do, can register via the telephone, online or paper form and be informed of research opportunities as they arise. The registration process is managed by Alzheimer's Society and Alzheimer's Research UK.

The Prime Minister set a challenge for the NIHR: that within 12 months of launching we would aim to have 12,500 volunteers signed up. By the beginning of March 2016 over 16,000 people had signed up to being informed of research opportunities. Over 1,000 of these volunteers are from the West Midlands. We are trying to promote Join Dementia Research as much as possible and are sure this number will continue to grow, especially with the availability of free promotional materials to help us spread the word.

Why not see/hear for yourself people's experience of taking part in research as part of Join Dementia Research: https://www.joindementiaresearch.nihr.ac.uk/content/stories

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

SYMBAD drug trial for managing agitation in dementia

Agitation is common in people who suffer from dementia and can cause problems for the patients, families and the people caring for them. Agitation can be persistent: up to 80% of patients with symptoms still have those 6 months later.

There are medicines available to treat agitation, but it is not clear which treatments work best for people with dementia. Current treatments include antipsychotic medication, but these only have limited positive effects and can cause harm. Non-drug treatments are recommended in the first instance, but there is a need for medicines to be available, if non-drug treatments fail. This trial will be comparing two commonly used medicines with a placebo to see if either are suitable for treating agitation in dementia.

AD Genetics

The study team wish to try and understand more about how certain genes affect the likelihood of developing Alzheimer's disease. They are particularly interested in understanding more about how genes cause and affect young-onset Alzheimer's disease (sometimes called early-onset Alzheimer's Disease). Young-onset Alzheimer's disease affects people before the age of 65.

At the moment very little is known about why some people develop Alzheimer's disease at such a young age. To try and better understand this, a study team are conducting the first large-scale study of young-onset Alzheimer's disease. This will help us identify what genetic, biological and environmental factors are involved in the onset and progression of the disease. We are inviting people who first experienced symptoms of Alzheimer's disease, or received a diagnosis of Alzheimer's disease, before age 65 to help with this project. Even if you are over 65 now you are still able to help if you first had symptoms before age 65.

The RADAR trial in Alzheimer's disease

RADAR is a ground breaking trial that hopes to find out if a drug commonly used to treat high blood pressure (known as hypertension) could slow down the progression of Alzheimer's disease that affects nearly 500,000 people in the UK. We believe the drug called Losartan could slow down the rate of brain shrinkage that is known to occur in Alzheimer's. RADAR will use images of participants' brains (made using Magnetic Resonance Imaging (MRI)) at the beginning and end of the study to measure whether Losartan reduces brain shrinkage and memory problems in Alzheimer's.

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 at https://www.joindementiaresearch.nihr.ac.uk/loginform

If you haven't yet registered with Join Dementia Research, sign up at https://www.joindementiaresearch.nihr.ac.uk/beginsignup



If you want to find out more information about Join Dementia Research and how you can help promote this or sign up, please contact Kim Fitzgibbon, Portfolio Coordinator at kim.fitzgibbon@bsmhft.nhs.uk or Tel: 0121 301 4326 / Mobile: 07985 883477.



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 75 practices in the West Midlands are taking part, and patient recruitment has commenced, with over 4,500 patients taking part nationally. 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: 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.

Current 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.



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.

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

Recruitment has started in the West Midlands! Would your practice be interested in helping us with this important study?

We already have 27 practices signed up, and many thanks to the first few practices to start the study in the region, who have already recruited 43 patients.

The Trial Manager is Jen Dumbleton, and her contact details are as follows: jennifer.dumbleton@nottingham.ac.uk, 0115 823 1053. Further details can also be found on the trial website: http://allheartstudy.org/.

CANDID

CANcer Diagnosis Decision rules

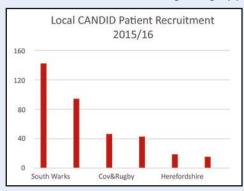
In primary care the key areas of concern for both doctor and patients are delay in diagnosing cancer, getting high risk patients referred first, and keeping investigation to a minimum.

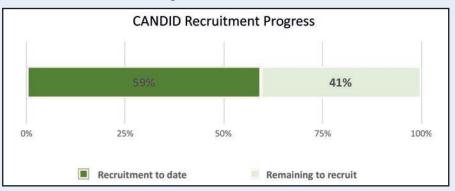
There have been few valid studies to assist decision-making in primary care, either to get a patient referred quickly or to assist in making sure an anxious patient is effectively reassured. This study seeks to work out which of the symptoms and examination findings are the most effective in predicting lung or colon cancer. Clinical information will be collected using standardised internet based forms.

Willing patients complete lifestyle questionnaires and provide blood or saliva samples (including for genetic analysis). The National Cancer Registry will be monitored to see which patients develop cancer, and statistical analysis will determine the most important clinical variables that predict cancer. The clinical prediction 'rules' or decision aids developed from these studies will then be tested for validity with a further 2,000 patients for each condition.

HOW TO GET INVOLVED

For further information please see the CANDID <u>website http://www.southampton.ac.uk/candid/index.page</u> which has resources available to download, including a surgery poster and information for the waiting room screen.





CURRENT RECRUITMENT

Congratulations to our top 2015/16 recruiting Candid practices:

Atherstone Surgery: 55

Sherbourne Medical Centre: 53

The New Dispensary: 47

For local support please contact Jennifer.lee@warwick.ac.uk

Brains In Transition (BrIT)

Linear and non-linear brain changes over the transition to psychosis



Study aims

- Better understand the brain changes that occur during the transition from the at-risk mental state to the development of a psychotic episode
- Establish to what extent these changes in brain patterns and clinical presentation can be used to improve early detection of individuals at greatest risk

Overall the study could lead to better targeting of therapeutic interventions aimed at preventing or at least ameliorating the onset of psychotic disorders such as schizophrenia.

What does the research involve?

- Brain imaging (MRI) sessions
- Interviews and questionnaires about your service user's mental health and history
- We would like to see participants at least twice over a 12 month period
- Assessments will take approximately 2-4 hours
- Participants will receive £20 every time they take part

We are able to share results from assessments with the care-coordinators. Hopefully this will assist teams in the assessment of their service users.

For further information, please call or text us on: 07934 996 686 or 0121 414 4937 or email: brit@contacts.bham.ac.uk



We are looking for volunteers (16-35 years old) to take part in an imaging study

about brain changes associated with mental health at the University of Birmingham





TIME: continuing to recruit

TIME (Treatment In Morning vs Evening) is recruiting patients who take 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.

Recruitment Progress

TIME is on target to recruit 20,000+ adults with treated hypertension by late Summer 2016. An initial mailing in 2014 to GP practices has been followed up by the research networks in all UK countries, and local approvals continue to be granted to allow interested practices to be registered as Patient Identification Centres (PICs) to invite suitable patients. A Docmail account has reduced costs and administration time for practices. Several regions have joined recruitment with new practices continuing to register their interest. Patient recruitment has also taken place through hospital trust and pharmacies acting as PIC sites. Additionally, the research resources UK Biobank and SHARE have been involved in inviting their participants.

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 remains open to anyone in the UK who takes tablets for blood pressure once daily. The aim of the study is to recruit over 20,000 participants of varied demographics and study them over a period of up to five years. Patients are being invited via GP surgeries, hospitals, and pharmacies. Patients may also respond directly to advertising or social media.

Consenting participants are randomly allocated to take antihypertensive medication either at night or in the morning. The study is conducted entirely online with patients registering and consenting through the study website and being followed up by email.

Participants do 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.



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

Patients register for the study at <u>www.timestudy.co.uk</u>, where they can read more detailed information.

Mental Health

















Anyone can be affected by mental health issues

Mental Health Research Update

It is estimated that 1 in 4 people in England will experience a mental health problem in any given year. Mental health problems are one of the main causes of the burden of disease worldwide (estimated at £16 trillion). In the UK they are responsible for the largest burden of disease (28%) at £70-100 billion each year, compared to 16% each for cancer and heart disease (www.mentalhealth.org.uk). It is clear mental health research is needed to improve the effectiveness of treatments for people experiencing mental health difficulties, as well as for finding ways of preventing poor mental health.

Attitudes to mental health

The stigma of poor mental health is changing for the better, although there is still room for improvement. The NHS Confederation key facts and trends in mental health (2016) states that Time to Change's Attitudes to mental illness 2014 report illustrated that the number of people acknowledging they know someone close to them who has had a mental illness increased from 58% in 2009 to 65% in 2014. 40% of people surveyed said they would be comfortable talking to their employer about a mental health problem, although nearly half (48%) said they would feel uncomfortable, showing that there is still some way to go.

Often the first port of call for anyone experiencing mental health problems will be to access services within primary care and more specifically, seek help from their GP. As attitudes towards mental health change for the better, we could see an increase in such help-seeking. According to a Care Quality Commission (CQC) report from 2015, at any given time an average of one in four patients of a fulltime GP requires treatment for a mental health condition. They found nearly three million adults were on local GP registers as experiencing depression. GPs often have to make difficult decisions based on a short time in consultation with the patient. Although GPs are informed by the NICE guidelines that recommend the best treatment, based on research findings, what suits one person may not help another. Our knowledge of which treatment would work best for individuals can only improve through research.

It is sometimes felt that those with mental health problems would not want to take part in research because of how they are currently feeling, or that because of their current symptoms they might not appreciate being involved in research. We strongly advocate that everyone has the right to make that decision themselves and with the support of those around them. The NIHR has collated people's stories about taking part in research. We are currently looking at collecting stories about taking part in research from people within the West Midlands.

Caroline Kemp is a carer for her daughter who has a severe form of bipolar disorder. She states that:

"Research changed my life because it's given a whole new dimension to my life; I feel like a person again"

Collaborative working

The CRN primary care and mental health teams have been working closely together to ensure we provide a high standard of research involvement to patients, their family members and staff. To further this, the primary care team received mental health awareness training which received feedback such as

"I feel the skills I have developed today will be invaluable. I have a much bigger insight into the issues surrounding mental health"



PANDA-RCT

This study is seeking participation from West Midlands GPs. Depression is a common condition that affects between 2% and 3% of the population at any one time and is commonly treated with antidepressant medication. In England and Wales there were 47m prescriptions for antidepressants in 2011. Selective serotonin reuptake inhibitors (SSRIs) are the first line antidepressant recommended by NICE guidelines.

Some people with depression will recover spontaneously and it is not clear at present which people will benefit from a course of antidepressants. Furthermore it is not known whether the current diagnostic criteria for depression indicate benefit from antidepressants. As a result, general practitioners often have to make a difficult decision about whether an individual will benefit from an SSRI.

Study aims

This study is designed to refine the indications for the use of antidepressants in people with

Mental Health

depression. Our aim is to investigate the severity and duration of depressive symptoms that are associated with a clinically important response to sertraline in people with depression. We plan to assess severity and duration using a standardised assessment that can then be used to guide prescription in primary care. We will include patients presenting in primary care aged 18-74 with depressive symptoms where both the GP and patient are unsure whether there will be significant clinical benefit from taking SSRI antidepressants. Participants will be required to take the antidepressant sertraline while response will be assessed. Some participants may receive a placebo instead.

Mental health and its effect on physical illness

It is well known that people with poor mental health also have an increased prevalence of physical illnesses. For example, for every 10 people in the general population who have cardiovascular disease, 25 people with severe mental health problems with have this also. Infographics - http://mentalhealthpartnerships.com/resource/physical-health-risks-for-people-with-severe-mental-health-problems/

Dr Helen Tyrrell, Priory Gate Practice:

"Mental health problems are such a big part of our workload and are often very challenging. Research into improving or patients mental health and the treatments would provide us with more evidence about how we should approach managing these patients. Knowing which subgroups of patients would benefit from medication would be useful to avoid unnecessary possible side effects and the burden of taking regular medication on patients and also may provide a cost savings. Often our depressed patients do not look after themselves and proactive management into their general health and CVD risk factors will hopefully reduce their morbidity and mortality."

Primrose



PRIMROSE2

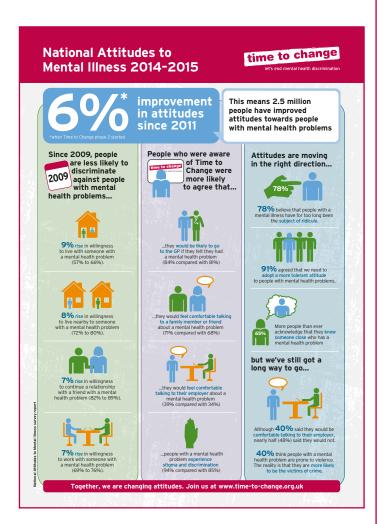
People with severe mental illnesses (SMI) die early from cardiovascular disease (CVD). They have increased CVD risk factors including abnormal lipids, diabetes, smoking and obesity. They make frequent contact with primary care, yet are less likely to be screened for risk factors or receive interventions such as statins.

In a cluster randomised controlled trial, we will test the effectiveness of an intervention with GP practices working to reduce CVD risk in people with SMI. The intervention will include:

- physical health reviews
- prescription of medications such as statins and
- monitoring of adherence to recommended treatments

The study will recruit 350 patients with severe mental illnesses (Schizophrenia, Persistent Delusional Disorder, Schizoaffective Disorder or Bipolar Affective Disorder), aged 30-75 years old with raised total cholesterol, or total cholesterol/HDL cholesterol ratio, and one other risk factor, from 60 GP practices across England.

All participants with SMI registered with GP practices in the trial will be screened for CVD risk. 70 general practices will be involved, 35 using the new intervention and 35 providing standard care. Over a period of one year, approximately five patients from each practice who meet the inclusion criteria will receive either the intervention or treatment as usual. The intervention will involve intensive management of CVD risk factors with regular appointments to monitor progress with reducing cholesterol, prescription and adherence to statins and signposting to services for weight management and smoking cessation where other CVD risk factors are detected. At the end of the study, we will establish whether practices trained in the intervention reduce total cholesterol more than standard care.



For more information on any of the studies mentioned, or on mental health initiatives in general, please contact: Carly Craddock, Research Delivery Manager (DeNDRoN, Mental health and Neurological Disorders) phone: 0121 301 4320, email: carly.craddock@bsmhft.nhs.uk/carlycraddock@nhs.net





Clinical Research Network
West Midlands



Network recruits more than half a million patients into clinical research in the West Midlands

New figures published by the National Institute for Health Research (NIHR) have confirmed that the Clinical Research Network West Midlands is the highest recruiting Network in England.

The NIHR is the research arm of the NHS, and this research is delivered and supported by 15 local Networks. In the last ten years the Network has recruited 544,115 participants into high quality studies across the West Midlands - 64,278 of these in the last 12 months alone; the highest in the country.

Ultimately, clinical research means patients get access to new treatments, interventions and medicines, and investment in research means better, more cost-effective patient care. And with more than 3,000 different studies available in the West Midlands across 30 health specialties, Network Clinical Director Dr Jeremy Kirk explains how over the last decade the region has earned its reputation as the most active in the country.

Dr Kirk commented:

"It is a fantastic reflection of the hard work and enthusiasm of our dedicated staff and researchers within the Clinical Research Network West Midlands that we have recruited over 64,000 patients this year into portfolio studies, the largest number of any region in England. Moreover, that since the formation of the NIHR 10 years ago we have recruited more patients than anyone else not only confirms our regional credentials as a research powerhouse, but has also meant that over half a million patients regionally have been recruited into high quality studies.

The more patients that we can encourage to take part in vital clinical research, the quicker the NHS can introduce new and better treatments for the benefit of all patients, as well as using NHS resources more efficiently."

Participants have been recruited from every NHS Trust in the West Midlands, from more than half of the region's GP practices, and in hospices, nursing homes, pharmacies, schools and prisons.

David Loughton, Chief Executive of the Royal Wolverhampton NHS Trust, which hosts the Network, adds:

"The success of the CRN in the West Midlands is testament to a lot of hard work, commitment and excellence and as a Trust we are delighted with this success story."

For further information contact: Claire Hall, Communications Lead, NIHR Clinical Research Network West Midlands, Tel: 01902 447207, Email: claireanne.hall@nihr.ac.uk, Web: www.crn.nihr.ac.uk/westmidlands

Join us on Facebook and Twitter

As part of our strategy to increase research awareness amongst the public, the NIHR Clinical Research Network West Midlands now has a social media presence. We are asking all of our colleagues, if possible, to please *follow* and *like* us on Twitter and Facebook.

The addresses are:

Twitter: @CRN WMid

Facebook: www.facebook.com/CRNWMid







Local News & Research

Congratulations!

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 for joining us in research:

- Dr Rowlands & Dr Bates at Lapworth Surgery
- Dr Foulerton at Pool Medical Centre
- Lisle Court Medical Centre
- Hill View Medical Centre

Welcome!

STUDY RECRUITMENT

- Avonside Surgery: thanks go to the practice staff for their involved and interested approach to taking part in research in general and for their helpful assistance to our research nurse
- Forrest Medical Centre: for taking a whole-team approach to embracing research and for their interest in promoting wider discussion/educational sessions for clinicians
- Winyates Health Centre: for the high level of GP interest and involvement in recruiting to the GARFIELD study
- **St Stephen's Surgery:** for having recruited so well to CANDID, with the majority of GPs providing referrals

PROMOTING RESEARCH

Our grateful thanks for hosting local research symposia go to:

- Trinity Court Surgery
- Much Birch Surgery
- New Road Surgery, Bromsgrove
- Elbury Moor Medical Centre

Image courtesy of punsayaporr at FreeDigitalPhotos.net

And finally... FAREWELL

 Phoenix Family Care: Beth Cartwright, the practice manager is retiring. Beth has been influential in the practice becoming research active and we wish her well in retirement



Patient and Public Involvement Engagement Event April 2016 Healthwatch Warwickshire and the Clinical Research Network:

West Midlands (CRN: WM)

On April 14th 2016, Healthwatch Warwickshire 'the independent consumer champion' held one of a series of Personal Independence and Community Resilience Workshops at St. Peter's Presparatory in Leamington Spa. The event was to provide an opportunity for members of the public, local residents, community and faith groups, local third sector organisations, commissioners and providers of services, district councils and elected members to come together, look at personal independence and empowerment and share their views and lived experiences of asserting themselves in health and social care.

The local CRN: WM primary care team were invited to attend to raise awareness about clinical research in primary care and join in discussions. Research facilitator Rebecca Harrison and research nurse Eleanor



Hoverd were on hand to talk about opportunities for patient and public involvement and participation in primary care clinical research and to find out what clinical research means to members of Healthwatch, the public and local residents.

Chris Bain, Chief Executive Healthwatch Warwickshire:

'[CRN: WM]... made a useful and informative contribution to the day and we welcomed their presence'

A Research graffiti wall was displayed for people to write what research meant to them:

- Awareness Wellbeing Cancer trials Check-ups Scrutiny
- Works if it influences action and policy Right treatment
- The future Finding answers to our questions Cures/learning/steps

Herefordshire Cardiovascular Disease Conference

The Herefordshire CVD conference was held at the Three Counties Hotel, Hereford on 3rd March 2016, and was well attended by local clinicians, who heard a range of speakers outlining both national best practice, and local strategies, on how to embed CVD prevention in every day care. Particularly well received were the updates on diabetes from Dr Vinod Patel, and stroke prevention in AF from Dr Yassir Javaid.

There were opportunities for organisations to highlight their work via stands which were open throughout the day. Our Clinical Research Network group, led by Dr Dominic Horne, networked during breaks.





Studies currently available to practices in Herefordshire include ALL HEART, TIME and TASMINH4. Brief summaries of these were available for participants to take away and discuss further with their practice teams.

We are grateful to those Herefordshire practices already participating in NHS research and would welcome the opportunity to discuss future opportunities with those practices yet to become research active.

For further information, please contact your local research facilitator, Jenny Lee email: jennifer.lee@warwick.ac.uk phone: 02476 575919

Local News & Research



A GP Registrar's Role in Research, with Particular Reference to the CANDID Study By Dr Karl Kotwal, Rother House Medical Centre

One of the most attractive features of general practice is the sheer scope and diversity

of the work that it can involve. However, research in primary care isn't something that is taught or indeed encouraged in the GPVTS programme. This to me is counter-intuitive when you think about the fact that around 90% of all NHS contacts take place in primary care and so really we should be at the very forefront of research.

At medical school and beyond it was understood that if you were going into a hospital position as a specialist, then research was a necessary requirement for the advancement of any position within that specialty. However, in general practice this was not the case. I find this a real shame that more GPs are not involved with research simply because good quality research underpins all of our decision-making. This is especially important in general practice where we have time constraints with limited resources and need to make critically important decisions without the aid of instant imaging, pathology and specialist review which is so readily available in secondary care. In this respect it is the history taking that is so vitally important in our decision-making.

CANDID CANcer Diagnosis Decision rules

Take the CANDID study for example.

- Abdominal complaints are amongst the most common in general practice
- How do you spot the cancers from the benign complaints?
- What are the right questions to ask and how should the answers be interpreted?
- How common is tenesmus, rectal bleeding, change in bowel habit etc.?

Only by looking back retrospectively can we answer these questions. This research study will lead to more sensitive and specific questioning that in turn will help clinicians make better diagnosis and decisions. It would be interesting to know how many of the 2WW GI referrals are confirmed cases of cancer and by changing our questioning, how we can improve on this. This is one example of exciting research that we as GPs can easily become involved with if we engage in research within our practices.

One of the things I was most concerned about was the idea of asking patients to participate in research, in this case the **CANDID** trial.

Personally if I feel a two week wait is warranted then I will be open and honest and explain that I am concerned the symptoms may be caused by a possible cancer and that in order to exclude this as soon as possible I am referring the patient on what is called a two week wait appointment.

The reason I do this is because I feel the patient has a right to know what I'm thinking or concerned about and secondly when they arrive at the appointment, they are prepared for a possible discussion surrounding cancer and this is easier for the patient and the clinician involved. However, as soon as the "C"-word is mentioned, I'm sure that patients will find it difficult to take in any further information. This is where a GP can use good and clear communication skills, together with the correct timing to ask the patient to participate in research. I might say something like:

"We are lucky at our practice to be involved in an important research study looking into the symptoms that you have described. It would be very useful for our research team to contact you to discuss this further. Is this okay with you and do you have any questions about that?" I find that if you raise the issue at the right time in the right way, and with empathy and respect, then most patients will happily consent. Fortunately in my experience I have not had difficulty in recruiting people to the study.

The benefits are clear. General practice, our patients and our understanding of the disease process are changing all the time. Patients are becoming more aware of their symptoms and the factors that affect disease are also becoming more apparent, such as the role of diet in cancer. The general practitioner's role is to correctly identify and interpret these symptoms and to reassure or investigate as appropriate. Without research how are we to keep up with this changes?

Being a research practice benefits not only the patients but also the GPs. Participation and affiliation with clinical research networks allow us to:

- contribute to the wider scientific community
- stimulate debate within the practice and
- give us a further sense of worth /pride within the NHS

The experience for myself has been a wholly positive one because it was made easy for us by having a research nurse on site to talk to and support us with clear and simple resources to work from which meant that it didn't take too much time to implement.

My fear was that the study would become too time consuming and stressful and wouldn't fit into a 10-minute consultation, but this has not been the case. We are lucky at my practice that we have had this opportunity to become involved in research and make a positive contribution. Depending upon the circumstances of the practice, I would recommend that more of them should become involved in research and GPs should try to incorporate this into their every-day practice.



Calling those Interested in Infant Feeding

Researchers are looking for GPs, health visitors and midwives with an Interested in supporting safe infant feeding. Coventry University is leading the development of a new online and mobile resource for parents which will support them to make confident infant feeding choices, and support them with sustained breastfeeding and/or safe and responsive bottle feeding. It is essential that the website is designed to meet the needs of both parents and health professionals so your opinion is highly valued.

The UNICEF Baby Friendly Initiative recommends that all parents are encouraged to build positive relationships with their infants. As part of this, breastfeeding and skin to skin contact should be encouraged and supported for all. When required, parents should be given the information they need to bottle feed safely and responsively in order to minimise health risks and maximise parent-infant bonding.

Research shows that many pregnant women and parents are looking online for information about pregnancy, parenting and infant feeding. The resources they find vary widely in accuracy and many parents find it difficult to scan through the wealth of information and decide upon reliable sources, which can result in increased anxiety.

The iFEED study is funded by the Medical Research Council Public Health Intervention Development Scheme (MRC PHIND).

If you would like to contribute to the development of the intervention please contact Dr Naomi Bartle at the Centre for Technology Enabled Health Research on 02477 655497 or naomi.bartle@coventry.ac.uk

Local News & Research



Re-energising General Practice – a bright new future

RCGP Midland Faculty's Annual Education, Research and Innovation Symposium

On 16th June, almost 100 GPs, trainees and health researchers arrived at Warwick University for the RCGP Midland Faculty's Annual Education, Research and Innovation Symposium. Despite the heavy rain (at one point the car park entrance was closed due to flooding), attendees arrived full of enthusiasm and the day didn't disappoint. It was an inspiring programme, full of optimism as keynote speakers discussed:

- A Bright New Future (Dr Dan Lasserson)
- Doing Things Differently (Dr Helen Stokes-Lampard giving the Helen Lester Memorial Lecture)
- Putting Innovation into Practice (Dr Barbara King)

During the breakout sessions, local researchers from across the region presented their work on a diverse range of topics. In the morning, sessions focussing on older people, and children & young people ran in parallel with the presentation of audits which were under consideration for the RCGP Donald Crombie Audit prize. The afternoon sessions addressed a number of long-term conditions including chronic headaches and TIAs, how we deliver medical education and the role of research in general practice. Throughout the day, communication between general practice and other health and social care providers was a common theme, as was the management of chronic conditions.

Looking round the dining room at lunch-time highlighted the diversity of attendees; provosts and professors shared tables with health service users and medical students, animated discussions taking place all round the room.

The poster session after lunch was

well-attended with delegates packed into the poster room to hear the presenters give a three-minute synopsis of their work and answer questions, with the clinical cases providing some lively debate.

The importance the Royal College places on these regional symposia was highlighted by their strong presence at this event – there were no less than three RCGP Provosts in attendance (a record we think) – and their active engagement with the presenters throughout the day.

The organising committee were spoilt for choice with the number of high quality abstracts submitted for consideration and the programme was extended to accommodate additional oral presentations. This high standard was also evident on the day with the judges facing some difficult decisions when it came to awarding prizes. Abstracts for all presentations, oral and poster, will remain available on the Warwick Primary Care website for at least the next six months:

http://warwick.ac.uk/rcgp2016

SAVE THE DATE:

Warwick Primary Care will be hosting next year's symposium on 18th May 2017



The planning team from Warwick Primary Care
Back row: Helen McGowan, Joanne Reeve, Faraz Mughal
Front row: Helen Atherton, Sarah Mitchell, Emma Scott, Jeremy Dale

PRIZE WINNERS

RCGP David Morgan Prize for best oral presentation: Grace Turner – Not so transient: Fatigue, psychological and cognitive impairment following transient ischaemic attack (TIA)

RCGP Donald Crombie GP Audit prize:

Alex Hammant – eGFR levels in diabetes
mellitus type 2 patients prescribed metformin:
an audit in GP practice

RCGP Best poster prize: Aimee McCreedy,
Sophie Walford & Shahab Hagollahi –
PSA monitoring in patients discharged from
urology to primary care: an audit of GP
compliance with PSA protocol

WPC clinical case poster prize: Annabelle Machin

– "Is there a different medication I could have doctor? These anxiety pills are useless!"

WPC best student oral presentation:

Karina Bennett & Andrew Morris – Do specialist paediatric palliative care services benefit children and young people with life-limiting or lifethreatening conditions and their families?

Study Results



Smokers who try to cut down the amount they smoke before stopping are less likely to quit than those who choose to quit all in one go, Oxford University researchers have found. Their study is published in journal Annals of Internal Medicine.

Most experts say that people should give up in one go, but most people who smoke seem to try to stop by gradually reducing the amount they smoke before stopping. This research helps to answer the questions 'Which approach is better?', and 'Are both as likely to help people quit in the short and long term?'.

Dr Nicola Lindson-Hawley from the Nuffield Department of Primary Care Health Sciences led the research. She explained: 'We recruited 697 smokers who had chosen to stop smoking. They were split into two groups. One group – the 'abrupt cessation' group – set a quit day and stopped all smoking on that day. The second group – the 'gradual cessation' group – set a quit day but gradually reduced their tobacco use in the two weeks leading up to that date.

'Both groups had advice and support and access to nicotine patches and nicotine replacement therapy, like nicotine gum or mouth spray.'

Once quit day had passed, volunteers were assessed weekly for the next four weeks, and after six months. As well as asking them about how they were doing, the researchers measured the amount of carbon monoxide they were breathing out – an objective way to check whether people were actually sticking to their quit plan.

At four weeks, 39% of the gradual cessation group had kept off tobacco, compared to 49% of the abrupt cessation group, meaning that the abrupt group were 25% more likely to quit. The difference between the groups began on quit day, when more of the abrupt group attempted to quit (defined as having at least 24 hours with no tobacco), compared to the gradual cessation group.

Dr Lindson-Hawley said: 'The difference in quit attempts seemed to arise because people struggled to cut down. It provided them with an extra thing to do, which may have put them off quitting altogether. If people actually made a quit attempt then the success rate was equal across groups. We also found that more people preferred the idea of quitting gradually

If you want to quit smoking, do it now

Health Society Science Research



Image courtesy of digitalart ID-10043838 at FreeDigitalPhotos.net

than abruptly; however regardless of what they thought they were still more likely to quit in the abrupt group.

'It is important to note that these results were found in people who wanted to quit soon and who were receiving counselling support and using nicotine replacement therapy. For these people the best advice appears to be to pick a day and stop smoking completely on that day. However, as we found that at the start of the study many people cannot imagine being able to stop completely. For these people it is much better to attempt to cut down their smoking than do nothing at all and we should increase support for gradual cessation to increase their chances of succeeding.'

Mike Knapton, Associate Medical Director at the British Heart Foundation, which funded the study, said:

'This study shows that the most effective way to quit smoking is to stop all at once, rather than gradually reducing the number of cigarettes. This BHF funded research also highlights just how crucial it is that smokers have access to advice and support from NHS smoking cessation services.

'Quitting smoking is the single best thing you can do for your heart health which is why we successfully encouraged thousands of smokers to quit for good this No Smoking Day, Wednesday March 9th. Setting a date, today, to ditch the cigarettes is the best start towards a smoke free life.'



The paper, Gradual versus Abrupt Smoking Cessation, is published in journal Annals of Internal Medicine on Tuesday 15 March (DOI: 10.7326/M14-2805).

Study Results

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

PAST-BP (Prevention After STroke-Blood Pressure)

Study aim

This was an open label randomized controlled trial to assess whether using intensive blood pressure targets leads to lower blood pressure in a community population of people with prevalent cerebrovascular disease. The study ran in 99 general practices throughout England.

Participants

People with a history of stroke or transient ischaemic attack whose systolic blood pressure was 125 mm Hg or above.

Interventions

Intensive systolic blood pressure target (<130 mm Hg or 10 mm Hg reduction from baseline if this was <140 mm Hg) or standard target (<140 mm Hg). Apart from the different target, patients in both arms were actively managed in the same way with regular reviews by the primary care team.

Main outcome measure: change in systolic blood pressure between baseline and 12 months

Results

529 patients (mean age 72) were enrolled, 266 to the intensive target arm and 263 to the standard target arm, of whom 379 were included in the primary analysis (182 (68%) intensive arm; 197 (75%) standard arm). 84 patients withdrew from the study during the follow-up period (52 intensive arm; 32 standard arm). Mean systolic blood pressure dropped by 16.1 mm Hg to 127.4 mm Hg in the intensive target arm and by 12.8 mm Hg to 129.4 mm Hg in the standard arm (difference between groups 2.9 (95% confidence interval 0.2 to 5.7) mm Hg; P=0.03).

Conclusions

Aiming for target below 130 mm Hg rather than 140 mm Hg for systolic blood pressure in people with cerebrovascular disease in primary care led to a small additional reduction in blood pressure. Active management of systolic blood pressure in this population using a <140 mm Hg target led to a clinically important reduction in blood pressure.

The Past-BP study team would like to thank all the practices involved for all their efforts in support of this primary care research study.









The full report is available at BMJ 2016;352:i708: http://dx.doi.org/10.1136/bmj.i708

Page 15



Warwick Medical School

Public Health Education

What if there was a Masters that enabled you to help both individuals and whole communities? Imagine if such a course could give you the skills to protect populations against disease or play a part in ground breaking research. With academic professionals at the forefront of their fields advising bodies such as Public Health England on key public health issues, we are well placed to give you the knowledge to make a real difference. Your learning with Warwick can open up a wealth of opportunities.

Who the course is for

This course is suitable for both UK and international students. If you are someone involved in the practice of public health, seeking membership of the UK Faculty of Public Health, working in health promotion or are interested in pursuing an academic career in public health, this course could be perfect for you.

Benefits

Our Masters in Public Health allows you to draw on expertise from 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 at Warwick Medical School and guest clinical or academic lecturers.

- pgt-portfolio1@warwick.ac.uk
- http://www2.warwick.ac.uk/fac/med/study/cpd/
- +44 (0)24 7657 5553

Masters programme

You can take this programme in one year, as a full-time student, or on a part-time basis over a period of three years. Based on modular learning, this course gives you the opportunity to progress from Certificate to Diploma to a full Masters degree. If you choose to study on a part time basis you will complete your Certificate in your first year, your Diploma in your second year and the full Masters in your final third year. Upon successful completion of the programme, you will be awarded with a Masters in Public Health (MPH).

