Clinical Research Network
West Midlands

NHS
National Institute for
Health Research

Autumn 2018

Edition No. 4

PARTICIPATE

What General Data Protection Regulation (GDPR) means for research in general practice

Research is part of NHS core business and therefore the likely lawful basis for processing activities that identify potential research participants is the same as for care and other core NHS activities, i.e. 'performance of a task in the public interest', as NHS organisations are public authorities.

How can the CRN help?

The CRN Primary Care Team is currently developing a local Google site which will contain all the necessary up to date study information your practice and patients require, including links to external Sponsor sites. Therefore please cite us in your privacy notice.

We will also be producing a privacy notice and revised processing agreement to outline the roles and responsibilities of the CRN team.

For useful links and further information on GDPR, please see our article on page 13.

In this edition, we feature articles on:

- Changes to contractual arrangements between the Clinical Research Network and to organisations directly supporting the delivery of National Institute of Health Research (NIHR) Portfolio research on page 14
- ATTACK, a trial looking at whether the addition of low-dose aspirin to usual care reduces the risk of major vascular events in people with chronic kidney disease (CKD) who do not have pre-existing cardiovascular disease (CVD), see page 2
- I-WOTCH, practices are still needed within Birmingham Cross City CCG, Dudley CCG and Herefordshire CCG, see page 4

Not all studies will run in all areas, or be suitable for all practices – for more detailed information, please contact your local research facilitator, contact details on page 20.

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

- Study - Home Treatment for Young People with Chronic Fatigue Syndrome
- Study - ATTACK
- RCGP - Sentinel Practice Network

Contents

West Midland Wide Studies

CHESS

Chronic Headache Education and Self-management Study

CHESS is a multi-centre, randomised controlled trial evaluating an education and self-management support programme for people living with chronic headache, led by Professor Martin Underwood at the Clinical Trials Unit, University of Warwick. Participants are randomised to either:

The CHESS education and self-management intervention

A two day group intervention delivered by a nurse and allied health professional.

DAY ONE: Living, understanding and dealing with chronic headache: headache information and mechanisms, acceptance of chronic headache, impact of thoughts, mood and emotions on headaches, breaking unhelpful thought patterns.

DAY TWO: Learning how to adapt and take control of life with chronic headaches: stress management, lifestyle factors, medication, sleep management, relaxation, mindfulness.

This is followed by a one to one consultation with a nurse and up to eight weeks telephone support.

The control intervention

Usual care plus a relaxation CD.

Our progress to date

More than 119 practices have agreed to take part in the study. We have successfully recruited 342 participants; our target is 689. We have delivered 17 intervention groups across Coventry, Warwickshire, Birmingham, Staffordshire and London.

We are still recruiting to the study

For practices this involves:

- Search of practice population to identify eligible patients, and screen list for exclusions
- Receive written information about participants' headache classification
- Access to medical records for review of headache related consultations and medication at 12 months for those that have consented to take part in the study

If you are interested in taking part in the study please contact either your local research facilitator, details on page 20 or Kimberley White, Trial Manager, phone: 02476 151 634, email: chess@warwick.ac.uk

This project is funded by the National Institute for Health Research – Programme Grants for Applied Research (project number RP-PG-1212-20018).

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or Department of Health.

Aspirin To Target Arterial Events In Chronic Kidney Disease

ATTACK

A pragmatic multicentre open-label randomised controlled trial to determine whether the addition of low-dose aspirin to usual care reduces the risk of major vascular events in people with chronic kidney disease (CKD) who do not have pre-existing cardiovascular disease (CVD). This is a very simple study, with a very low workload for participating practices.

This study, run by the same researchers as those managing the HEAT, FAST GOUT and ALL HEART primary care studies, is due to start in autumn 2018. Participating practices would receive service support costs to cover their time to help with this important study, and support would be provided.

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

The Trial Manager is Jen Dumbleton, email: jennifer.dumbleton@nottingham.ac.uk, phone: 0115 823 1053

EUROASPIRE V

ESC European Society of Cardiology

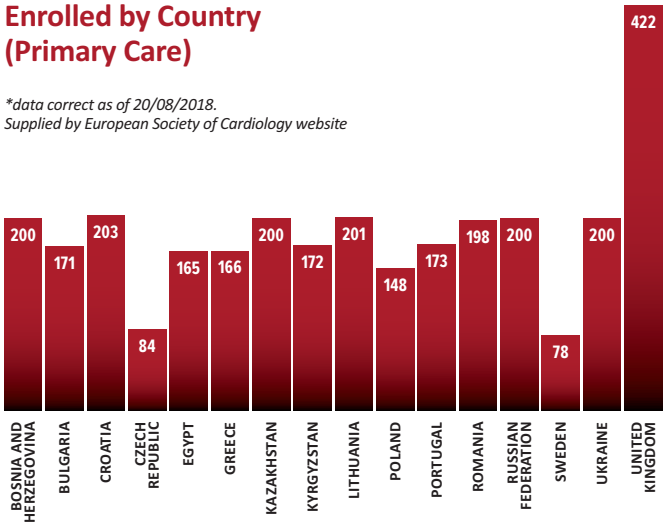
European Survey of Cardiovascular Disease Prevention and Diabetes

The West Midlands team has so far successfully recruited 256 patients for the EUROAPSIRE V/ASPIRE-3-PREVENTstudy. This is impressive and over 60% of the total number of patients recruited so far in the UK*. There are seven CRNs currently recruiting patients to the study, with five of these actively recruiting. Agnieszka Adamska, Coordinating Officer of Imperial College London said,

'Whilst the team had a head start because it was the first to begin data collection, the level of organisation and commitment to the research is commendable.'

Enrolled by Country (Primary Care)

**data correct as of 20/08/2018.*
Supplied by European Society of Cardiology website



Cancer: Life Affirming Survivorship Support in Primary Care – RENEWED Online Study

Background

An estimated 2.5 million people in the UK are cancer 'survivors' (people who have finished primary treatment for cancer, whether or not they are cured), with this number on the increase. Anxiety and depression are common within this population as are fatigue and lack of physical activity. Studies show that healthy lifestyle changes and support for improving psychological wellbeing could improve quality of life for cancer survivors. The RENEWED online intervention provides patients who have finished primary treatments for breast, colorectal or prostate cancer with self-management support for a healthy lifestyle and improved mood. This may lead to an increase in their quality of life and prevention of cancer recurrence.

This study requires 2,500 participants from an estimated 500 GP practices and is effectively a search and mail out study with the addition of Practice Nurse or Health Care Assistant support to a small number of patients. Recruitment ends July 2019.

What is involved for participants?

Eligible participants are randomised into one of three groups:

1. Usual care/Control group
2. Access to RENEWED online web intervention - they will be able to use the website as much as they like over 12 months
3. Access to RENEWED online web intervention with Practice Nurse or Health Care Assistant support (or Clinical Research Network Nurse if applicable)

Participants complete online questionnaires at 6 and 12 months and will receive a £10 High Street Voucher.

What is involved for practices?

1. Database search based on specific inclusion/ exclusion criteria
2. Mail out to potential participants using DOCMAIL
3. Provide a suitable Supporter (Practice Nurse / Health Care Assistant or Clinical Research Network Nurse if applicable) who needs to complete an online training session of approximately 15-20 minutes
4. Supporter to provide up to x 3 support sessions of 10 minutes which can be face-to face, by phone or email
5. Notes review for all recruited patients at 12 months
6. Supporters may be invited to take part in an interview about their experiences of the study

Practices will be financially reimbursed for their involvement in the study.

For further information, please contact your local research facilitator, details on page 20 or contact the Programme Manager, Jane Barnett, phone: 023 8059 1752, email: renewed2@soton.ac.uk

Funded by NIHR

Antibiotics for Respiratory Tract Infections in Children in Primary Care (ARTIC PC)

Acute respiratory infections are among the commonest conditions managed in primary care. The Department of Health recognises that antibiotic resistance is an increasingly serious public health problem in England, Europe and the world with rising resistance rates for a range of antibiotics, and a clear relationship between primary care antibiotic prescribing (responsible for 80% of prescribing) and antibiotic resistance. We are looking to investigate the usefulness of antibiotics in children, aged six months – 12 years, with the aim of providing evidence to inform the management of chest infections.

What does it involve?

Children will be provided amoxicillin antibiotic or placebo and asked to keep a symptom diary for up to 28 days. They can opt to provide a throat swab, a blood sample and have a chest x-ray. A follow up visit with optional peak flow will take place.

Aims

- To estimate the effectiveness of amoxicillin overall and in key clinical subgroups of children presenting with uncomplicated (non-pneumonic) lower respiratory tract infection
- To estimate the cost-effectiveness of antibiotics overall and in key clinical subgroups of children presenting with uncomplicated lower respiratory tract infection
- To explore the estimates of effectiveness according to key pathophysiological subgroups

What are the benefits?

- Fully funded tied to level of involvement
- Service Support Costs for consultation time
- Full support by dedicated trial manager

We are actively looking for sites in the West Midlands area. Please contact your local research facilitator, contact details on page 20 or email eudenj@cardiff.ac.uk if you are interested in taking part.

i-WOTCH

Improving the Wellbeing of people with Opioid Treated CHronic pain

Seeking GP practices to host i-WOTCH study on opioid withdrawal for chronic pain

We are currently recruiting GP practices within Birmingham Cross City CCG, Dudley CCG and Herefordshire CCG to take part in the I-WOTCH study. We are a multi-centre, randomised controlled trial aiming to test the effectiveness and cost effectiveness of a multicomponent self-management intervention targeting withdrawal of strong opioids for people living with persistent pain in comparison to best usual care. The chief investigator for the study is Dr Harbinder Sandhu at the Clinical Trials Unit, University of Warwick.

We plan to recruit 468 participants from around 200 general practices, community pain/musculoskeletal services and pharmacies across two locations: the Midlands and North East England

The I-WOTCH intervention is targeting patients using Buprenorphine, Dipipanone, Morphine, Diamorphine, Fentanyl, Methadone, Oxycodone, Papavertum, Pentazocine, Pethidine, Tapentadol, or Tramadol for the treatment of persistent non-cancer pain. These drugs account for 95% of UK strong opioid prescribing in primary care.

What will it involve for participants?

All participants will be asked to:

- Provide written consent and complete postal questionnaires at baseline, four, eight and 12 months
- Complete a weekly diary booklet recording symptoms and quality of life for four months from baseline

Participants will be randomised to either:

- **Usual GP care plus a self-learning manual**
  Participants will receive a manual with advice about chronic pain management and potential implications and adverse effects of using opioids, and a relaxation CD plus usual GP care
- **Usual GP care plus a support programme**
  Participants will attend a three day self-management course led by an I-WOTCH nurse and a lay facilitator held at a venue close to their practice. There will be an average of 12 people in a group. Participants will have two one-to-one meetings and two telephone calls with the nurse. The nurse will create an opioid tapering plan for the participant at the first meeting and then monitor and discuss their progress over the calls and final one-to-one meeting. Participants will receive the self-learning manual, relaxation CD, educational DVD and mindfulness CD plus their usual GP care

What will it involve for GP practices?

- Identification of potential participants from computer record search
- Checking of list before mail-out
- Mail out of study invitation letters (via Docmail)
- Access to patient records at a later date for data collection of consultations, health service activity, prescriptions and NHS number

Funding Acknowledgement: This project is funded by the National Institute for Health Research, Health Technology Assessment (project number 14/224/04). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA, NIHR, NHS or the Department of Health.

Funded by NIHR

If your GP practice is interested in the study or for more information, please contact your local facilitator, details on page 20.

Promoting the Practice Research Pack

The Primary Care Patient and Public Involvement Team (PPIE) has developed a Practice Pack that contains all the information you need to understand how the Clinical Research Network works with you and your staff, and also to promote research happening within your GP practice to patients. The pack contains general research information, slides and short video clips that can be used on waiting room screens.

One slide informs patients that the practice is research active and takes part in high-quality clinical research, and signposts patients to find local clinical research studies via www.ukctg.nihr.ac.uk or that more information can be found about your local clinical research network at: www.nihr.ac.uk/wmidlands

There is a slide about Join Dementia Research and one showing five good reasons to take part in research. The practices can decide which slides/video(s) they would like to use and which are compatible with their waiting room screen software.

In addition to the above you be will provided with up to date study information as and when the practice takes on a new study. If a poster has been designed and is ethically approved this will be sent to you also.

We will also provide the NIHR logo that can be used on practice letterhead and information about social media and how the practice can follow the CRN West Midlands via Facebook and Twitter.

There will also be included in the pack, a privacy notice and leaflets for patients about taking part in research. These are being developed and will be available to be included in the pack in due course.

This practice pack is to be disseminated over the next few months to practices who are research active but for practices who are interested in using these materials in the meantime please contact your local research facilitator, details on page 20.

SuMMiT-D Feasibility:
Patients at the Heart of Research Development

Developing the SuMMiT-D system

Over 300 patients from a variety of backgrounds, healthcare professionals, and researchers from six leading universities have shared their thoughts on managing type 2 diabetes with our interdisciplinary team. They have suggested that text messages could be used to help support patients with taking their medication and managing their condition. These suggestions have resulted in the development and continuous refinement of the SuMMiT-D text messaging system.

The **aim** of the system is:

- To encourage and support people with type 2 diabetes to develop the habit of taking their medications as intended and
- Offer them hints and tips that could support them with the self-management of their condition

The messages will be individually tailored to patients' medical records, thus offering more individualised support.

What's next for SuMMiT-D: how can your practice help?

We are currently looking for practices to take part in a feasibility trial to further refine the text messaging system and test the SuMMiT-D processes with a large group of people. Your practice will be able to contribute to this important research by identifying eligible patients. You will also get the chance to test an exciting new flagging system that will notify you of potentially eligible patients.

Chief Investigator: Professor Andrew Farmer
Sponsor: University of Oxford
Funder: NIHR Programme Grants for Applied Research

You can find more about SuMMiT-D at: www.summit-d.org or contact your local research facilitator, details on page 20.

Do you see teenagers with fatigue?

They may come to your surgery with recurrent headaches or abdominal pain, nausea and dizziness. If the fatigue has lasted longer than three months and it is preventing them doing things, they may have Chronic Fatigue Syndrome or CFS/ME.

Until recently, children in this region did not have access to a specialist local service. FITNET-NHS has changed this as all children are offered one of two treatments from a specialist at the Bath Paediatric CFS/ME Service.

Assessment and treatment is provided **at home.**

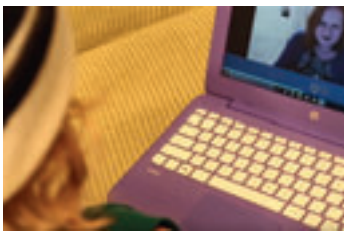
Children will receive either:

1. **FITNET-NHS, a Cognitive Behavioural Therapy (CBT) program - delivered online**
2. **Activity Management - delivered via Skype**

What does it mean for your practice?

- Agree to a database search and mailout to potential participants (young people aged 11-17 with a recent diagnosis of CFS/ME or post-viral fatigue)
- Display patient leaflets and posters in your practice (optional)
- Opportunity to refer: www.ruh.nhs.uk/cfs

What are the benefits for your practice?



- Ability to offer specialist CFS/ME home treatment to young people who have no access to specialist treatment
- Reimbursement for patient identification activities
- Revalidation activities: participating in research
- Involvement in developing and testing new ways of offering treatment in UK NHS

This project is funded by the National Institute for Health Research HTA 14/192/109. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA, NIHR, NHS or the Department of Health

For more details, please contact either Alastair Mobley on alastair.mobley@nihr.ac.uk or your local research facilitator, details on page 20.

For more information about the trial, including a clinician video, treatment details, how to refer, patient leaflets and trial contacts, please see our website: www.bristol.ac.uk/fitnet-nhs

West Midlands Patient Research Ambassadors Annual Network and Celebration Event - March 2018

The Clinical Research Network West Midlands Patient and Public Involvement and Engagement (PPIE) Team organised a regional networking and celebration event inviting all Patient Research Ambassadors (PRA) and leads, with over 65 people attending from across the region. The format of the day was built around opportunities for discussion and networking to share best practice, examples of effective PRA input and impact, and exploring the challenges and solutions of a PRA role to support NHS organisations. The use of innovation and digital technology was also explored. Contributions from this event will shape the local PRA Delivery Plan 2018/2019.

The Network's Chief Operating Officer Pauline Boyle said:

'This event provided an opportunity for Patient Research Ambassadors from across the region to meet each other and there was a really good atmosphere on the day. It showed how passionate patients and public members are about research in the West Midlands'.

Anne Devrell (Chair of the West Midlands Patient Research Ambassadors Regional Forum) said

'The whole event provided a real sense of partnership and support. It was also evidence that the West Midlands region is an active and creative network, committed to making research the best it can be for patients and researchers alike. Table discussions, that exemplified real working partnerships between researchers and patients and the public, were inspiring and thought provoking. Being able to bring research champions from the grass roots to leadership environments is effective and vital if we are to grow involvement, knowledge and success in the future'.

West Midlands Patient Research Ambassadors Regional Forum (WMPRARF)

This is a platform to engage and encourage Patient Research Ambassadors (PRAs) and Trust and health organisation managers from across the West Midlands to share ideas and best practice with each other. The forum has gone from strength to strength since its inception in 2017, and has organised three meetings so far with another planned this year on 28 November (1.00pm - 3.00pm) at the Birmingham Research Park. Attendance at the meetings has steadily increased, with members using the forum to interact and collaborate on effective practice for application within their own settings.

Anne Devrell, the Forum Chair said

'It's so rewarding to be a part of such a dynamic and committed group. Our rationale is that we are a hub for PRA practice and development. We bring our own experiences to the group and attendees take away ideas and contacts that they can share within their own settings or use as starting points for their own PPIE strategies and activities. Being able to share the challenges and successes of working in research as a volunteer or as a professional in this forum is such a great opportunity to support others face to face in a positive and solution-focussed environment'.

Raising Research Awareness Through Patient and Public Group (PPG) Meetings

The CRN is always looking for ways to inform patients and the public about the research we do and how they can become involved. One way we can do this is by giving talks to the PPGs which meet regularly at GP Practices. We were therefore delighted when Practice Managers from both Winyates Health Centre and Spring Gardens Medical Practice invited us to give a presentation at their PPG meetings earlier this year.

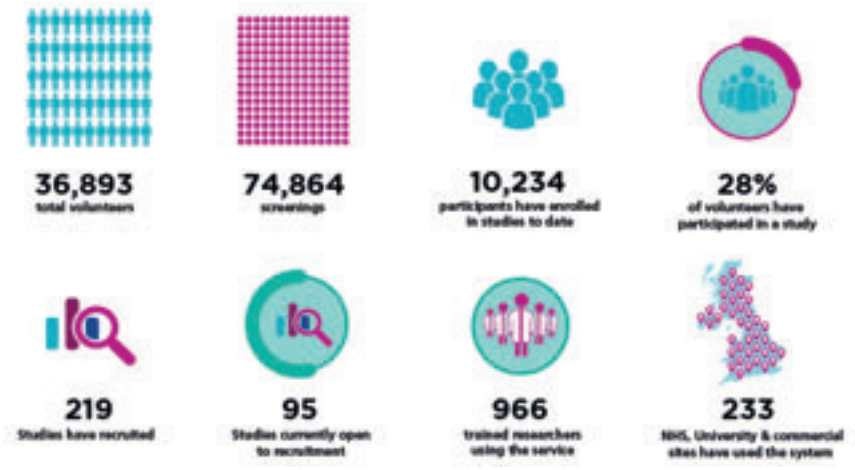
The meetings provided us with an opportunity to explain what the CRN does, the types of studies being run at their practice and who they are funded by. We explained all the different ways in which lay members could get involved with research themselves and were able to highlight the various web links that give access to studies taking place across the whole country, such as the UK Clinical Trials Gateway. We were also able to promote the role of the Patient Research Ambassador and explain the important influence patients can have on generating ideas for the next research study by highlighting the recent NIHR campaign for more research topics.

The talk generated a lot of interest and support for research at these practices, with everyone appreciating how important the need for research is. However, although hugely supportive there was also a lack of awareness that their practice had been engaged with research, so the search for new ways to publicise and make research more visible at our research active practices must continue.

If your practice is interested in a member of our CRN team presenting at one of your PPG meetings in the future, please get in touch with your local research facilitator, details on page 20.

Join Dementia Research (JDR) www.joindementiaresearch.nihr.ac.uk is still being widely promoted across the UK and members from the West Midlands primary care Patient Public Involvement and Engagement (PPIE) team are actively developing and supporting new ways of approach to spread the word to a wider audience and increase the volunteer recruitment rate for the region As a reminder, the initiative provides a platform for members of the public to register their interest in volunteering to participate in dementia related research. By signing up to the register, volunteers provide their consent to be contacted by researchers whose studies have been downloaded onto the system.

Join Dementia Research in numbers



updated 31 July 2018

Anyone over the age of 18 can sign up. You do not need to have a dementia related diagnosis. It is also open to family members, carers and friends. The goal is that by 2020 100,000 volunteers will have registered.

As at 31 July 2018, nationally 36,893 volunteers had signed up of which 30,816 do not have a diagnosis, 6,077 do. (Within the West Midlands region it has been established that 47,388 people have a diagnosis. 2,229 volunteers have registered, 1,861 without a diagnosis, 368 with one.) As you can see there are a lot of dementia diagnosis individuals, their families and friends who could be made aware of the opportunity.

JDR Roaming Kiosk

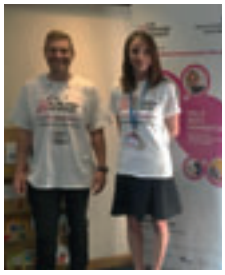
We have set up roaming kiosks hosted in GP surgeries to promote JDR directly to patients. The kiosks house a small tablet which is linked to the JDR website and allows the public to view what the database is and express an interest in being contacted directly by the national JDR team. The kiosks will be monitored to established how well used they are and whether they have been successful in increasing the volunteer recruitment numbers. A review of the support for pharmacies to help with the promotion of JDR is also being conducted.

If you would like any further information about JDR, how we may be able to assist you with promoting JDR or receive JDR promotional literature, please do feel free to contact your local Primary Care team member or Jacqueline Smart on jacqueline.smart@nihr.ac.uk

International Clinical Trials Week 2018

As part of International Clinical Trials Week 2018, the Network north locality team visited local GP practices to promote Join Dementia Research with the aim of encouraging both dementia sufferers and healthy volunteers to sign-up to the research service.

A number of practices were visited over Shropshire and Staffordshire with the Join Dementia Research (JDR) kiosk also present at the RCGP Symposium held at Keele University. There were a total of 67 registrations of interest on the JDR kiosk, with ten individuals pursuing their registration by signing up to the JDR database.



Thank you to Westgate Practice, Kingsbridge Medical Practice, Wolstanton Medical Centre, Audley Health Centre and TELDOC (Oakengates Medical Centre & Malinslee Medical Practice) for allowing members of CRN WM North to promote Join Dementia Research.

PPIE and Patient Stories

Anthony's Story

I agreed to be part of the Care 75+ research study believing that your results in time will help ageing people to come to terms with their ageing and to improve their quality of life.

The experience thus far has been very pleasant. Both Research Nurses, Anita and Jan, have at all times informed me about what will be taking place and although I failed the cognitive word test at the time, I believe I remembered the key words a few days later.

It has been, and is, a pleasure to host you at home and I look forward to seeing you again, in six months' time for my first follow up visit.

Anthony, Staffordshire

Alfred's Story

Alfred had not been involved in research prior to taking part in the CARE 75+ study, which explores how health problems and frailty may develop in later life. He shared with us that his wife sadly died of cancer and this was a contributing factor in his decision to participate in a clinical trial.

Alfred added that he feels participating in research is a good idea as it will benefit other people and the community.

Prior to participating in CARE 75+, he received a lot of information explaining the study and his involvement.

Alfred said:

'I gave my time gladly and liked having the nurses visiting me, research does brighten the days up and is something I have looked forward to.'

He also found the study measurements and questions easy to follow and answer. He adds:

'I will tell other people about research and I would definitely like to take part in other studies'.

Alfred Bentley, Shropshire

Trevor's Story

Trevor was invited by his GP practice to take part in the Euroaspire study which explores the management of coronary patients and individuals at risk of developing cardiovascular disease in primary care, with regards to their lifestyle and use of drug therapies.

He says:
'Two years ago I was asked to take part in a study by my GP surgery - I think it was something to do with the skin. However, I didn't follow it up but when I had the letter through the post asking me if I'd like to take part in this cardiac study I was keen to be a participant. I spoke to my son who said it would be a brilliant opportunity, as he worries about my blood pressure.

'I was a little nervous at first as I didn't know how the research staff would be and was not sure what would be happening, but the research staff were brilliant making me feel very relaxed. I received some information through the post about the research and it was easy enough to understand.

'I read that I needed to have some blood taken, which I wasn't worried about and I knew it would be taken three times over a couple of hours. I rang the surgery and made an appointment and the day I was asked to attend I didn't have any worked booked as I am self-employed, so I didn't lose any money as such.

'They asked me not to eat anything and to only drink water but to take my normal tablets. I only live a short distance from the surgery so I walked. The appointment took just over two hours and I would not hesitate to take part in another research study, and would encourage people to do the same.'

Trevor, Shropshire

Welcome to Geoff Robson, Patient Research Ambassador

My name is Geoff Robson. Having retired after working in the rail industry for 40 years, I wanted to be involved in some form of voluntary work within the NHS.

Having been involved with my local Patient Participation Group, I became aware of the Clinical Research Network and was asked by its Head of Patient Public Involvement and Engagement, if I would be interested in becoming a Patient Research Ambassador.

Although I have effectively been in the role for a few months I can see the amount of work to be done and the challenges that lay ahead. However, I am already finding the role very interesting and rewarding and am looking forward to contributing towards the success of research with a focus on primary care.

To contact Geoff, initially please send a message via your local research facilitator, contact details on page 20.

Has Your Practice Ever Considered Getting Involved in Primary Care Research?

GP **David Shukla** offers a personal perspective on the benefits

In 2007 I joined a GP surgery in Dudley already established in teaching and training, and as a young partner I was keen to bring something new to the practice. We regularly received a newsletter from the local Clinical Research Network (CRN), detailing research studies being run in primary care and recruiting GP practices. The CRN is part of the National Institute of Health Research (NIHR). I contacted the CRN for further information, we were visited by two research facilitators who explained what was involved and provided details of studies considered suitable for a practice with no research experience. We felt that getting involved could benefit the practice by giving our patients the opportunity to partake in research relevant to them, which could potentially bring about benefits to their care.

We were encouraged to undertake training in Good Clinical Practice (GCP), which is the international ethical, scientific and practical standard to which all clinical research is conducted. Compliance with GCP provides public assurance that the rights, safety and wellbeing of research participants are protected, and is a requirement of the Research Governance Framework for Health and Social Care (2005) which covers all research in the NHS in England. The NIHR offers GCP training either as a face-to-face workshop, or as an online module.

Cough study

The first study we joined was the 3C cough study which recruited patients presenting with an acute cough. It involved asking a few questions about presenting symptoms, recording a detailed examination, and then undertaking a follow-up notes review which was conducted by our practice nurse or healthcare assistant one month after initial attendance, detailing what had happened to the patient in the interim (e.g. recovered, admitted, referred, died or not returned).

Within a few weeks we were up and running with the study and the partners and GP registrars were recruiting patients. With an autumn start, the timing was perfect and our acute cough presentations generated practice income in the region of £30 per patient recruited. By the end of the recruitment period we had consented 117 patients, second highest in the West Midlands, and the study team reached their 30,000 recruit target overall.

The patients enjoyed being given a little extra time in consultations and asked more detailed questions, and the staff felt increasingly skilled in managing this particular clinical area.

So we took on other studies involving conditions including cancer, atrial fibrillation, chronic obstructive pulmonary disease (COPD), gout, heart disease, *Helicobacter pylori* infection and smoking cessation. Taking part in these studies meant that some of our patients were given access to novel treatments and received more intensive monitoring and review, as well as accessing additional support in managing their chronic conditions and generally enjoying the altruism of giving something back to the NHS. As clinicians, we valued learning more about the conditions, gaining an understanding of how research is carried out and being able to add something different into our annual appraisal documentation. Income generated from our involvement was invested back into the practice, allowing for additional staff training and support.

The support we received from our local CRN team was fantastic, they would frequently pre-select us, knowing that we would recruit well. We then completed the Royal College of General Practitioners' (RCGP) Research Ready accreditation, which is a framework to ensure practices run research in accordance with correct clinical and legal frameworks (including contacting indemnity providers to ensure this is in place, and notifying the Information Commissioner's Office).

Our participation also paid off in our **Care Quality Commission** (CQC) practice inspection, where we were able to demonstrate how research

benefited patients and contributed to continuous quality improvement (QI), e.g. the FAST study (**F**ebuoxstat versus **A**llopurinol **S**treamline **T**rial) improved management of our patients with gout by optimising urate-lowering therapy for them. The TargetCOPD2 trial invited current and ex-smokers into the practice for lung function testing, resulting in a rise in recorded COPD prevalence with the associated benefits for patients previously not known to be suffering from the condition – the so-called 'missing millions'. We achieved an overall 'outstanding' rating from the CQC, with specific mention of our research activity in the report.

Several years on, we now participate in approximately five studies per year and have just taken on our first commercial research study, partnering with a major pharmaceutical company. The work required in a commercial study is more detailed and intensive and, again, the support we have received from the CRN has been invaluable.

Data handling

Fortunately we have not experienced any difficulties with research activity, but we have been careful to ensure that our clinical coding and records are kept up-to-date, and we screen every list of patients generated by the research searches to ensure we don't contact anyone recently bereaved or with a recent significant diagnosis, where it may be felt inappropriate to invite them at this time.

Many practices have been concerned about the impact of the General Data Protection Regulation (GDPR) and how this may affect the way in which patients are invited into studies. Is individual

continued on p10

Has Your Practice Ever Considered Getting Involved in Primary Care Research?

continued from p9

patient consent now required to participate? The Health Research Authority (HRA) has further specific guidance on this, but it is hoped that very little will change in practice and patients can be recruited as before. Article 9 of the GDPR provides exemptions for research carried out in the public health interest, or in helping the NHS carry out its statutory duty to 'inform patients of research studies in which they may be eligible to participate' (NHS Constitution 2015). Practices are encouraged to use posters, leaflets and notices on their website and new patient forms to inform patients that the practice is research active, where they can find out more information about what this means, and how to opt out should they wish to (NHS Digital's national data opt-out system came into effect 25 May 2018).

I now work directly for the CRN as a Primary Care Research Lead and have clinical oversight of delivery of research studies in Birmingham and the Black Country. About 45% of our GP surgeries are research active, and with more GPs taking on portfolio roles and looking for other interests, research delivery can provide opportunities. The CRN is adapting its support model for primary care, taking account of changes such as the formation of large super-partnerships, federations, vanguards and other new care models. Working at scale is likely to have benefits for research activity in primary care, hopefully giving more patients the opportunity to be involved in research studies.

Involvement with research benefits patients, doctors and other practice staff and is generally very easy to undertake with limited time resource and the support of a local CRN team. It's also academically satisfying and provides relief from the demands of the day job – and, on the whole, patients are happy to take part.

Dr David Shukla is a GP Partner at Eve Hill Medical Practice in Dudley, Clinical Research Specialty Lead for Primary Care in the West Midlands and Clinical Research Fellow at the University of Birmingham's Institute for Applied Health Research

Published in www.mddus.com/resources/publications-library/insight/q2-2018/research-ready

Welcome to Alastair Mobley

I have been working for the NHS for three years in multiple roles built around clinical research. I started out working for the CRN as a Research Support Facilitator, after which I moved to the Queen Elizabeth Hospital to become a Cardiology Clinical Trial Coordinator where I was involved in conducting study visits with patients in both observational and interventional studies. In April, I returned to the Network to start my current role as a Primary Care Research Facilitator in the central locality.

I was born and raised in Wolverhampton, moving away to study a degree in Medical Biochemistry at Swansea University, and then returning to the Midlands to complete a Masters in Biomedical Research at the University of Birmingham. I am an avid music and sports fan filling my weekends with concerts or match days spent at Molineux watching the Wolves.

alastair.mobley@nihr.ac.uk

Understanding Vaccination Uptake Amongst Polish and Romanian Migrants

Qualitative Interview Study

At the London School of Hygiene and Tropical Medicine we are conducting an interview study to explore vaccination uptake amongst Polish and Romanian communities in England. The study is funded by the National Institute for Health Research and is being undertaken as part of the Health Protection Research Unit in Immunisation.

http://immunisation.hpru.nihr.ac.uk/

The main aims of the study are to:

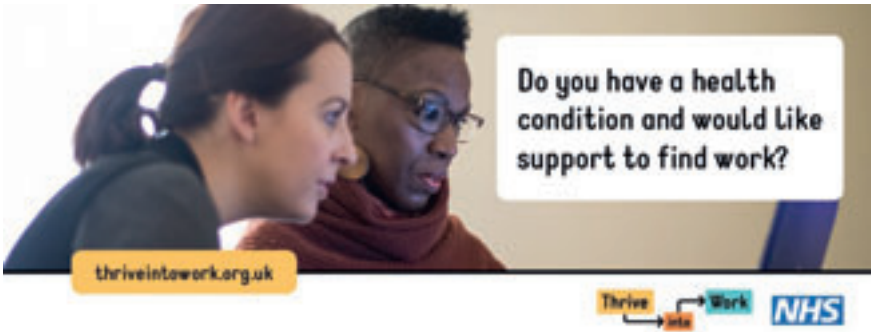
1. Gain insight into vaccination knowledge, attitudes and behaviours amongst Polish and Romanian communities
2. Identify any barriers/facilitators to vaccination
3. Consider ways to improve vaccination uptake

The study involves a one-off interview, lasting approx. 30-40 minutes, which can take place over the phone or in person.

We are looking to collate feedback and experiences from healthcare professionals working in general practices in the B7, B8, B9, B10 and B24.

Study findings will be used to directly inform service developments, improvements and practice.

Please get in touch with Sadie Bell, Research Fellow at the London School of Hygiene & Tropical Medicine, who is leading this research if you have any questions about the study and/or you are interested in taking part. Sadie can be contacted on 0207 9272885 or Sadie.Bell@lshtm.ac.uk



A new programme to help people with mental health conditions, long term health conditions and physical disabilities into work has launched, giving GPs and other NHS teams an extra service that could help their patients' health and wellbeing.

The programme is based on a very well-evidenced model, known as Individual Placement and Support (IPS) that aims to achieve tight integration between health and employment services and provide personalised, intensive support for clients. IPS has been tested in over 20 academic trials internationally for people with mental health issues. The programme is live! Providers are meeting with GP practices, community teams, local authority, CCGs as well as employers to ensure the referral process and access into the project runs smoothly. There are two referral routes into the programme: GP e-referrals and referrals though a website. For Birmingham individual practices need to install the e-template. Please contact me for the e-template and further information (Fozia.ikram@nhs.net 07920150070). A completed e-template referral can be sent directly to myself or through the e-RS system once commissioned by your CCG.

The Clinical Research Network West Midlands are offering service support costs and referral rates for appropriate GP and Practice Nurse referrals to support the recruitment on this research project.

Please contact the CRN in your area for more information:
Saif Uddin (Birmingham & Black Country), saif.uddin@nihr.ac.uk
Jenny Simm (Wolverhampton), jenny.simm@nihr.ac.uk

Dr Fozia Ikram-Bashir, Thrive into Work IPS Programme,
Clinical Engagement Lead, 07920150070

Welcome to Sim Dhillow

I am new to the CRN and have really enjoyed the first few weeks in my role as a primary care Research Support Officer. Prior to this, I worked in the NHS as a Medical Staffing Officer; this was my first role within the public sector and gave me a great insight into the inner workings of the NHS.

My background has been mostly in the private sector in HR and IT. I have worked in recruitment, HR and client services roles. I have had the pleasure of working in small companies and large blue chip corporations like Ernst & Young.

I look forward to meeting and working with you and I would like to say thank you for the warm welcome.

simranjeet.dhillow@nihr.ac.uk

Introducing West Midlands Central Research Champions

Ella Thompson

Ella is the Business/ Practice Manager at The Ridgeway Surgery in Sedgley. A Practice Manager for the last ten years, constantly looking for new opportunities for the practice, Ella introduced the practice to research a few years ago and the practice has never looked back since, completing a number of studies annually. She feels strongly that there is a moral obligation to promote research and would like to encourage her practice manager colleagues to consider getting their practices involved, or alternatively looking at what can be done to overcome the obstacles that stand in the way of research participation.

Jitu Mandhyan

Jitu has worked within primary care since 2008 and has gained relevant high-level experience over the years within GP practices. Jitu's interests lie in research and he has participated in several studies, building a good relationship with the research team at University Hospitals Birmingham NHS Foundation Trust. He has worked within prestigious Research Ready organisations such as Modality Partnership, and Burbury Medical Centre, which have been actively involved in ongoing primary care research studies with CRN, giving him an understanding of the organisation's model and ethic

Tom O'Sullivan

Tom lives and works in Solihull where he is the Chief Executive of a large scale GP provider, GPS Healthcare. After he organised effective training, the practice moved to a CQC rating of Good Overall with Outstanding for Well Led. Tom has an academic interest in organisational development, particularly workforce and leadership. He has promoted clinical research in his own practice and now wants to reinvigorate engagement in clinical research across the Solihull locality.

Blood Vessel Health In Atrial Fibrillation

Atrial fibrillation is the most common sustained heart rhythm disorder and is associated with substantial risk of severe stroke, cognitive decline and dementia. Research is required to better understand the reasons for this and to develop effective countermeasures. Work at the University of Birmingham has recently identified vascular damage/ dysfunction in atrial fibrillation, indicated by elevated blood markers and impairments in blood vessel regulation. Medications that prevent the formation of blood clots (e.g., anti-platelet and anticoagulant drugs) are prescribed to reduce the risk of stroke in atrial fibrillation. These in turn may have different effects on the blood vessels as a complex interplay between inflammation, coagulation and blood vessel function exists in atrial fibrillation. This University of Birmingham sponsored research project seeks to understand the influence of these drugs on the health of blood vessels. We hope that these investigations will provide important new insights into the elevated risk of cerebrovascular events in atrial fibrillation.

Patient involvement

The single study visit lasting one morning will be performed in the University of Birmingham Institute of Cardiovascular Sciences, City Hospital, Birmingham. The study includes a small blood sample, completion of some questionnaires, monitoring of brain blood flow, arm blood flow, breathing, and blood pressure. Travel to the hospital and parking charges will be reimbursed.

Enrolment period

Recruitment is ongoing until February 2019.

Practice involvement

We are currently looking for practices to identify and invite three groups of atrial fibrillation patients (men and women) aged over 18 years to participate, with a particular focus on the **second** and **third** group.

1. Patients who are prescribed Apixaban
2. **Patients who are prescribed Warfarin**
3. **Patients who are prescribed Aspirin**

If your practice would be interested in helping us with this important study, please contact your local research facilitator. Practices will be reimbursed for their time.

REtirement in ACTion

A RCT and Economic Evaluation of a Community-based Physical Activity Intervention to Prevent Mobility-Related Disability for Retired Older People

The REACT study is led by Dr Afroditi Sathi, University of Birmingham with collaboration from the University of Bath and the University of Exeter to assess the effectiveness of a community-based physical activity intervention for reducing the progression of mobility-related functional limitations in older people who are at high risk of transition from independence to mobility-related disability. A total of 768 participants were required with 256 from Birmingham.

A total of 777 adults aged 65 and over were recruited which comprised 513 women and 264 men with an average age of 78 years. A total of 174 participants from the Birmingham and Black Country region were randomised into the study. All participants were asked to attend a baseline measurement session then to be followed up at six, 12 and 24 months. All six month measurement sessions have been concluded, with the 12 month measurements finishing in November 2018. Between now and November 2019 the study team will be organising the final assessment sessions for all the other REACT volunteers – in total 777 participants.

Follow-up data

As the study is now approaching the analysis phase, in order to establish the representativeness of their study sample, comparison will take place between the characteristics of people who expressed interest in REACT, and the entire database of people who were invited to take part.

Sarah Moorlock, the researcher at the University of Birmingham running the REACT study, will have been in contact to ask participating practices to provide a list of the gender and ages of all eligible patients mailed out to. The excel mailing list would be stored within the REACT folder on your practice network drive. Please do not send identifiable information – just gender and age. Many thanks to those GP surgeries who have already provided this data.

Once all assessments are complete, the information collected will be analysed and sent to participating practices with a summary of results. There is still much work for the study team to undertake, but completion should be by Spring 2020.

Although it is too early to provide data to practices, the study team has received a lot of anecdotal reports from people in the intervention group stating that they have found the exercise has helped their mobility/function/arthritis/strength/balance and that the social element has helped them build bonds/make friends/reduce isolation.

REACT is currently the largest ever UK study of its kind and the study team would like to express their thanks for all the help and support provided by GP surgeries in Birmingham and Black Country.

Research Facilitators:	Sheila Bailey/Marie Crook
Research Associate:	Sarah Moorlock
Chief Investigator:	Dr Afroditi Sathi
Sponsor:	University of Bath *(currently transferring to University of Birmingham)*
Funder:	National Institute for Health Research (NIHR) Public Health Research Programme

General Data Protection Regulation (GDPR)

Please find highlights of further guidance published by the Medical Research Council (MRC) and the Health Research Authority (HRA).

What GDPR means for research in general practice

Research is part of NHS core business and therefore the likely lawful basis for processing activities that identify potential research participants is the same as for care and other core NHS activities, i.e. 'performance of a task in the public interest', as NHS organisations are public authorities.[1]

What is the National Opt-Out? Is this related to GDPR?

The national patient opt-out in England is not related to GDPR, it's about confidentiality. Opt-outs don't apply when there is research consent, irrespective of the GDPR lawful basis, and don't apply to mailing study invites to patients.

The national opt-out only applies to studies that have section 251 support from CAG.[2] NHS Digital has applied the national opt-out from 25 May. By 2020 all Health and Care Organisations are required to apply the national opt-out.

What action do we need to take?

Inform your patients that your practice undertakes research.[3]

Transparency is about better informing patients, public and participants about research; it is not about getting permission. Making transparency information understandable, and drawing people's attention to it, is key.

All NHS organisations should have a notice on their website that references their role in participating in research. The HRA have produced some transparency wording for NHS participating sites that explains what research is and what can be expected.[4]

There should be a layered approach, so once your organisational notice is in place project-specific information should highlight it. This also may include a link to the CRN Primary Care Google site to signpost patients to for further information.

How can the CRN help?

The CRN Primary Care Team is currently developing a local Google site which will contain all the necessary up to date study information your practice and patients require, including links to external sponsor sites. Therefore please cite us in your privacy notice.

We will also be producing a privacy notice and revised processing agreement to outline the roles and responsibilities of the CRN team.

1. FAQ list. - GDPR - FAQs - Medical Research Council www.highlights.rsc.mrc.ac.uk/GDPR/index.html
2. Confidentiality Advisory Group - Health Research Authority www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/
3. GDPR and Data Protection Act 2018 : Key facts for research. 13 June, 2018 https://mrc.ukri.org/documents/pdf/mrc-hra-gdpr-key-facts-for-research/
4. Transparency - Health Research Authority. 26 April, 2018 www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-detailed-guidance/transparency/

Group Practice Enhanced Research Delivery Scheme

Thank you to all practice groups who applied to pilot the Group Practice Enhanced Delivery Scheme, we were very impressed with the standard of applications but unfortunately we could only select a small number of Practice Delivery Groups where funding allowed.

The aim of the pilot scheme is to:

- Increase the overall number of participants recruited to NIHR research projects
- Increase the ability of the practice group to deliver complex studies by using of group level resources and expertise to set up and run such studies (e.g. Hub & Spoke model working)
- Work towards hosting and delivering primary care commercial studies

We are pleased to announce our successful applicants are:

Westgate Practice
www.westgatepractice.co.uk

Oswestry Practice Group
The Caxton, Cambrian Medical Centre, Plas Ffynnon Medical Centre

Teldoc
www.teldoc.org

North Staffordshire Practice Group
Kingsbridge Medical Centre, Audley Health Centre, Wolstanton Medical Centre

Stafford Primary Care Alliance
Stafford Health & Wellbeing, Holmcroft Surgery, Wolverhampton Rd Surgery, Castlefields Surgery, Gnosall Surgery

East Staffordshire Primary Care Partnership
All Saints Surgery, Alrewas Surgery, Balance Street Health Centre, Barton Family Practice, Northgate Surgery, Peel Croft Surgery, The Tutbury Practice, Wetmore Rd Surgery

Walsall Alliance
www.walsallalliance.co.uk/member-practises

SDS MyHealthcare
www.sdsmyhealthcare.com/our-federation

Please note Practice Delivery Groups in the South Locality will be selected in due course.

We look forward to working closely with our newly selected Practice Delivery Groups and reviewing progress of the scheme over the next two years.

Our dedicated CRN Team will support Practice Delivery Groups to meet the set criteria outlined in the scheme, with the aim of enabling practices to generate additional research income by working as a group, for example through increased research delivery and recruitment, efficiency savings and establishing commercial study delivery.

Changes to the Local Clinical Research Network (LCRN) Contractual Requirements

There have been some recent changes to the contractual requirements that must be in place by October 2018 to enable the LCRN to provide funding or resource to organisations to directly support the delivery of National Institute of Health Research (NIHR) portfolio research.

The Performance Operating Framework 2018/19, which exists between the West Midlands CRN Host organisation (Royal Wolverhampton Hospital NHS Trust) and the NIHR Clinical Research Network Coordinating Centre (CRNCC) (and therein the Department of Health and Social Care), confirms the requirement to implement a sub-contract arrangement with any providers of health and social care services that receive an allocation of LCRN funding.

In order to comply with the host contract, we will be issuing a DHSC approved contract, described as a 'Partner B' or 'Partner C' contract. The contract to be used is dependent on the level of CRN funding to be received at each site.

We are currently customising the contracts for each site and will be issuing these shortly via a member of the CRN team, who will liaise with you to get these signed ASAP to ensure that funds can continue to be released. This will more than likely be the Research Facilitators or Research Nurses with whom you regularly communicate, however we appreciate that some organisations receive funding without CRN support and these organisations will also need to have contracts in place to enable them to receive payment. We appreciate that these are legal contracts, however please note the contracts cannot be amended or altered in any way.

If you require further information, please contact your locality Research Manager:

Sue Elwell	sue.elwell@nihr.ac.uk
Louise Jone	louise.jones@nihr.ac.uk
Jenny Stevens	jenny.stevens@nihr.ac.uk

Invitation to join a Sentinel Practice Network

The Royal College of General Practitioners Research and Surveillance Centre (RCGP RSC) is inviting practices to join the RCGP RSC sentinel network of approximately 260 practices across England. The Centre is mainly funded by Public Health England to be the main source for national surveillance. The RSC has also received funding from NHS England to double the network and to create a Workload Observatory.

Why join the RCGP RSC?

- **Be part of a Sentinel Practice Network and contribute to important healthcare decisions**
  Opportunity to contribute to improvements in Public Health, including the conditions that impact primary care most
- **Rewards to your practice**
  Opportunity to participate in funded research, without the hassle of signing additional paperwork. Member practices can have free Research Ready Advanced accreditation (standard cost of £50 per year).
- **Learning and development**
  Continuous support on coding and various aspects of clinical work from dedicated Practice Liaison Officers. Practices will also have access to an individual interactive dashboard. Paid online training, which can be used for re-validation, will be available to clinicians
- **Compliant with NHS Information Governance Toolkit and GDPR**
  RCGP RSC is compliant with all existing legislation and national guidance on use of patient level data

For more information about the Network, please go to: www.rcgp.org.uk/rsc

To express interest or for further information please contact Ms Mariya Hriskova – m.hriskova@surrey.ac.uk

Network recruits highest ever number of patients into clinical research in the West Midlands

According to figures published by the National Institute for Health Research (NIHR) a record 70,720 people took part in clinical research in the West Midlands in 2017/18 - the most ever in a single year.

The 2017/18 NIHR Research Activity League Table details how much clinical research is happening, where, in what types of trusts, and involving how many participants. The League Table can be accessed from the website: www.nihr.ac.uk/nihrleaguetable

The top five Trusts in the West Midlands for the total number of clinical research studies undertaken are:

- University Hospitals Birmingham NHS Foundation Trust (UHB): 8,074 participants in 298 studies
- Heart of England NHS Foundation Trust (now merged with UHB): 6,534 participants in 190 studies
- Birmingham Women's & Children's NHS Foundation Trust: 4,731 participants in 177 studies
- University Hospitals of North Midlands NHS Trust: 2,711 participants in 176 studies
- University Hospitals of Coventry & Warwickshire NHS Trust: 4,653 participants in 157 studies

'This is the first time we have exceeded the 70,000 mark, beating our target by 10,100 recruits. In addition, we are not only the top recruiting region for commercial clinical trials, but were also second (of 15 networks) for the total number of patients recruited to non-commercial trials,' says Clinical Director of the Clinical Research Network West Midlands (CRN WM) Professor Jeremy Kirk.

'Our grateful thanks go to every single person who participates in clinical research, or supports someone who does. Without them, we wouldn't be able to find new and better treatments for patients in the future. It is also a fantastic reflection of the hard work and enthusiasm of our dedicated staff and researchers in the region.'

And the West Midlands has once again proved that it is one of the best places to carry out clinical research with the number of people taking part in primary care studies in the region increasing by 118%. In addition, Birmingham Women's & Children's NHS Foundation Trust featured in the top ten for the biggest increase in research activity. The Trust is third in the table, with 34 more studies taking place compared to the year before.

Nationally, there has been an increase of 45% in participants recruited to studies sponsored by the life sciences industry - with a rise in the West Midlands of 30%.

Professor Kirk adds: *'The increase in the number of patients taking part in clinical research last year and the improvements we are seeing in studies delivering to time and target are fantastic achievements that are contributing to better health and care outcomes in our region.*

'As a result, more and more patients will benefit from new and better treatments becoming available.'

Participants were recruited from 27 of 28* NHS Trusts in the West Midlands, from a third of the region's GP practices, and in hospices, nursing homes and pharmacies.

David Loughton, Chief Executive of The Royal Wolverhampton NHS Trust, which hosts the Network, comments: 'The success of the CRN in the West Midlands is testament to the hard work, commitment and excellent staff we have leading the Network, and the willingness of patients to take part in research studies. As a Trust we are delighted with this success story.'

There are currently more than 1,400 different studies taking place in the West Midlands across 30 health specialties. You can read about the experiences of patients who have taken part in research in our region on the Network website: www.nihr.ac.uk/nihr-in-your-area/west-midlands/get-involved.

*now 25 Trusts following the recent mergers of South Staffordshire & Shropshire NHS Foundation Trust and Staffordshire & Stoke on Trent Partnership NHS Trust, and Burton Hospitals NHS Foundation Trust with Derby Teaching Hospitals NHS Foundation Trust.

Feedback to the CRN from Practices and Study Teams

The support from the CRN in recruiting to the I-WOTCH study has been key to its success. The CRN team have been proactive in reaching out to GPs over the network and gaining their interest and participation. To date we have had interest from over 100 GPs following contact from the CRN. Not only have we recruited from practices that are already research active but we have been able to engage with GPs that are new to research. We have engaged GPs from South Warwickshire, through to Birmingham and Staffordshire. We have also received CRN support in creating and tailoring our GP searches which is crucial for the study and ensuring we invite the correct cohort of patients over three different database systems. As the I-WOTCH study team are not familiar with the GP databases or even the geography and relationships between GPs we find the knowledge and experience the CRN bring a valuable asset that helps us plan and recruit efficiently. This CRN knowledge has even helped us consider and find venues to host the I-WOTCH intervention groups within the Midlands.

A big achievement led by the CRN was the ability to secure the study excess treatment costs for a further four intervention groups to be run within the central and south localities in 2018. This area had previously recruited in 2017, however we were eager to return following an excess of participant interest; we are pleased to be able to return and continue to offer the I-WOTCH study to patients in this area.

As we hit our busiest recruitment phase from April through to November 2018 we hope to continue our good working relationship with the network as we move into East Midlands in addition to West Midlands. We hope to continue to mail out in a timely manner from GPs all over the Midlands to help us recruit to our target of 468 participants randomised.

Telemonitoring And/or Self-Monitoring of blood pressure IN Hypertension (TASMINH4): a randomised controlled trial

Background

Raised blood pressure (BP) is common and although it causes very few symptoms, treating blood pressure can reduce the chance of stroke or heart disease occurring in the future. Research teams at the University of Oxford and the University of Birmingham set out to answer whether high BP is better, or as well controlled, if it is adjusted according to home readings rather than clinic readings taken by the GP or practice nurse. In addition the research aimed to answer whether texting home BP readings to the GP surgery results in better control than self-monitoring and posting a paper copy of home BP readings to the surgery.

Findings

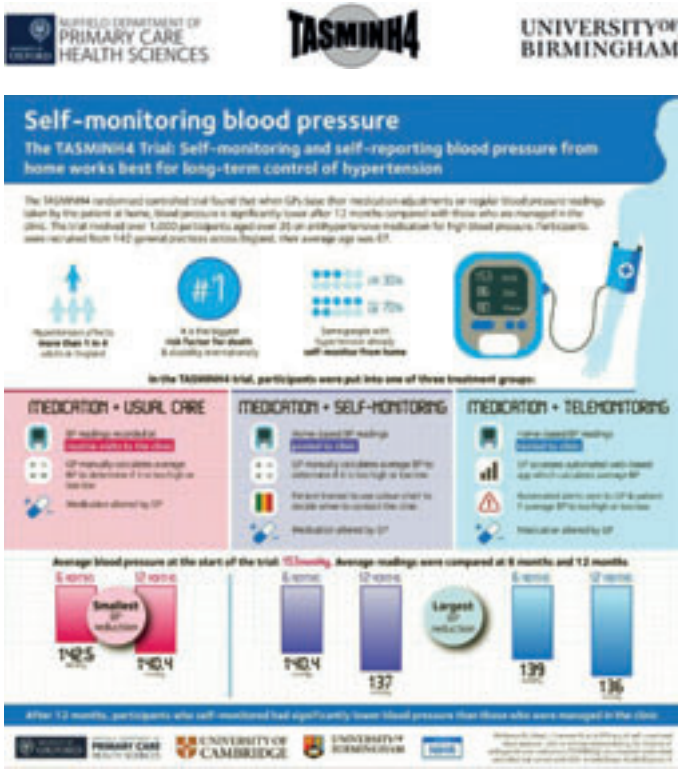
Of 2,383 patients who attended a screening clinic at their GP practice, 1,182 (50%) were eligible to be in the trial. The main reason that patients were ineligible was that their BP was already controlled and not above the target set out in the best practice guidelines. 395 of these patients were randomly assigned to be in the self-monitoring by post group, 393 were randomly assigned to the self-monitoring by text group and 394 were randomly assigned to receive usual care from their GP surgery. All patients participated in the trial for 12 months following group assignment. The TASMINH4 BP trial ran from November 2015 until February 2017.

The average age of patients in the trial was 67 years. The majority of patients did not have a history of heart disease or stroke but 9% had a diagnosis of type 2 diabetes and many patients had another ongoing medical problem. At the start of the trial patients in the self-monitoring by post group had an average BP of 153/85mmHg, patients in the self-monitoring by text group had an average BP of 153/86mmHg and patients in the usual care arm had an average BP of 153/86mmHg.

1,003 patients (85%) overall returned to their GP practice for a final follow-up appointment. The self-monitoring by post group had an average BP of 137/78mmHg, the self-monitoring by text group had an average BP of 136/79mmHg and the group under usual care of their GP practice had an average BP of 140/80mmHg.

Once BP readings were rounded to whole numbers, this was a reduction of 5/1mmHg for the self-monitoring by text group, and a reduction of 4/2mmHg for the self-monitoring by post group when compared to the group receiving usual care. Both are significant reductions when analysed statistically. Although the differences between the self-monitoring by post group and the self-monitoring by text group are minimal (1/1mmHg), the self-monitoring by text group reduced their BP quicker than the self-monitoring by post group and had significantly lower BP at six months than the usual care group.

BP medications increased in all groups. However the self-monitoring by text group had a larger increase in medications which equated to approximately one extra dose per day. The



patients self-monitoring by post had a smaller increase in the number of BP medications than the usual care group, but this was not statistically different. Importantly, additional medications did not cause an increase in side effects or any adverse events for the self-monitoring groups. We believe that the decrease in BP can be mostly explained by the greater amount of medication in the self-monitoring groups, although further analysis is planned. We currently have no evidence of other differences (for instance in exercise, diet or alcohol intake) between the groups.

Overall

In TASMINH4 we have been able to show that when GPs use BP from patients monitoring at home to guide blood pressure care this results in better control than when BP is measured directly by the GP or practice nurse. There is also evidence that patients texting their BP readings to their GP results in the BP being controlled more quickly. Ensuring more effective BP control could significantly reduce the risk of heart attacks and strokes in the future for patients with high BP.

Future work

The main findings from the trial have now been published but further analysis continues to assess other effects and benefits from self-monitoring. We have investigated whether the system of texting BP readings is acceptable to patients, GPs and practice nurses, and the barriers currently stopping it from working in GP practices. This will enable us to develop the system for future use. Work is also being carried out to assess whether self-monitoring would be more cost effective for treating high blood pressure than the current process and further analysis to look at how well the texting system was used are also planned.

References: www.nihr.ac.uk/news/nihr-funded-research-highlights-role-of-home-monitoring-in-reducing-high-blood-pressure/8014

More than 1,200 general practices participate in UK's largest interventional academic drug trial

Five-year study draws to an end after recruiting over 30,000 aspirin users across primary care

A study aiming to reduce the risk of stomach bleeding in aspirin users is believed to be the UK's largest interventional academic drug trial, thanks to its delivery within a primary care setting. The study, known as HEAT, was funded and supported by the National Institute for Health Research (NIHR) and closed last month after recruiting patients over a five year period. Due to the large number of participants that needed to be recruited, the study was delivered with the involvement of 1,260 general practices across the UK.

Professor Chris Hawkey, Chief Investigator of the study at the University of Nottingham explained: "Aspirin use is widespread, especially among the elderly, and there is increasing evidence that it may slow down certain cancers. However, a side effect of long-term use can include ulcer bleeding. We know interventional trials are influential, however if the outcome being investigated occurs infrequently, studies need to be conducted on a large scale. By delivering the study in primary care, we were able to develop methods unique to this setting which not only reduced costs substantially, but also made the study an attractive prospect for practices to participate in."

Study Aims

The study aims to find out whether a short course of antibiotics, which removes a particular type of bacteria in the stomach, can reduce the risk of gastric bleeding in aspirin users. If successful, the study will help to reduce NHS costs and improve health outcomes by reducing hospital admissions and increasing patient safety.

The wide availability of GP electronic records in primary care meant that practices were able to issue more than 185,000 invitation letters to potential participants. The MIQUEST search tool was used to identify potential patients to take part in the study, which saved practices time and ensured consistency as a result of each practice using the same search.

In most instances, several hundred potential patients were identified per practice. Use of the highly secure Docmail postal system ensured that invitations were received within 48 hours of patient identification, whilst maintaining record confidentiality.

After invitation letters were issued, more than 30,000 patients were consented to take part in the study across the UK. Much of this was due to the support of the NIHR, who in addition to supporting study set-up, funded approximately 80 clinical research nurses to recruit patients.

Jen Dumbleton, Clinical Trials Manager for the study, said:

'We didn't incur any nursing recruitment costs, because we were able to use clinical research nurses available through the NIHR. We also used a mixed model of recruitment, which gave us added flexibility. For example, in some regions we used practice nurses and in others we used a combination of nurses and healthcare assistants.'

Once recruited, patients were tested for the presence of the bacteria, known as H. pylori. Health check data such as blood pressure, Body Mass Index, alcohol consumption and smoking status, was also collected and returned to the GP record. This had the added benefit of saving participating practices the time of collecting this data separately.

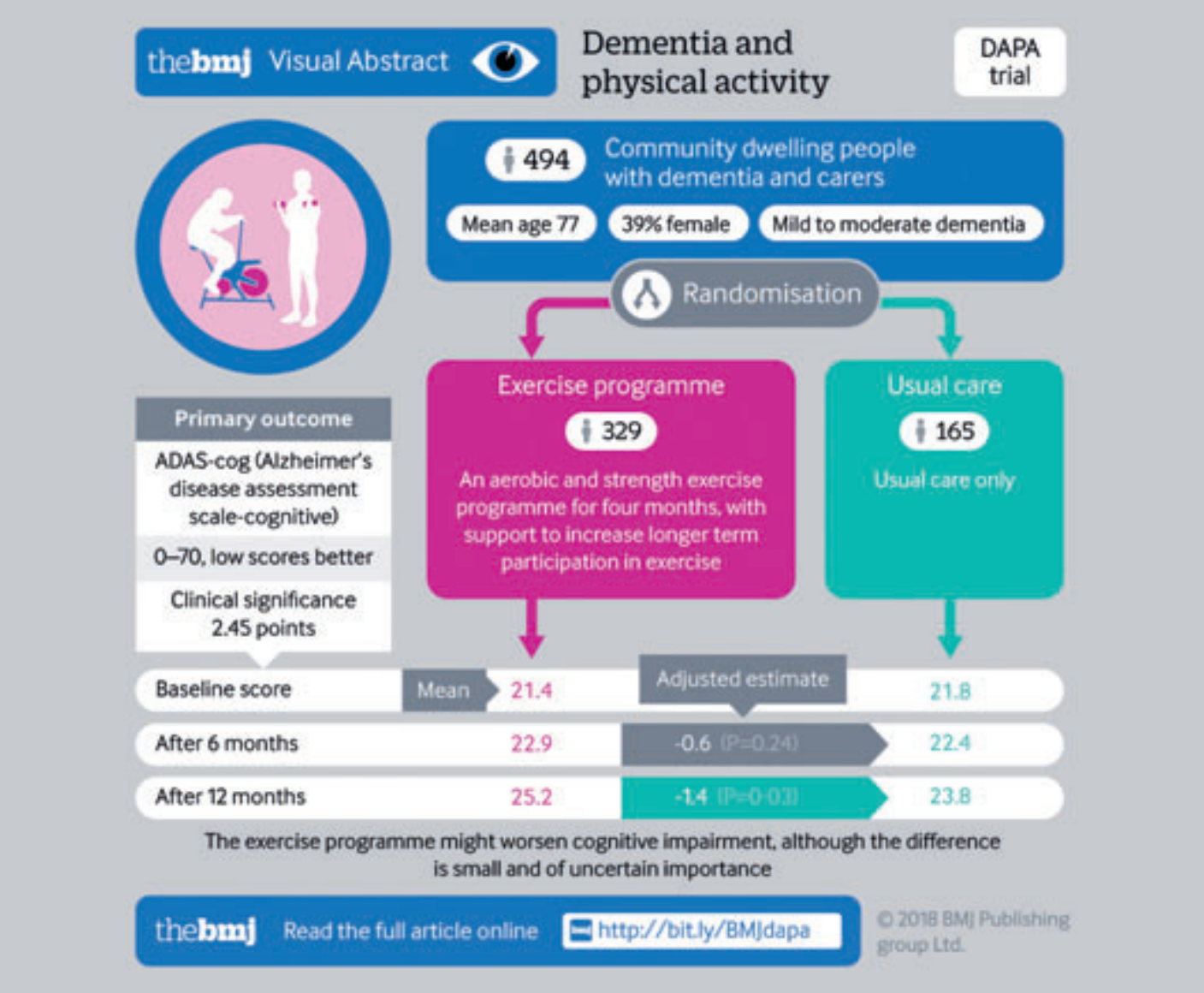
The study team despatched treatment to H. pylori positive participants by post and followed up a week later to check compliance and adverse effects, with practices only required to collect serious adverse event data within four weeks of treatment. This again removed the burden of prescription and study follow up from practices.

Every six months, practices also refreshed the MIQUEST search in order to identify changes in the medical records of patients who had consented to the study. For a large scale trial such as this, staff time is usually the biggest cost. The ability to follow up with participants electronically not only kept costs down, but also meant the data was more reliable.

Phil Evans, GP and NIHR National Specialty Lead for Primary Care, said: "The HEAT study is an excellent example of how you can scale up research within a primary care setting. We know that studies such as this are often carried out in specialist settings, but to deliver one on such a large scale in primary care is unheard of. I hope this achievement will encourage researchers to take advantage of the support provided by the NIHR, as well as highlight the benefits that general practices can reap by taking part in research."

In total, 5,357 patients tested positive for H. pylori. These patients will continue to be followed up, with results of the study expected to be published in 2020.

Study Results



Objective: To estimate the effect of a moderate to high intensity aerobic and strength exercise training programme on cognitive impairment and other outcomes in people with mild to moderate dementia.

Design: Multicentre, pragmatic, investigator masked, randomised controlled trial.

Setting: National Health Service primary care, community and memory services, dementia research registers, and voluntary sector providers in 15 English regions.

Participants: 494 people with dementia: 329 were assigned to an aerobic and strength exercise programme and 165 were assigned to usual care. Random allocation was 2:1 in favour of the exercise arm.

Interventions: Usual care plus four months of supervised exercise and support for ongoing physical activity, or usual care only. Interventions were delivered in community gym facilities and NHS premises.

Main outcome measures: The primary outcome was score on the Alzheimer's disease assessment scale-cognitive subscale (ADAS-cog) at 12 months. Secondary outcomes included activities of daily living, neuropsychiatric symptoms, health related quality of life, and carer quality of life and burden. Physical fitness (including the six minute walk test) was measured in the exercise arm during the intervention.

Results: The average age of participants was 77 (SD 7.9) years and 301/494 (61%) were men. By 12 months the mean ADAS-cog score had increased to 25.2 (SD 12.3) in the exercise arm and 23.8 (SD 10.4) in the usual care arm (adjusted between group difference −1.4, 95% confidence interval −2.6 to −0.2, P=0.03). This indicates greater cognitive impairment in the exercise group, although the average difference is small and clinical relevance uncertain. No differences were found in secondary outcomes or preplanned subgroup analyses by dementia type (Alzheimer's disease or other), severity of cognitive impairment, sex, and mobility. Compliance with exercise was good. Over 65% of participants (214/329) attended more than three quarters of scheduled sessions. Six minute walking distance improved over six weeks (mean change 18.1 m, 95% confidence interval 11.6 m to 24.6 m).

Conclusion: A moderate to high intensity aerobic and strength exercise training programme does not slow cognitive impairment in people with mild to moderate dementia. The exercise training programme improved physical fitness, but there were no noticeable improvements in other clinical outcomes.

Trial registration Current Controlled Trials ISRCTN10416500.

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Fourfold Asthma Study (FAST)

During serious asthma attacks patients may have to be admitted to hospital for treatment including oxygen, nebulised bronchodilators and high dose steroids that can sometimes have adverse side effects.

Three people die from asthma in the UK every day and, according to the National Review of Asthma Deaths, two thirds of these deaths could have been prevented with basic asthma care, which includes patients getting a written asthma action plan from their doctor which, among other advice, outlines the medicine they should use.

The Fourfold Asthma Study (FAST) – published in the *New England Journal of Medicine* – compared two asthma self-management plans in a large trial involving nearly 2,000 patient volunteers in England and Scotland. Around half the patients were randomly assigned to the plan that prescribed a quadrupling of inhaled steroid during periods of worsening asthma and the other half followed the current standard self-care plan over a period of 12 months.

The study showed that the participants in the quadrupling group had a 20% reduction in severe asthma attacks compared with the usual care group and they also had fewer asthma-related hospital admissions as only three patients in the quadrupling group were admitted to hospital compared with 18 in the usual care group.

Professor of Asthma and Respiratory Medicine, Tim Harrison, from the University's School of Medicine, and the NIHR Nottingham Biomedical Research Centre, Nottingham University Hospitals NHS Trust said:

'Our study shows that patients can reduce the risk of a severe asthma attack by following a self-management plan which includes a temporary four-fold increase in their preventer medication when their asthma is deteriorating. This means less need for oral steroids such as prednisolone, less admissions to hospital with severe asthma and hopefully fewer deaths from asthma'.

Long-term asthma patient, Richard Harris, 68, from Stamford, Lincs, who took part in the trial, said:

'The study has made a real difference to my quality of life and my asthma is under much better control as a result. At the completion of the study I continued to follow the quadrupling self-management plan with the agreement of my GP. I could not praise the team at Nottingham highly enough. They manage to combine high levels of professionalism with a friendly approach that makes the patient feel part of the team, with valued opinions and information.'

Dr Samantha Walker, Director of Research and Policy at Asthma UK, and co- author of the study said:

'This ground breaking research could make a real difference to the 5.4 million people in the UK with asthma. This study showed that increasing the steroids in someone's preventer inhaler could prevent them having severe asthma attacks and needing to go to hospital. We'd urge any healthcare professionals who want to increase their patient's asthma medication to fully explain what it means, let them know about potential side effects and include it in their written asthma action plan. People with asthma who would like to increase their medication should talk to their healthcare professional and should not delay getting help or support even if they do have an asthma attack.'

The FAST trial ran in six West Midlands Clinical Commissioning Groups, recruiting 50 patients across 14 GP practices.

The FAST trial was managed by the Nottingham Clinical Trials Unit and funded by National Institute for Health Research (NIHR). Professor Hywel Williams, Director of the NIHR's Health Technology Assessment (HTA) Programme, said:

'We are proud to have funded this original researcher-led study. The research shows that quadrupling inhaled steroids during periods of worsening asthma reduces severe asthma attacks by a substantial amount, resulting in a reduced need for oral steroids and fewer hospital admissions. The study is good news for asthma sufferers all over the world as it shows how patients can better manage their condition and ultimately improve their quality of life.'

The other UK centres involved in the study were Liverpool School of Tropical Medicine and Aintree University Hospital, Leicester NIHR Biomedical Research Centre, Oxford NIHR Respiratory BRC, University of Aberdeen, Southampton Biomedical Research Centre and Newcastle Upon Tyne Hospitals NHS Trust.

For more information about any study, or further information about anything else in Participate, please contact your local research facilitator

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