Clinical Research Network
West Midlands

NHS
National Institute for
Health Research

Spring 2018

Edition No. 3

PARTICIPATE

A very warm welcome to the spring edition of Participate

We are working now as one team across the whole West Midlands, responsible for supporting the delivery of research studies at over 600 primary care research sites (GP practices, pharmacies, physiotherapy clinics) and our aim is to support any primary care research site to be involved in research.

Our links with the Universities of Warwick, Keele and Birmingham result in us having close ties with academics and we also support the development of researchers in these institutions, many of whom go onto run their studies through the Clinical Research Network.

Opportunities in commercial research

Whilst our Portfolio consists mainly of academic studies, we have partnered with commercial companies and are able to offer our research sites opportunities to run commercial (industry) studies. We have a designated team to support this from helping you complete Expressions of Interest forms, to getting trained to deliver these studies. Commercial research is attractive to research sites, predominantly because the financial support tends to be of a greater magnitude.

Working with new care models

Our recent focus has been on developing ways to work more with New Care Models, and we are pleased to be working with a number of GP super-partnerships, federations and Clinical Commissioning Groups (CCGs) to ensure patients have access, and are offered opportunities, to be involved in research relevant to them. As always, we would be delighted to hear from any individuals or organisations interested in delivering research. You are welcome to email Dr David Shukla at david.shukla@nhs.net if you wish to find out more information about our work, or be included in our New Care Model working.

In this edition we feature articles on:

- Getting practices ready to engage in commercial research on pages 9-11
- An update on dementia related research from Join Dementia Research (JDR) on page 3
- CHESS: a multi-centre, randomised controlled trial evaluating an education and self-management support programme for people living with chronic headaches on page 4

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

- Study – I-WOTCH
- Patient Research Ambassador – Adlai Harid
- Spotlight on Commercial Research

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Delivering research to make patients, and the NHS, better

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 across the whole Midlands region 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 100 general practices, community pain/musculoskeletal services and pharmacies across three locations: the Midlands, North East England and Greater London.

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 twelve 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

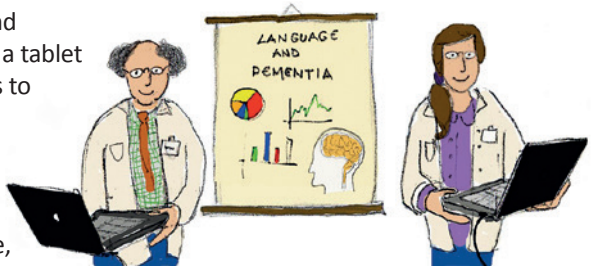
If your GP practice is interested in the study or for more information, please contact your local facilitator, details on page 12.

Language Sensing Study for Dementia Diagnosis and Monitoring

The rate and accuracy of dementia diagnosis varies greatly. According to Arthritis Research UK (ARUK) figures from 2016 only 59% of people currently living with dementia receive a formal diagnosis. Current methods for diagnosis are expensive and intrusive, including brain scans and expensive spinal fluid tests. It is important to seek cost-effective non-invasive methods to support timely and accurate diagnosis.

To assist dementia diagnosis and monitoring, the aim is to use computational methods to create a method for detecting changes in linguistic ability that is cost effective and can be embedded in user-friendly mobile technology in the future.

We propose to develop new approaches for tracking cognitive decline based on the analysis of longitudinal spoken and written language, collected using a tablet application that encourages users to reminisce in speech and writing. We plan to develop automated computational methods for measuring topic transition, syntactic and semantic coherence, emotional fluctuation as well as social interaction based on language data by participants with dementia and healthy controls. We can then use the patterns of change over time as predictors for presence or progression of dementia. A tablet application for recording conversations and written thoughts based on images from the past has already been developed at the University of Warwick, in collaboration with a University spin-out company, Clinvivo. Recruitment of participants with dementia and age matched controls is currently ongoing, with the first two cohorts of participants already taking part in the study.

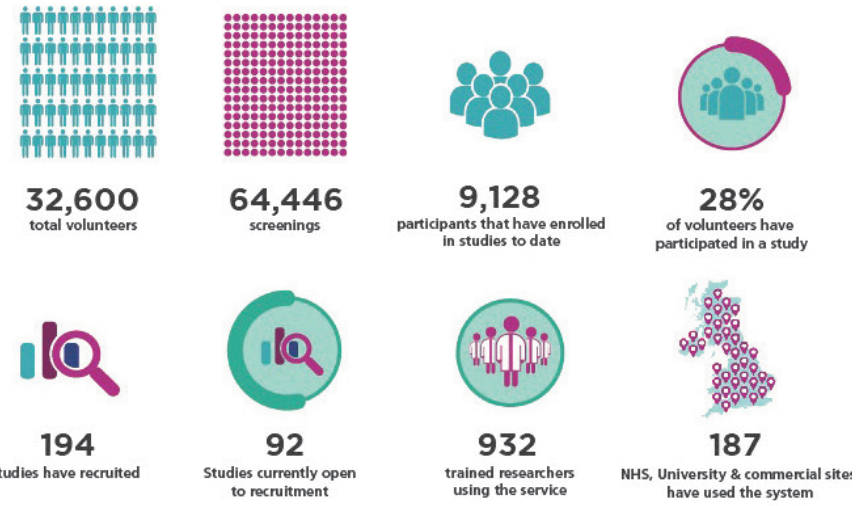


For further information, please contact your local research facilitator, details on page 12.

Are you interested in dementia related research? Would you know of anyone who would like to participate in dementia related research or be made aware of opportunities they may wish to know more about?

Join Dementia Research (JDR) (www.joindementiaresearch.nihr.ac.uk) is a national initiative that forms part of the Governments 2020 Dementia Strategy. The initiative was launched in February 2015 and provides the platform for members of public to register their interest in volunteering to take part in dementia related research. It gives patients and their carers the opportunity to be involved in studies which they may not have been made aware of.

Join Dementia Research in numbers



These statistics are accurate as of 30 January 2018

By signing up to the register, volunteers give their **consent to be contacted** by researchers whose studies have been downloaded onto the system. Volunteers are under no obligation to take part should they not wish to do so. They can choose which studies they wish to know more about.
Anyone over the age of 18 can join. You don't have to have a dementia related diagnosis. Family members, carers and friends are all invited to join.

To join up is simple; it can be done online, via the telephone or by completing a pre-paid, self-addressed paper registration form. The goal is that by 2020, 100.000 volunteers will have signed up to the register.

As at 4 January 2018, 32,600 had signed up, of which 26,616 did not have a diagnosis or known diagnosis, leaving only 5,670 with a diagnosis. As well as increasing this number we are actively looking to encourage those with a diagnosis to consider signing up.

If you are interested in finding out more about Join Dementia Research either to sign up or find out ways of supporting its promotion, please contact the Help desk directly or contact your local research facilitator, details on page 12 or Jackie Smart email: jacqueline.smart@nihr.ac.uk

QUAlity of life, Sleep and rheumatoid ARthritis: QUASAR

The quality of life, sleep and rheumatoid arthritis, or QUASAR, has been designed by Dr John McBeth of the University of Manchester to investigate the relationships between sleep and quality of life and asks participants to wear a sleep monitor 24 hours a day for 30 days, while using a smartphone app to record daily symptoms.

Talking about the importance of the study, Dr McBeth explains:

"There's evidence that people with rheumatoid arthritis (RA) report high levels of sleep disturbance and we don't yet know why that is. What we do know is that research suggests that disturbed sleep is linked to poor health related quality of life. By focusing on the interaction between how people sleep and factors that affect our everyday lives, for example levels of pain and fatigue and our mood, it is hoped that the results of the QUASAR study will enable us to develop new, or better target existing, sleep interventions to ultimately improve the quality of life of those with rheumatoid arthritis who experience sleep disturbance."

Who is eligible?

- ≥18 years
- Diagnosis of RA and use of DMARDs
- Access to an Apple/Android smartphone/tablet
- No shift work

Primary care support

QUASAR is open to new PIC sites who will be responsible for displaying posters. We would also like to chat to practices with the ability to screen GP databases to assist in the mailout of GP letters.

For further information, please contact your local research facilitator, details on page 12.

CHESS
Chronic Headache Education and Self-management Study

Chronic Headache Education and Self-management Study

Chronic headache, a headache occurring on 15 or more days a month for at least three months, is a problem affecting around 1 in 30 of the population. The CHESS study is a multi-centre, randomised controlled trial evaluating an education and self-management support programme for people living with chronic headaches, led by Professor Martin Underwood at the Clinical Trials Unit, University of Warwick.

What is involved for participants?

- A telephone classification interview with a CHESS study nurse to classify their headache type
- Written information and advice about their headache type provided to each participant and their GP
- Complete a smartphone diary app for 12 months which collects details of headache frequency, duration and severity
- Each participant is randomised to receive either
  A) Control = Continue usual GP care plus receive a relaxation CD
  B) Intervention = Attend an education and self-management programme
  (Includes a two day education and self-management group, a one to one appointment with study nurse and up to eight weeks telephone support)

What is involved for GP practices?

- Search of practice population to identify eligible patients, and screen list for exclusions
- Receive written information about individual participant headache classification type
- Access to consented participant records for review of headache related consultations and medication at 12 months

If your practice is interested in taking part in the study or you would like any further information regarding CHESS please contact your local research facilitator, details on page 12 or Kimberley White CHESS Trial Coordinator: chess@warwick.ac.uk Tel: 02476 151 634

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.

WARWICK CLINICAL TRIALS UNIT

Funded by NIHR

ATTACK

Aspirin To Target Arterial Events In Chronic Kidney Disease

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 mid-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

OPtimising Treatment for MIld Systolic hypertension in the Elderly (OPTiMISE)

OPTiMISE

Background

Evidence suggests that large reductions in blood pressure, and too many drug prescriptions may be associated with an increase in serious falls and death in the elderly.

Assessing the safety of reducing medication in older patients (≥80 years) with controlled systolic blood pressure (<150 mmHg), who are receiving ≥2 antihypertensive medications. Systolic blood pressure control at three month follow-up will be compared between those randomly allocated to either removal of one blood pressure medication or usual care.

Participants will have the following visits

1. Consent visit and baseline visit for all participants
2. four week safety visit for those randomised to medication reduction
3. 12 week follow up for all participants

'It has been one of the more well supported studies that I have been involved with and certainly one of the more interesting.'

A quote from one GP involved in the study

Recruitment

Currently recruiting practices and looking to complete participant recruitment by August 2018.

*Due to the short follow up and strong support from the CRN and trial team for this study, it would be a great first CTIMP trial for any GP looking to get more involved in research! *

For more information, please contact your local facilitator, details on page 12. https://www.phctrials.ox.ac.uk/studies/optimise

RISE
RETURN TO WORK WITH INDIVIDUALISED SUPPORTED EMPLOYMENT

We are currently seeking the support of GPs in Birmingham and Solihull areas to put up a self-referral poster about our study.

RISE is a feasibility study, in which we are looking to help people with chronic pain who are unemployed to get back to work. We are offering eligible participants an unpaid six week placement for up to 16 hours per week in which they can work to overcome obstacles to returning to work. Participants will have the support of a case manager. Participants will attend a short work preparation course to help them tackle obstacles they may be facing. Participants will complete questionnaires at baseline, six weeks, 14 weeks and six months after the placement. Some of the participants will be invited to be interviewed or attend a focus group at the end of their participation in the study.

The poster is available on request. Interested people are asked to contact the RISE study for further information, by telephone or email.

We are currently recruiting participants from Heart of England NHS Foundation Trust, University Hospitals Coventry and Warwickshire NHS Trust, South Warwickshire NHS Foundation Trust and the Job Shop in Coventry. We have placements with Serco Group plc, University Hospitals Birmingham NHS Foundation Trust and Coventry City Council.

We aim to recruit 30 participants in total to the study before the end of May 2018.

For more information, please contact Joanne O'Beirne-Elliman, RISE study on 02476 151 622 or RISE@warwick.ac.uk or contact your local research facilitator, details on page 12

TAPS: Treatment of Aches and PainS Trial

TAPS

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 (and back pain).
- Practices will be randomised to deliver one of two approaches for patients presenting with musculo-skeletal 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

If you are interested in finding out more, please contact your local research facilitator, details on page 12 or the TAPS Trial Manager Stephanie Tooth phone: 01782 734835 email: s.j.tooth@keele.ac.uk

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.

Arthritis Research UK | primary care centre | Keele University

Alternatives to Face-to-Face GP Consultations Unlikely to Deliver Hoped-for Benefits in Practice

The realities of implementing alternatives to face-to-face GP consultations, such as telephone, email, online and video consultations, mean that hoped-for reductions in GP workload and increases in available appointments for patients might not be realised, an NIHR-funded study has found.

This is the finding of research by led by researchers at the University of Bristol, published in the British Journal of General Practice.

NHS policy encourages general practices to introduce alternatives to face-to-face consultations as a way of increasing access to healthcare and reducing GP workload. However, the evidence on their use and effectiveness is limited.

The researchers studied, in depth, how a variety of technological alternatives to GP consultations were being used in eight general practices of different sizes, in different geographical areas – some urban, some rural – and in different areas of socioeconomic deprivation in the UK. They found that although there were some potential benefits, there were also significant barriers to implementation, with practices often responding to incentives to introduce new technologies without a clear rationale or clearly thinking through the likely costs and benefits for patients and practice staff.

There was also insufficient training of non-clinical staff, such as nurses and receptionists, on how to use the technologies appropriately and communicate the benefits to patients.

Professor Chris Salisbury from the University of Bristol's Centre for Academic Primary Care said:

"Technological alternatives to face-to-face GP consultations are being pushed as the solution to reducing GP workloads and increasing patient access to primary care services. The reality on the ground is that implementation is difficult. Practices are introducing the technologies for different reasons and a 'one size fits all' approach will not work.

"Our study shows that, currently, GP practices are struggling to identify and implement the most beneficial uses of these new technologies and they are frequently being adopted without sufficient understanding or support.

"In particular, we identified a tension between the desire to make access to health care easier and more convenient, while at the same time aiming to reduce GP workload. We found that new ways of accessing health care advice may well increase rather than decrease GP workload."

The research was a collaboration between the Universities of Bristol, Warwick, Oxford, Edinburgh and Exeter.

Dr Helen Atherton, from the University of Warwick and lead author of the study, said:

"Our findings suggest that policy-driven top-down approaches that use financial incentives as a way of encouraging adoption of alternative consultation methods is not the best way forward if efficiencies are to be made. Instead, individual practices should take a considered and tailored approach, based on the needs of their practice population, and available resource, so that there is equitable delivery of care."

More information on the study is available on the NIHR Journals Library.

News from our Practices

ACHIEVEMENTS OVER AND ABOVE

Promoting Research

Many thanks to:

- Forum Health Centre for hosting the joint Coventry/Rugby/North Warwickshire annual research symposium.
- Forrest Medical Centre for their continued participation in clinical research and providing clinical system support for studies.
- Broad Street Surgery for their support in early feasibility work.

Returning to Research

Alton Street Surgery have made a successful return to research activity with the Hospital Discharge Study, to which they recruited well. We look forward to working with them on more studies soon.

Study Specific

ARCHIE:

- Spring Gardens Medical Group recruited the first ARCHIE patient in West Midlands.
- The Marches in Leominster recruited their first ARCHIE patient yesterday having only been open to recruitment for a week.

DISCHARGE COMMUNICATION STUDY:

- Bennfield Surgery was the first of our practices to sign up and recruited the first patient. Westside Medical Centre and the Revel Surgery both engaged fully with this study.

DECIDE:

- Northumberland House Surgery and Meon Medical Centre both recruited well.

IFEED:

Our thanks go to the following four practices who helped with searches:

- Atherstone Surgery
- Bedworth Health Centre - Dr Singhs
- Grange Medical Centre
- Manor Court Surgery

Our Top Recruiters:

COVENTRY:

- Phoenix Family Care - Heat
- Forrest Medical Centre - All Heart
- Sky Blue Medical Group - Candid
- Park Leys Medical Practice - Fast Gout

RUGBY:

- Westside - All Heart
- Bennfield - Fast Gout, Heat & Candid

NORTH WARWICKSHIRE:

- Atherstone Surgery - Candid
- Bedworth Health Centre - Dr Singhs - All Heart
- Hazelwood Group Practice - Fast Gout

GPs' Views Regarding Referral: a Qualitative interview study with GPs

It is sometimes hard for a GP to work out what is going on for a patient with bowel symptoms. Irritable bowel syndrome and inflammatory bowel disease can seem to be quite similar.

The majority of GPs in the West Midlands south area have faecal calprotectin testing available in their toolkit when considering investigations of suspected inflammatory bowel syndrome. The stool test was approved by NICE in 2013 for use in adult patients in primary care with the vision to reduce referrals to gastroenterology of patients who can be managed in primary care.

As part of a wider study undertaken at Warwick Medical School which investigates the role of faecal calprotectin testing in primary care, the present study aimed to explore GPs' views and experiences related to referral of patients with suspected inflammatory bowel disease or irritable bowel syndrome. We wanted to:

- understand reasons for referral and influences on the referral decision
- explore uncertainties at the time of making a referral decision and
- identify consequences of referral for both the GP and their patients from the GPs' perspective.

The information from the interviews will help in understanding the referral decision process and in highlighting the role of the faecal calprotectin test in referral decisions.

With the support of the CRN West Midlands we were able to recruit 19 GPs from across seven CCGs.

The interviews took place at the GPs' practices and lasted for about an hour. A range of perspectives were collected by recruiting GPs with varying level of experience with faecal calprotectin testing and from practices with different demographics and geographic locations. We have gained a lot of insight by talking to the GPs and we would like to thank all participating GPs for their time and contributions to this study. Analysis is now underway and we look forward to reporting our results later in the year.

This report is independent research supported by the National Institute for Health Research (NIHR Doctoral Research Fellowship, Mrs Karoline Freeman, DRF-2016-09-038). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

Dr Rachel Spencer

I am a First 5 academic GP with a part-time salaried role at Park Leys Medical Practice in Coventry. We have become a research active practice again after a long break and I am our practice research lead. I wanted to take up this First 5 champion role to help other young GPs (who may well not be partners) to engage their practices in research activity, and also, to promote research as an attractive portfolio career option (which it has certainly been for me). I am nearing completion of a PhD in Primary Care at the University of Nottingham and hope to take up an academic post in the West Midlands in the near future. My research interest is in all aspects of patient safety in primary care. I helped to design a package of prescribing indicators for GP revalidation for the RCGP and worked on the multi-centre NIHR patient safety toolkit (PSTK) project for general practices which was adopted by the RCGP. My doctoral work focuses on clinical and administrative error in general practice in relation to discharge summaries, this study was part of the local CRN portfolio last year. When I am not looking after my wonderful three year old twins I am a keen amateur musician playing the cello, piano and singing with a community choir.

drrachelspencer@gmail.com

Congratulations to Dr Claire Jones

Citation: *"Qualifying from St George's, Dr Jones is a GP in Worcester, and a GP Champion for Research for NIHR. She provides medical cover for Acorns Children's Hospice, is a mentor, teaches medical students and passionately attracts students for work experience, so helping to enthuse our doctors of the future."*

Dr Jones says: *"After 22 years as a GP, it was a wonderful privilege to be awarded Fellowship of the Royal College of General Practitioners. The presentation was on 17 November 2017 in the beautiful surroundings of the RCGP college in Euston Square, London."*

We were enthused and entertained with a brilliant lecture by Prof John Campbell who referred to the ESTEEM trial amongst other studies he has led.

James Mackenzie Lecture by Prof. John Campbell FRCGP, University of Exeter Medical School: *Patients' experience of primary care – a shot in the dark, or a shot in the arm for the NHS?*

My parents enjoyed celebrating with me, I had convinced them that RCGP Fellowship was at least equivalent to an OBE.

Thank you to NIHR colleagues who supported me in this.

John's Story

I am a 59 year old man who has had Ankylosing Spondylitis from my early twenties and as a result, I was well aware of the risk of taking anti-inflammatory drugs which could cause issues with my stomach and kidneys.

Over the years the numerous blood tests would monitor my kidney function, amongst other things. Nearly three years ago my GP contacted me and asked if I would like to participate in the Barack D trial https://www.phc.ox.ac.uk/phctrials/trial-portfolio/barack-d which was to study people with Chronic Kidney Disease (CKD).

Shock horror, I didn't even know I had CKD! But the good news was after speaking to the GP, it wasn't that serious.

I received a fairly comprehensive information pack of what the trail was monitoring. Did I read it all? Probably not.

The study required me to have regular blood tests, blood pressure readings taken and using a supplied monitor, I would have to take my own readings twice daily for a week every few months whilst taking the drug Spiroactilane. The amount of time this takes is reasonable, requiring me to attend the GP surgery every three months to test and complete questionnaires.

The benefit I saw in this was additional professionals were looking more closely at my health - no brainer, let's do it!

The effectiveness of the monitoring was shown very early in the study when it was seen that the drug was actually worsening my kidney function. I was asked to stop taking the drug but would I continue the monitoring, which I was more than happy to do.

Around a year later the results were such that my GP sent me to a Consultant who I also see every six months although he is happy with the progress of the disease.

'John', Autumn 2017

BARACK-D

Adlai Harid: Patient Research Ambassador

My name is Adlai Harid and I recently joined the Patient Research Ambassador (PRAI) initiative which I'm very excited to be a part of.

Briefly, I was born in Zimbabwe and I have been resident in the UK for the last 15 years. Since then I have graduated with a Criminology and Law degree from Coventry University and currently pursuing a Masters Program.

As an ideology I believe that the best gift you can ever give to your community is the ability to help others alleviate pressing issues and it is a privilege to be part of the PRA. Therefore, it is my passion to look at deprived areas of our society and how to effectively bring patients to participate and trust our Patient Research initiative.

I look forward to meeting you all and hopefully share more ideas in detail and take this opportunity to wish everyone a successful year in all your endeavours. Lastly, thank you to Eleanor Hoverd for her hard work and introducing me to the PRA role.

ARCHIE: The early use of Antibiotics in 'at Risk' Children with InfluEnza

Eva's Story

ARCHIE

I went to the Doctors with a really bad cough and because of our family history, we wanted to get it checked out. I have a condition that affects my breathing called asthma. A few years ago, my sister became really ill with a chest infection. She was rushed into hospital and had to go into intensive care. When I visited her, she was covered in tubes and asleep. A machine was breathing for her while the doctors tried to work out what was wrong. This got me interested in bio-medical science, because I knew when my sister was ill, people in a laboratory were trying to work out why she was sick.

I want to be a bio-medical scientist, because I'd like to help people all around the world with conditions like my sister, or different, and help to work out what's wrong with them. So when the Doctor asked if I would like to be part of the ARCHIE study, I was really interested and immediately said yes. The ARCHIE study is a piece of research trying to work out if giving early anti-biotics would reduce the chance of people like me, with conditions like asthma, getting a more serious infection.

The next day, a nurse came to my house and explained the study. She gave me a nose and throat swab. At first I didn't like the sound of the throat swab, but when she did it, it just felt like a little tickle. Then I had to take banana medicine for a week, which could have been real or fake... we didn't know. It was a randomised test, which I thought was really cool. Then I had to take my temperature every day for a month. I would definitely recommend being part of a medical study like ARCHIE because it changed my illness into a positive and it's nice to think it might help other children in the future like me and my sister. Hopefully one day, I'll be the one in the laboratory analysing the results under a microscope.

Thank you ARCHIE study!

The Myths of Commercial Research

By Sinead Collinge, Industry Operations Manager, Clinical Research Network West Midlands
sinead.collinge@nihr.ac.uk

In this article, I am going to address some of the most commonly asked questions about commercial research in the NHS.

What is 'Commercial Research'?

This is the term used to describe medical research sponsored and funded by for-profit organisations such as pharmaceutical, medical device and technology companies. These organisations are private companies that can design, collaborate and fund research to be delivered in the NHS.

If it's 'for profit', aren't patients just guinea pigs being used to make companies more money?

No, in the NHS this really isn't the case. Any NHS patient who gets involved in medical research, is a volunteer - they are never entered into any NHS research - commercial or non-commercial, without knowing and providing informed consent, so the term 'guinea pig' isn't helpful. The aim of the research, what the research will involve and any associated risks and benefits are fully discussed with the patient, prior to their involvement and they are able to withdraw from the research at any point, without their care being affected. Most clinical trials undertaken within the NHS are Phase II or later phase, where the aim is to see if the desired outcome is obtained over larger numbers of people. Some UK hospitals do have the capabilities to deliver early Phase I research. Patients are informed of all risks, their medical history is fully considered, and they are extremely closely monitored throughout the study. All research delivered in the NHS is reviewed by an independent national Ethics committee and ensures the research is of sound value and will not endanger patients. Each study is also reviewed by each hospital to ensure it can be safely delivered and patients cared for. Patients are not paid to be involved in NHS research, even if it is commercial, so there is no expectation from that side of things.

But don't the companies make money from it?

The fact of the matter is that commercial companies do make money from selling new drugs and devices; however they are only able to sell them if there is a need. The NHS will not buy new products that it doesn't need - they have to be approved by the National Institute for Health & Care Excellence and be able to prove they can improve patient care and outcomes. A commercial company will be doing research to prove there is a need for their product, and that the product is effective. Importantly, commercial companies will also do studies that can prove their medications or products are not effective and therefore will no longer pursue their development. This information is published and this will also prevent anyone duplicating that research. The commercial company will pay the NHS to deliver research, the funds will cover the activities performed by the NHS for the research and provide some capacity building so the Trust Research department can grow and further its own research capacity.

Are the doctors paid to do the research?

There is no personal payment to the doctors who deliver the research - so there is no conflict of interest. Doctors will only take on research that they truly believe will benefit current and/or future patients. There are also collaboration opportunities between commercial sponsors and doctors - where the doctors on the front line who know the clinical issues, can work with commercial sponsors to try and solve these issues.

Myths such as these can compromise the progress of medical research which is essential to advance the medical care we receive as NHS patients. Commercial research can provide patients the opportunity to access new treatments, and also provide a source of income for a Trust to be able to develop and expand its own research. Without the support and input from commercial sponsors we would not be able conduct the research we do and advance and improve patient care.

Commercial Research in Primary Care

By Raj Gill, Industry Manager (Primary Care), Clinical Research Network West Midlands
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This time last year the Primary Care Specialty nationally reached a fantastic milestone of recruiting the one millionth patient to clinical research. This milestone demonstrates how committed we are to giving our patients access to research and new treatments and innovations in healthcare.

Our vision for the future is to support general practices to continue their engagement in research amidst all of the changes in the NHS landscape. One way to continue this is to explore working with commercial research partners in order to give patients access to a wider range of research, access to cutting edge treatments, investment into practices wanting to expand their research capacity and drive economic growth for the UK. Supporting the life sciences industry is one of the National Institute for Health Research's high-level objectives and there is certainly an untapped potential within primary care.

How Does Commercial Research Work in NIHR Clinical Research Network (CRN)?

- All commercial studies promoted through the NIHR CRN are NIHR portfolio adopted, ethically approved, and undergo Health Research Authority approval as with any other study you may take part in
- Commercial studies in primary care can be observational or interventional. Interventional studies compare a new or different type of treatment with the best treatment currently available. Observational studies simply observe and collect data on participants within a particular condition to learn more about how their condition. Data is usually collected via questionnaires or interviews
- The studies within primary care are generally later stage phase III or IV trials testing new treatments for marketing authorisation purposes or to learn more about the long term effects of currently marketed medical products
- All research activity undertaken by the practice is reimbursed by the commercial company via an approved NIHR Industry Costing template. This includes salary costs, additional overhead costs and 20% capacity building element which can be reinvested back into the practice to generate further research capacity
- Our CRN GP steering group reviews all commercial studies to ensure they are suitable to run in primary care

Why Primary Care?

Commercial Research has been conducted in the CRN West Midlands for a number of years with 86% of our Trusts and a few practices engaging in commercial studies. Primary care accounts for over 90% of patients' first interaction with the NHS and holds a rich source of data in the form of medical records for registered patients. Also, with the changing NHS landscape, primary care is delivering more services than ever meaning that commercial companies can look to this setting to identify patients for their studies, especially those with long-term chronic conditions. The new models of care emerging provide even more opportunities to deliver commercial studies within the primary care context, taking advantage of the larger patient population and specialisms within the clinical teams. With income for general practice declining each year and costs of running a practice on the rise, commercial research can be one way of securing an alternative income stream.

Current Commercial Research Activity in the West Midlands

In 2017, the CRN appointed an Industry Manager for Primary Care to increase commercial research activity across the West Midlands. There has been a significant increase in the number of expressions of interest submitted by practices across the region, especially due to a lot of 'new' practices undergoing training provided by CRN. We are currently seeing a number of our 'new' commercial research practices being selected for commercial studies in areas such as Dermatology, Diabetes and Osteoporosis. A number of our practices have also excelled in recruiting to studies on time and to target which not only enables implementation of the scientific findings into clinical care quicker but also ensures that the reputation of the practice is upheld, which will ensure repeat business with commercial companies in the future.

The DECIDE study is a commercially sponsored study so your practice may already be involved in commercial research!

What does Commercial Research Entail for the Practice?

Practices wanting to deliver commercial research will act as research sites meaning that they take on the delivery of the study using their own practice staff.

Working in this way does require a cultural shift in the practice's approach to research. It is advised that practices wanting to deliver commercial research develop a 'research team' at the practice including representation from each staff

group i.e. GP, practice nurse, administrator and practice manager. Forming this research team facilitates better communication, enables quick assessment of studies to determine interest and ensures efficient set up and delivery of commercial studies. Utilising practice nurses / HCAs / medical associates enables the wider practice to develop professionally through research as well as reducing burden on the GPs.

"With the support of the Network's Industry Manager we were able to secure a commercial study and were assisted with set up at the practice which enabled us to deliver the study efficiently and successfully recruit to the study on time and to target. We shared the delivery of the study with a core research team at the practice including our practice manager to facilitate contract and costings negotiation, two GPs receiving informed consent, our practice nurse to deliver the intervention and a member of our admin team to support the data entry requirements. This enabled us to deliver commercial research in the context of a busy general practice."

Feedback on commercial research by a GP in Dudley

How does a Practice get Involved in a Commercial Research Study?

Applying to take part in a commercial study requires practices to follow a nationally defined process and is different in the way in which practices may apply to take part in academic studies.

As commercial studies are promoted to the CRN at a national level and studies may be in the funding/application stage, the companies want to be able to assess quickly how many sites they can find in the UK to deliver their study with the required number of patients needed per site. To express interest in these studies requires practices to complete Site Identification forms which demonstrate to the study teams how they can reach the criteria specified. These forms are then sent to the commercial company to assess which sites they want to progress with. Competition is high for commercial studies as they are often looking for a small number of sites across the UK and companies can receive a huge number of applications from interested sites. The key to securing a commercial study is providing an accurate and high quality Site Identification form, demonstrating previous clinical research experience and being available to liaise with the commercial company when they make contact.

How can the Network Support you?

The Industry Manager is available to support practices with engaging in commercial research. This includes:

- Providing training on how to complete high quality expressions of interest
- Support the practice to set up commercial studies at the practice including target setting, contract reviews, and cost negotiations
- Attendance at all study set up visits
- Oversee and review patient recruitment
- Escalate any issues with delivering the study at local or national level for support and to share best practice
- Capture lessons learnt at study closure

"We had applied for a number of industry studies but recently had received no interest. It was frustrating and time consuming filling in the lengthy forms with no results. We were shown how to complete more effectively adding considerably more information and 'selling ourselves'.

I am delighted to say we have received a call this week checking out our continued interest and an agreement is to be sent out. Thank you…"

Feedback on the Commercial Research Training by a GP in Worcester

Not Ready to Deliver Commercial Studies yet?

Have you considered acting as Participant Identification Centre (PIC)?

Practices can refer potentially suitable patients to commercial trials taking place in local practices or hospitals through the use of postal invites, posters or opportunistically in consultation. This enables your patients to access commercial studies taking place locally but also allows practices to experience commercial research with less commitment. If you would be interested in this please let your local Research Facilitator know.

Interested to hear more about Commercial Research?

If you would be interested in engaging with commercial research and learning more about how to make it work within your practice, please contact:

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Primrose

Prediciton and management of cardiovascular risk for people with severe mental illnesses

Findings from a cluster randomised controlled trial in primary care.

A study led by Professor David Osborn in the University College London (UCL) Division of Psychiatry has been published in the Lancet Psychiatry. The study developed a new intervention to reduce cardiovascular disease risk factors for people with severe mental illnesses (SMI), and tested this new intervention against routine General Practice care.

People with SMI, such as schizophrenia, bipolar disorder, or psychosis, have a well-established increased risk of morbidity and mortality from cardiovascular disease. Although the study found similar cardiovascular outcomes in both the Primrose intervention group and routine care, the new intervention was associated with fewer psychiatric admissions and therefore lower costs.

The study was funded by a National Institute for Health Research Programme Grant for Applied Research (NIHR PGfAR) and included researchers from the University College London, University of Southampton, Kings College London, Imperial College London, Camden and Islington NHS Foundation Trust and The McPin Foundation.

Researchers ran a cluster randomised controlled trial with 327 participants across 76 general practices in England recruited through the Clinical Research Networks (CRNs). The participants, aged 30–75 years old, had SMI, raised cholesterol and one or more modifiable cardiovascular disease risk factors. 38 general practices, including 155 patients, were randomly assigned to the Primrose intervention and 38 general practices, including 172 patients were randomised to routine care.

In the West Midlands, 18/76 GP practices and 56/326 patients were recruited.

Participants receiving the Primrose intervention had up to 12 appointments over six months from a trained primary care professional. They received manualised interventions for cardiovascular disease prevention, including adhering to statins; improving diet; increasing physical activity; quitting smoking; or reducing alcohol. The participants allocated to routine care received feedback on screening results and usual care from their GP practice.

Researchers found that total cholesterol concentration at 12 months went down in both the intervention and routine care groups and did not differ between the two groups. This could be due to good care in the treatment as usual group; short duration of the intervention; or low prescribing rates of statins. They also found a reduction in psychiatric hospital admissions and lower service costs in the Primrose group. However, they cannot conclude that the primary care intervention is more effective than routine care in reducing cardiovascular disease risk.

People with SMI are still experiencing an increased risk of morbidity and mortality from cardiovascular disease compared to the general population, so there is a vital need to continue to find and offer effective treatments to this group of people.

For further information please see visite: www.ucl.ac.uk/primrose or follow Primrose on Twitter: @UCLPrimrose

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

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