

PARTICIPATE

Merger of CCGs – what difference will it make for Primary Care research?



The NHS Long Term Plan set out the direction of travel for the NHS over the next decade with a range of implications for Primary Care research. Among them was the move towards more collaborative working between CCGs, and for Integrated Care Systems (ICSs) to cover England by April 2021. Importantly, the plan anticipated that there would be typically one CCG per ICS. This accelerated impetus towards CCGs working more strategically, at a larger scale. Across the West Midlands, the last year has seen CCGs merging and others sharing working arrangements (such as joint Accountable Officers) in preparation for merger by 2021.

What are the implications for Primary Care research?

Commissioning at a larger scale should allow advantages for the NHS and for patients. Working at a larger geography, covering populations of over one million, means CCGs are more able to drive collaboration between partner organisations, including health providers and local government to join up care and transform health, so creating opportunities for research across traditional interfaces. It should allow CCGs to more strategically plan for, and intervene in, long-term health conditions, to target groups with common characteristics and to address inequalities. Primary Care research should play an important part in generating evidence that supports more effective care and outcomes, responding to gaps in knowledge through designing and delivering research focused around the commissioning priorities and needs of local populations.

Inevitably, there is a risk of disruption to Primary Care research as new CCG arrangements come into place. The CRN Primary Care team will continue to work to ensure that such risks are minimised, that the merged CCGs are fully engaged with the importance of such research and are on board with getting systems running to ensure that the day-to-day delivery of Primary Care research continues to run smoothly.

We are looking forward to opportunities to work with the merged CCGs to innovate and develop new approaches to driving the development and delivery of research across more integrated healthcare system.

In this edition we feature articles on:

- Increasing physical activity in older people with joint pain (iPOPP), see page two
- Colour COPD, sputum colour charts to guide antibiotic self-treatment of acute exacerbation of COPD, see page four
- The impact of Giant Cell Arteritis on patients' lives, see page 13

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

- Study – Colour COPD
- Study – ERICA, Electronic Risk Assessment for Cancer
- Study Results – Rococo

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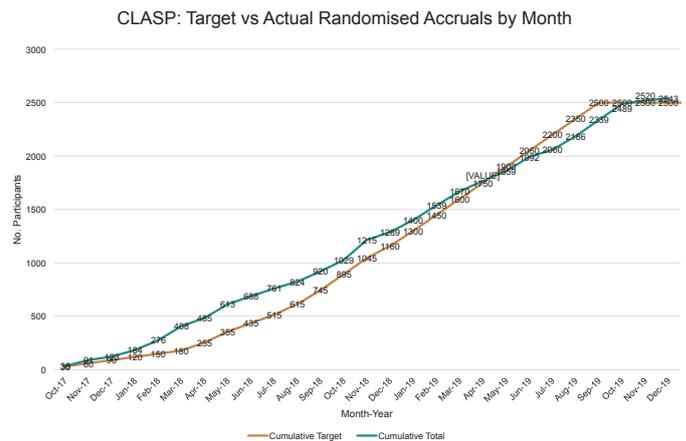
Cancer: Life Affirming Survivorship Support in Primary Care

RENEWED Online Study



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 study aim is to evaluate an internet-based intervention (Renewed) to help support lifestyle changes and improve psychological wellbeing for breast, colon and prostate cancer survivors to improve quality of life. The RENEWED online intervention provides patients who have finished primary treatment for breast, colorectal or prostate cancer with self-management support for a healthy lifestyle and improved mood. This may lead to an improvement in their quality of life and prevention of cancer recurrence, with the primary outcome looking at whether using the web-based Renewed programme results in a difference in quality of life at six-month follow-up compared to treatment as usual. The long-term aim is for the intervention to potentially help cancer survivors with other forms of cancer.

We have now **completed recruitment**, exceeding the original target of 2,500 participants. This has taken nearly 500 practices across England, Wales and Scotland with over 50,000 Docmail letters sent out. **Thank you for your support and contribution to reaching this target.**



Notes reviews now need to please be completed for all participants in the study for the 12-month period following randomisation. We are in the process of sending each practice a list of participants requiring notes review. These are completed online via an iSurvey link (you can request a paper copy of the form if preferred). Notes reviews are just for the 12 months post study entry period. Practices will be reimbursed £20 per notes review for their time.



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

Increasing Physical activity in Older People with joint Pain (iPOPP)

Study background

Physical activity levels in older people with chronic musculoskeletal pain are low. Lower activity levels are associated with increased pain and disability. Walking is a straightforward way of increasing physical activity, which is accessible, inexpensive and low impact.

iPOPP is a three-arm randomised controlled trial which aims to test whether a brief behavioural intervention increases average step count compared to usual primary care or receiving a pedometer and activity diary in the post in adults aged 65 years and over with chronic musculoskeletal pain.

We are looking for approximately 57 practices to take part in the study. We need a practice population size of 400,000 within the West Midlands in order to recruit a total of 1,085 patients. Each practice will provide approximately 20 participants.

If your practice is interested in taking part, or for information, please contact Lucy Andrew, CRN Research Facilitator, details on back page, or Kate Fisher iPOPP Trial Manager on **01782 734882** or k.i.fisher@keele.ac.uk.

What will be asked of practices?



- Allow access to CRN staff to conduct a practice list search for potentially eligible patients
- GP to screen patient list for ineligible patients, CRN to complete Docmail invites for suitable patients
- Provide clinic time and space for a Health Care Assistant to deliver the walking intervention to patients (n=6, based on a list size of 7,000), which includes 2 x 30 minute appointments, the latter of which may be a telephone consultation

If you are signed up to the CRN Research Sites Initiative Scheme, this study will be paid at Grade One, £300.

What are the benefits of participating?

For patients this trial offers the opportunity to:

- get involved in research and potentially receive a programme of support to increase physical activity levels

For practices this trial offers the opportunity to:

- give their patients the chance to be involved in research
- participate in research which can be reported as part of appraisal and revalidation

The IMPPP study - Improving Medicines use in People with Polypharmacy in Primary Care



IMPPP is a large randomised clinical trial looking at how practice pharmacists and GPs, with the help of a new computer tool, can work together to improve the use of medicines in patients who are prescribed multiple medications in Primary Care.

What does the study involve?

The trial will operate in 54 GP sites across Bristol and West Midlands. Each practice will recruit 50 patients over a six-month period, and the participants will be followed up for a further six months.

Each participating practice will identify 260 eligible patients to be invited at the start of the study. Once patients have been invited to participate in the study, the practices will be randomised to either the intervention or control group. Practices in the control group will be asked to continue their usual care.

For practices in the intervention arm, the trial will involve GPs and practice pharmacists working together to deliver a structured polypharmacy medication review. Reviews will be conducted in batches over a six-month period. The study will fund additional time required for a practice pharmacist to undertake

reviews. Where a practice does not have a pharmacist, one will be provided to undertake the reviews.

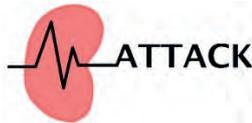
Practices will be provided with an IT tool which will support the case-finding, study administration and monitoring, and delivery of the polypharmacy medication review.

Practices will receive training for GPs and pharmacists, regular feedback and financial incentives for each full review completed. Funding will also be provided to cover the cost of reviews, initial trial set-up and clinical training.

For further information or if you are interested please contact Jenny Simm - Research Facilitator, contact details on back page. Prof. Carolyn Chew-Graham – Co-Investigator (Keele University), email: c.a.chew-graham@keele.ac.uk phone: 01782 734717. Dr Deborah McCahon – Trial Manager, email: deborah.mccahon@bristol.ac.uk

Attack

Aspirin To Target Arterial Events in Chronic Kidney Disease



is 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 who do not have pre-existing cardiovascular disease. 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 running across the West Midlands, with over 1,000 patients recruited to date. 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 on 0115 823 1053 or jennifer.dumbleton@nottingham.ac.uk

What is the clinical and cost effectiveness of using a goal-directed allopurinol-based treat-to-target protocol in people with recurrent gout flares?



Patients will be randomised to either:

A: Treat to Target ULT or B: Usual GP care

Core Practice Activities

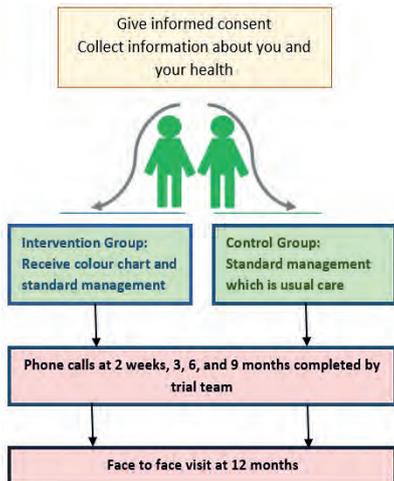
- Database search to identify patients with gout (CRN Support)
- GP to screen patient list for any inappropriate/ineligible patients
- Mail-out (DocMail or paper copies) and reminder after four weeks if no-response (CRN Support)
- Provision of suitable clinic room for patient visits with CRN Research Nurse
 - Screening (30 minutes)
 - Baseline, one year and two years post randomisation (one hour each)
 - Practice Nurse required to initiate ULT as per the T2T protocol and will receive face-to-face training by the study team
- Data extraction of consented patients records
- Display study poster [Provided by study team]

Practice Target: six to seven patients



If your practice is interested in taking part, or for more information, please contact Gerri Mulcahy, CRN Research Facilitator, contact details on back page.

Colour COPD – Sputum colour charts to guide antibiotic self-treatment of acute exacerbation of COPD



Colour COPD is a pragmatic multicentre, randomised controlled trial to determine whether the addition of a sputum colour chart to the existing self-management plan provided to patients with COPD improves their use of antibiotics and steroids and reduces the number of exacerbations they experience in a 12-month period. This is a very simple study, with a very low workload for participating practices.

This study will be running across the West Midlands and Greater Manchester. We are looking for 80 GP practices in total across the two locations. Participating practices would receive service support costs to cover their time to help with this important study, and support from the trial team will be provided.

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

The trial team can be contacted on colourcopd@trials.bham.ac.uk or 0121 414 8137

Electronic Risk Assessment for Cancer - ERICA

The ERICA study is a large randomised controlled trial assessing the clinical and cost effectiveness of six electronic risk assessment tools (eRATs) for bladder, kidney, lung, colorectal, ovarian and oesophago-gastric cancers in general practice. We will recruit 530 English practices to compare the effect of eRATs (vs usual care) on: cancer staging at time of diagnosis, cost to the NHS, patient experience of care, and service delivery.



We hope to see a 4-5% increase in the proportion of early stage cancers diagnosed if the intervention is successful.

The trial runs for two years, with the software being available on EMIS, Vision and SystemOne. A pop-up appears when a patient aged 40+ has recorded symptoms/ test results with a 2+% risk of one of the six cancers. A symptom checker is present for recording additional clinical events, leading to the recalculation of a new risk score. GPs decide the next appropriate course of action themselves. We estimate one to two pop-ups per GP per week.

For the main trial outcome, we are not asking practices to collect data; this is provided by National Cancer Registration and Analysis Service. Practices may choose to take part in nested studies involving giving feedback on the eRATs. Participating practices receive £470.55 if randomised to the intervention arm and £204.40 in the control arm. We provide full support for practices and will liaise with CCGs to arrange software installation.

Principal Investigator: Professor Willie Hamilton, CBE.

For more information, please contact us:

Tel: 01392 726555

Email: erica@exeter.ac.uk

Web: www.theericatrial.co.uk

Twitter: @EricaTrial

Watch our introduction videos:

<http://erica-hub.co.uk/>

Review the local document pack:

www.theericatrial.co.uk/gp-resources/



Absenteeism and presenteeism costs the NHS approximately £2.4 billion per year and is associated with worse patient outcomes. The main causes of NHS staff absenteeism are musculoskeletal complaints and mental ill-health. Lifestyle factors such as smoking, obesity and low levels of exercise leading to poor cardiovascular health are also important factors.

Enhancing The Health Of NHS Staff is a multicentre, randomised controlled pilot trial of an employee health screening clinic for NHS staff. The aim of this NIHR funded trial is to evaluate the effectiveness and cost-effectiveness of a complex intervention in reducing absenteeism and presenteeism in NHS staff, comparing a hospital-based staff health screening and referral clinic with usual care. This pilot trial is due to start later this year. We aim to recruit 480 participants across three NHS Hospital Trusts in the West Midlands and Herefordshire

What will it involve for participants?

- Participants will provide written consent and complete on-line questionnaires at baseline, 26 and 52 weeks
- Participants randomised to either attend the staff health clinic and receive assessment for their musculoskeletal, mental and cardiovascular health (or lifestyle advice for those <40 years) or usual care – they would not attend the staff health clinic but would see their GP if they had any health concerns

What will it involve for GP practices?

We will inform you if any of your patients consent to participate, notify you of any test results and potential actions that you may wish to consider, and may invite you to tell us about your experience of receiving information from the trial and the acceptability of the process.

If you would like to find out more please contact the trial team on 0121 414 8137 or ethos@trials.bham.ac.uk

Join Dementia Research - Innovation and Improvement Project

By Claire Brown, Research Nurse



Join Dementia Research (JDR) is an NHS and dementia charity initiative aimed at making it easier for people with and without dementia to participate in research studies. JDR provides people with the opportunity to register their interest and be matched with suitable research studies. Anyone over 18 can sign up online, by telephone, by completing a registration form, or through expressing interest via a JDR kiosk.

Recruitment to JDR has been slow, both in the West Midlands, and nationally. As part of the CRN West Midlands Primary Care wider Patient and Public Involvement and Engagement (PPIE) Strategy 2017/18, a group of Research Nurses, Research Facilitators and a Patient Research Ambassador planned an Innovation and Improvement (I&I) project to look at this issue. This included a smaller I&I project, looking specifically at the use of the JDR kiosks and how to maximise their impact.



The working group met every quarter to plan and monitor progress. The project looked at raising awareness of JDR in different settings with a variety of approaches. Impact was measured through qualitative descriptions (feedback) and quantitative measures (JDR registrations, expressions of interest via kiosks).

The kiosks were found to promote best engagement when staffed, they were rarely used when left unattended. In future, JDR kiosks should be focussed on larger events and venues to maximise expressions of interest while ensuring efficient use of staff time, and used in conjunction with leaflets and paper registration forms to offer alternative avenues for engagement. They need to be in a location where there is good Wi-Fi, or with CRN staff who can access mobile phone connectivity.

Promoting JDR with a stand at events such as Memory Walks and the 5k Chocolate Run

proved particularly successful, as well as attending events like Memory Cafes and group sessions such as Singing for the Brain. Group members also attended practice nurse forums, patient participant group meetings and linking in with care homes; all were found to be an effective way to promote JDR and the JDR Learn Tool. Collaboration with CCGs has also been very successful; it was piloted in Herefordshire where they have included JDR as one of their five-year Dementia Strategy priorities, and set local targets for registrations.

Pharmacies were shown to be a more challenging area to promote JDR, with data suggesting only one registration resulted from promotion at four pharmacies during the project. Holding events in local libraries also showed varying degrees of success, the overall feedback being that it was quite time-consuming for CRN staff, with few resulting registrations as footfall on the day was unpredictable. Feedback from libraries has been that they are keen to support by displaying promotional materials.

Although the I&I project ended in December 2019, the group decided to continue working together to promote JDR and ensure the work to raise awareness continues.

For more information about JDR: <https://nhs.joindementiaresearch.nihr.ac.uk/>

Primary Care Clinical Research Lead



CRN West Midlands Primary Care are pleased to announce that Dr David Shukla has been appointed as the new CRN West Midlands Primary Care Clinical Research Lead (CRL); he will be starting in the role on 1 March 2020. David is a GP working in a busy teaching practice in Dudley and has been working with us as Primary Care Clinical Research Specialty Lead in the Central region since 2016. Prior to that, he was a GP champion for Primary Care.

Congratulations to Dr Shukla, we very much look forward to working with him in this new capacity. David will continue to undertake the CRSL role for the Central region.



Practice Pack

You may have seen a previous article about the 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 generally to patients. The pack contains general research information and patient facing materials. This is being currently being circulated. If you have not received these materials please contact your local Research Facilitator.

Improving Practice Nurses' Awareness of Join Dementia Research

Research Nurse Eleanor Hoverd and Public Research Champion Will Ryder spoke to Practice Nurses from Coventry & Rugby CCG about Join Dementia Research (JDR) at their Practice Nursing Forum. With only 0.9 % of dementia sufferers registered with JDR locally (see Figure 1) it is vital that health professionals are aware of JDR and how to signpost patients and carers, so they have the chance to register and take part.

Very few Practice Nurses at the forum had heard of JDR, five years after the launch of the Challenge on Dementia 2020 (DoH 2016) which had key aspirations that by 2020 there would be:

- Equal access to diagnosis for all
- GPs providing a lead role in coordination and continuity of care for people with dementia
- Every person diagnosed with dementia having meaningful care following their diagnosis
- All NHS staff having received training on dementia appropriate to their role

The opportunity to speak to Practice Nurses with a Research Champion, or member of the public that volunteers to raise health research awareness, highlighted the need for improved communication on JDR.

A Research Champion's perspective on what patients and carers want to know, and how to approach the subject of JDR during consultation was valuable and well received. Interestingly, recent JDR figures for Coventry & Rugby show that the most popular method for recruiting people with dementia is through the newspaper (see Figure 2). Practice Nurses do not feature as a recruitment source. Health professionals are in an ideal position to share information about dementia research with their patients and it poses the question as to whether many are aware of JDR and how to signpost patients and carers.

Figure 1 CCG/Health Board Region

CCG/HEALTH BOARD REGION	TOTAL VOLUNTEERS	WITH DEMENTIA	WITHOUT DEMENTIA	TOTAL NO. PEOPLE WITH DEMENTIA IN REGION	% OF PEOPLE WITH DEMENTIA REG. ON JDR
Coventry & Rugby CCG	178	29	149	3176	0.9%

Coventry & Warwickshire CCG JDR figures as at 12.2.20 (Source: Open Data Platform, JDR CRN West Midlands)

Figure 2 Recruitment Source

RECRUITMENT SOURCE	TOTAL WITH DEMENTIA	TOTAL WITHOUT DEMENTIA	TOTAL
Admiral Nurses	0	0	0
Care home	0	0	0
GP	0	1	1
Pharmacy	0	3	3
Hospital - Memory Clinic	1	0	1
Hospital - Neurology Clinic	0	0	0
Hospital - other / don't know	0	1	1
Other healthcare provider	6	15	21
Alzheimer's Research UK	3	12	15
Alzheimer's Society	5	22	27
Other charity	1	1	2
Dementia Friends	1	5	6
Local dementia group	0	1	1
Other dementia organisations	0	0	0
Newspaper	8	32	40
Online news articles	0	0	0
Radio	0	0	0
Television	0	0	0
Internet search	3	15	18
Social media	0	12	12
Exhibit/exhibition	0	8	8
A friend told me about it	0	6	6
Memory Walks (Alzheimer's Society)	0	0	0
Other	1	15	16
Unsure	0	0	0
Total	29	149	178

Recruitment sources. (Source: ODP, CRN West Midlands as at 12.2.20)

If you are interested in hearing more about JDR at a health professional event, please contact Eleanor Hoverd, Research Nurse on eleanor.hoverd@nhr.ac.uk

Join Dementia Research (JDR)

Firstly, many thanks again to those who support raising the awareness of JDR amongst the contacts that you have developed.

West Midlands update as at February 2020

- 22.42% of volunteers on the JDR system have enrolled into a study (national average 22.42%)
- 44.29% of volunteers with a confirmed diagnosis have enrolled onto a study (national average 36.13%)

These current results show what a great tool JDR can be to share research opportunities with members of the public, and for researchers to identify volunteers to contact.



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

Thank you to all practices who took part in the We've Got Your Back study

Total Patient Recruitment: 135

	Invites	Consents
Primrose Lane Surgery	30	8
Chancery Lane Surgery	25	16
Maypole Health Surgery	25	7
Limbrick Wood Surgery	23	10
St Stephens Surgery	21	5
Kingsbridge Medical Practice	19	9
River Brook Medical Centre	19	10
Phoenix Family Care	18	8
Yardley Wood Health Centre	18	5
The Marches Surgery	15	7
The Westgate Practice	15	4
Crown Medical Practice	14	10
Mill View Surgery	10	3
Plas Ffynnon Medical Centre	10	4
TELDOC	10	4
Forum Health Centre	9	6
Stafford Health and Wellbeing	8	4
Mortimer Medical Practice	7	5
Copsewood Medical Centre	5	2
Darlaston Family Practice	5	4
Dunrobin Street Medical Centre	3	0
Biddulphdoctors	2	0
Corbett Medical Practice	2	1
Kingsfield Medical Centre	2	1
Peel Croft Surgery	2	1
Wolstanton Medical Centre	2	0
Broadway Health Centre	1	0
Brookside Surgery	1	0
Stockingford Medical Centre	1	1

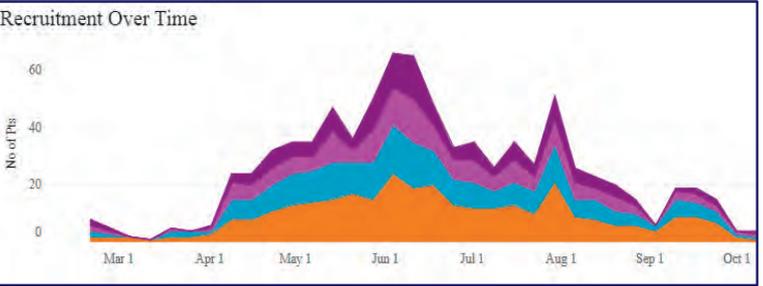
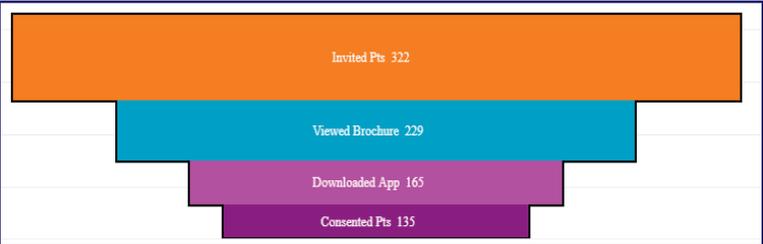


Well Done to Chancery Lane who recruited the highest number of patients to the study.

Limbrick Wood, River brook Medical Centre and Crown Medical Practice also recruited 10 patients into the study.



Results are currently being analysed from data collected via the uMotif app and EMIS record, they will be disseminated later this year.



Maximising outcome for patients with shoulder pain: Using optimal diagnostic and prognostic information to target treatment (PANDA-S)

What is the PANDA-S study?

The PANDA-S cohort study aims to investigate the short and long-term outcomes of shoulder pain and develop a prediction model using diagnostic and prognostic information to more accurately identify patients at risk of long-term shoulder pain and disability.



Practice Involvement

EMIS Pop Up Study

Weekly search of eligible consenting participants and send to Keele Clinical Trials Unit (CTU) secure email and Keele CTU to contact patient directly, posting detailed information about the study.

Or

Weekly search of eligible participants and send mail packs (provided by the study team) from the practice to the eligible participants.

GPs in participating practices may be invited to an interview about managing shoulder pain.

Medical record extraction for patients who have consented (with CRN assistance if required).



To register your interest or further information please contact Gerri Mulcahy, Lead Research Facilitator, details on back page, or Keele Clinical Trials Unit on 01782 732950

A Practical Introduction to Running Randomised Clinical Trials



The School of Primary, Community and Social Care at Keele University are running a short course this June, 'a practical introduction to running randomised clinical trials', to improve participants' knowledge and skills in the design, practical conduct, management and analysis of randomised clinical trials (RCTs).

Combining talks and workshop activities, you will be guided through the principles, methodology and practical implementation of RCTs.

Date: 30 June - 3 July 2020

Location: David Wetherall Building, Keele University ST5 5BG

Cost: Delegate £600

Course leaders: Dr Ed Roddy
Dr Mel Holden
Prof. Gillian Lancaster
Dr Martyn Lewis

The course is aimed at individuals who are planning to undertake or are undertaking clinical trials. This includes people with no previous clinical trials experience, those



embarking on clinical trial research for the first time, or those who have some experience of designing and running trials. We welcome attendees with clinical (including allied healthcare professionals) or non-clinical (including trial managers & R&D managers) backgrounds. The course is suitable for individuals interested in clinical trials in a variety of settings including primary care, the primary/secondary care interface and secondary care.

To register for this course, or for more information, please visit our website or scan this QR Code.



Practice Praise

Zone One in the North locality would like to praise the following GP Practices:

- Leek Health Centre
- Park Medical Centre
- Waterhouses Medical Practice

for their help with the research activity in their practices. They have been very responsive and accommodating for the CRN Research Nurses and Facilitators.

Special thank you to **Biddulph Valley Surgery** who have been very helpful and patient with the Q-PROMPT study.

Also thank you to the PANDA-S practices for their patience with the use of the shoulder pain pop up. The transfer over to SNOMED codes

on EMIS has caused some issues with the pop up firing inadvertently but this has now been rectified and the new codes have been reinstalled at practices.

Welcome to research

Welcome to the following GP practices who've recently come on board participating in studies such as NCMH and PMR-IS.

- East Staffordshire PCN
- Winshill Medical Centre
- Abbots Bromley Surgery
- Trent Meadows
- Carlton Street Surgery
- Stoke-on-Trent CCG
- Harley Street Medical Centre
- North Staffordshire CCG
- Loomer Road Medical Ltd.: comprises six sites, providing high quality care to in excess of 26,000 patients.

NIHR | Clinical Research Network West Midlands 2018/19

East Staffs Primary Care Network (PCN)

873

PARTICIPANTS RECRUITED TO STUDIES ACROSS EAST STAFFS PCN IN 2018/19



10

INDIVIDUAL PRACTICES SUPPORTED RESEARCH BY RECRUITING PEOPLE TO STUDIES

THE NETWORK RECRUITED PARTICIPANTS FOR

10

PRIMARY CARE STUDIES



55%

OF GP PRACTICES RECRUITED PARTICIPANTS INTO STUDIES

Studies included:



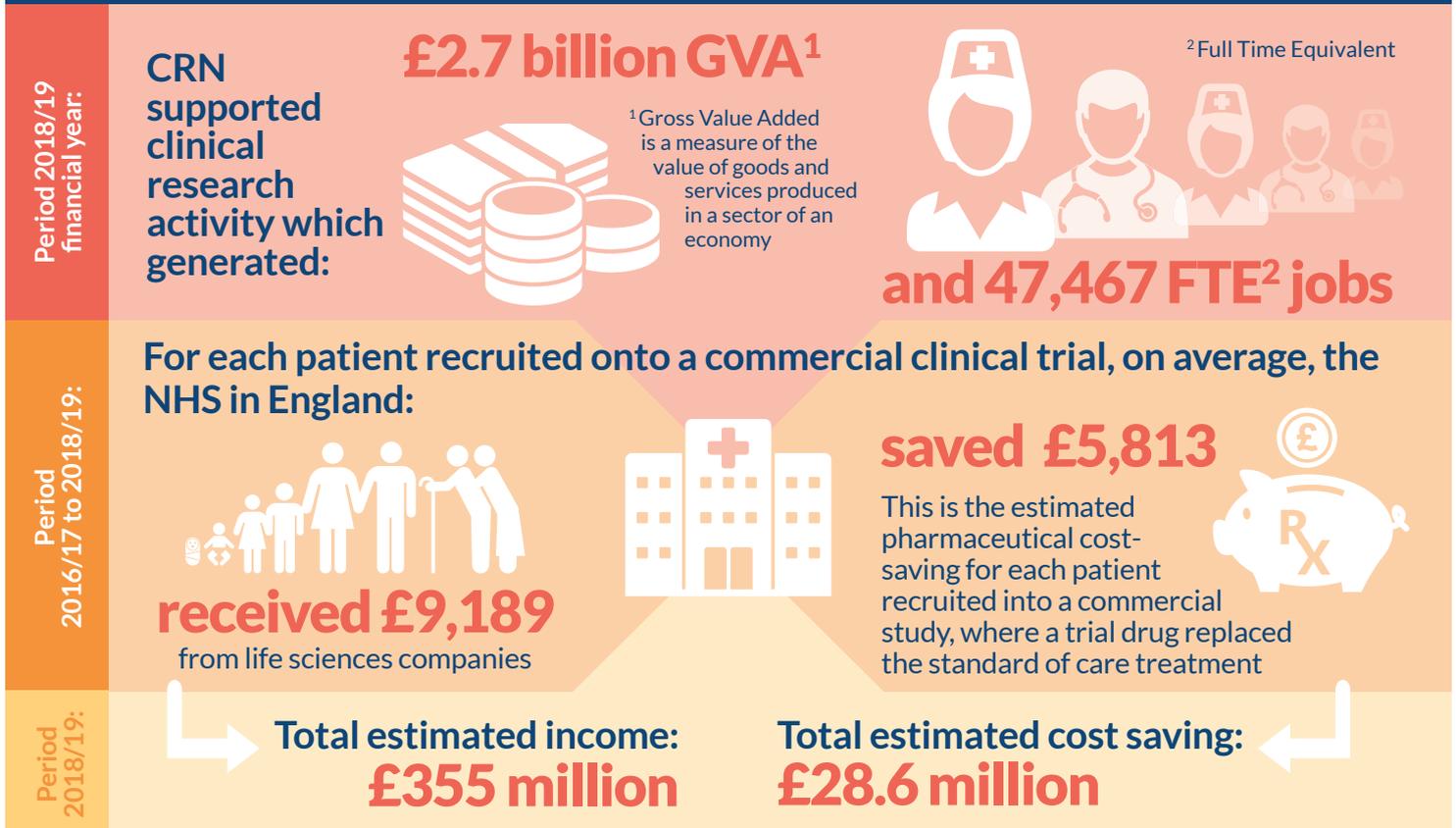
TAPS



NIHR | National Institute for Health Research

How clinical research delivered in the NHS benefits the UK economy

An independent report, commissioned by the **National Institute for Health Research (NIHR) Clinical Research Network** and produced by KPMG's Economics team, provides an assessment of the economic impact of the NIHR Clinical Research Network's activities to support clinical research in England over the period from 2016/17 - 2018/19. The report includes: an assessment of the economic contribution made to the UK economy through clinical research activity supported by the Network; analysis to quantify the value of payments made to NHS Trusts for commercial studies; and the value to the NHS of pharmaceuticals provided as part of commercial studies. The key findings are presented below.



...without the CRN's provision of feasibility services, procurement of 'high performing' sites would be significantly more sporadic and difficult.
Based on Sponsor Company feedback (page 49)

... the CRN's site identification services and set-up support to smaller organisations had impacted positively on its decision to operate clinical research in the UK...
Based on Contract Research Organisation feedback (page 49)

Please see the full report for details of the analysis and its limitations and assumptions.
www.nihr.ac.uk/impact-and-value-2019

For more information contact:
crn.bdm@nihr.ac.uk



CRN West Midlands 2019 VIP Awards

Commercial Studies - Delivering to Time & Target Award

Citation: The practices accepting this award on behalf of Primary Care have contributed significantly to the overall metric of recruitment to time and target. They have truly embedded research as a core business activity within their practices and the dedication from their research teams and engagement from their Principal Investigators are what sets them apart from their counterparts. As a result of their consistent performance they have been able to establish a good reputation with commercial sponsors and Clinical Research Organisations. They act as advocates for clinical research within Primary Care and maintain strong working relationships with the CRN.

WINNER: SHERBOURNE MEDICAL CENTRE

This award went to the organisation(s) which showed greatest contribution to delivering recruitment to time and target for commercial studies.

Consideration was given to the number of commercial studies opened, recruitment of first patient, recruitment to time and target, approval times, using commercial income to build capacity to take on additional studies and developing relationships with commercial partners.

The practice table shows those practices that contributed to HLO2a: the proportion of commercial contract studies, achieving or surpassing their recruitment target during their planned recruitment period, at confirmed CRN sites for Primary Care.

PRACTICE TABLE	NO. OF STUDIES
Sherbourne Medical Centre	6
The Atherstone Surgery	5
Spring Gardens Group Medical Practice	2
Omnia Practice	1
Plas Ffynnon Medical Centre	1
Primrose Lane Practice	1

Our congratulations and thanks go to our well-motivated and high-achieving practices.

Patient Research Ambassadors change to Research Champions

The Clinical Research Network Coordinating Centre has previously described and supported the roles of both Patient Research Ambassadors and Join Dementia Research Champions. These roles were recently reviewed and the decision has been made to refer to both as Research Champions in future.

Research Champions include patients, carers and members of the public, who may or may not have taken part in a research study.

What they all have in common is that they are passionate about getting more people involved in research so that better care and treatments can be developed for everyone.

Research Champions volunteer their time to help spread the word about health and care research to patients and the public. They also help research and clinical staff understand more about the experiences of those who take part in research.

Please make sure to use the new name from now on.



Geoff Robson

If you would like more information about the role of the Research Champions in Primary Care or have any questions please contact Eleanor Hoverd, Research Nurse, eleanor.hoverd@nhr.ac.uk

Narratives Experiences Online (NEON)



Understanding the impact of mental health recovery stories

Background to the study

The NEON study has collected mental health recovery narratives from around the world. NEON is now running three online trials looking at whether accessing stories in this collection can help people with experience of psychosis or other mental health problems, and carers. NEON is currently recruiting across England. Visit www.recoverystories.uk for more information.

What will it involve for GP practices?

- Displaying a poster and some postcards about the study in the surgery (to April 2021)
- Circulating the website details as widely as possible www.recoverystories.uk

How do I get involved?

Posters can be downloaded from www.researchintorecovery.com/neontrials/promotion

If you would like copies of the posters and cards to be sent to your practice please email neon@nottingham.ac.uk

Research Champion Case Study

Our Research Champion (Primary Care) Geoff Robson shares his story:

1. A brief overview

I spent 40 years working for the rail industry, the majority in Project Management with the last 15 years developing and delivering major infrastructure projects. Having fully retired in mid-2017 I wanted to pursue some new challenges and decided to volunteer for some form of work within the NHS, although at the time I had no real knowledge about the opportunities.

Having become involved as a Research Champion, previously Patient Research Ambassador (PRA), my experience of health research has been very positive, although it does bring its challenges, as many GPs, and the majority of the public, lack full awareness.

2. How did you first hear about Research Champions?

Through my local GP Patient Participation Group I found out about the role of Lay Member on the Clinical Research Network West Midlands Partnership Group and put my name forward. Although my application was unsuccessful, I was told about the role of Research Champion within the Network and asked if I would be interested.

3. What made you decide to become a Research Champion?

I discussed this at length with Mary-Anne Darby (the CRN's Head of Patient & Public Involvement and Engagement) who explained the role to me very well. To be actively involved in promoting research and helping others understand what research is about was a major motivation. As such,



I agreed to take it on. The support I have had has been really helpful, with one to one meetings with Mary-Anne for the first six months, and meetings and communication with the various research teams.

4. Why do you think NHS research is important?

Research is key to finding treatments and cures for diseases and conditions that affect the lives of many people, thus reducing the burden on e.g. doctors' surgeries, hospitals and care homes. The role of Research Champion provides an opportunity to inform and support those in the health industry to understand the type of research being undertaken and to ensure that the right level of public involvement is achieved.

5. What activities have you been involved with?

I have been involved in promoting involvement in dementia research including a radio interview, and organising an event at my local library. I helped at an event in a retirement

village in Birmingham, contributed at meetings and presented at the PRA Away Day, among other activities. I am currently developing a plan to raise research awareness among student doctors, and the impact it will have in the future; I have become a co-applicant in a submission for the Parkrun Research Project and reviewed a paper aimed at research into the control of antibiotic use. This has been very rewarding and has enabled me to use my experience from previous employment to review the documents.

The work I have done to date has helped inform GPs and the public about what research involves and the tools available to help people get involved. It has also helped me to use my knowledge and experience of communication, presentations and document review to support various research initiatives. This year I am looking forward to helping engage with care homes regarding Join Dementia Research (JDR) and providing support as needed. I will also continue to support the JDR and Equality, Diversity and Inclusivity working groups.

6. What would you say to others who are considering getting involved in research?

Do it! Participation is the best way to add value to the research process, using experiences as a patient and carer. If you are considering becoming a Research Champion, there may be opportunities depending on the area you live in. You don't need any specific experience of research or the health service, just a willingness to commit some time to promoting research through various means.

Remember, the role is voluntary so this does not necessarily mean that it will take up a great deal of time.

“I suddenly felt I’d aged”: a qualitative study of patient experiences of polymyalgia rheumatica (PMR)

Objectives

To explore patient experiences of living with, and receiving treatment for, PMR.

Methods

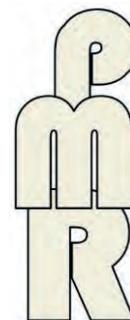
Semi-structured qualitative interviews, with 22 patients with PMR recruited from general practices in South Yorkshire. Thematic analysis using a constant comparative method, ran concurrently with the interviews and was used to derive a conceptual framework.

Results

Five key themes emerged highlighting the importance of:

- (1) pain, stiffness and weakness
- (2) disability
- (3) treatment and disease course
- (4) experience of care
- (5) psychological impact of PMR

Patients emphasised the profound disability experienced that was often associated with fear and vulnerability, highlighting how this was often not recognised by health care professionals. Patients' experiences also challenge medical convention, particularly around the concept of 'weakness' as a symptom, the use of morning stiffness as a measure of disease activity and the myth of full resolution of symptoms with steroid treatment. Treatment decisions were complex, with patients balancing glucocorticoid side effects against persistent symptoms.



Conclusions

Patients often described their experience of PMR in terms of disability rather than focussing on localised symptoms. The associated psychological impact was significant.

Practice Implications

Recognising this is key to achieving shared understanding, reaching the correct diagnosis promptly, and formulating a patient-centred management plan.

Publication

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What is the Impact of Giant Cell Arteritis on Patients' Lives?

Objectives

Clinical management of giant cell arteritis (GCA) involves balancing the risks and burdens arising from the disease with those arising from treatment, but there is little research on the nature of those burdens. We aimed to explore the impact of giant cell arteritis (GCA) and its treatment on patients' lives.

Methods

UK patients with GCA participated in semi-structured telephone interviews. Inductive thematic analysis was employed.

Results

The overarching themes from analysis were:

- ongoing symptoms of the disease and its treatment and
- life-changing impacts

The overall impact of GCA on patients' lives arose from a changing combination of symptoms, side effects, adaptations to everyday life and impacts on sense of normality. Important factors contributing to loss of normality were glucocorticoid-related treatment burdens and fear about possible future loss of vision.

Conclusions

The impact of GCA in patients' everyday lives can be substantial, multifaceted and ongoing despite apparent control of disease activity. The findings of this study will help doctors better understand patient priorities, legitimise patients' experiences of GCA and work with patients to set realistic treatment goals and plan adaptations to their everyday lives.

Rococo study: a real-world evaluation of an over-the-counter medicine in acute cough (a multicentre, randomised, controlled study)



Approximately one in five people in the UK suffer from acute cough over the winter season. This makes it one of the most common reasons to visit a GP in the colder months, and subsequently costs the NHS around two billion pounds per year.

Many patients opt to seek relief from acute cough from over-the-counter (OTC) treatments, but very little research has been conducted into the effectiveness of OTC cough medicines; many of which have been described as ineffective by patients. Some trials into acute cough have been attempted in hospitals in the past, however, their success has been limited. This is likely to be related to the choice of setting, as cough patients rarely present at hospital, resulting in poor participant recruitment to the trials.

In 2015, the Rococo study took a different approach and, at the time of delivery, it was one of the largest multicentre, randomised controlled clinical trials in participants with coughs. The trial compared a branded OTC cough medicine 'Unicough' with a simple cough linctus to see if it was capable of demonstrating significant reductions in acute cough symptoms. It successfully recruited 163 patients within just four months.

Rococo's recruitment success was primarily down to its real-world approach. Instead of focussing on secondary care it looked at where patients first seek relief for an acute

cough and, as a result, it was conducted exclusively through community-based sites. This included 14 pharmacies and four GP surgeries in England and resulted in Rococo being the first UK study to recruit participants seeking cough medicines from pharmacies.

Professor Surinder Birring, Consultant Respiratory Physician at King's College Hospital London and Chief Investigator for the study, explains its significance for the future of community-based health research:

"This was an important study for community-based research as it was the first cough study to be done in a pharmacy setting; the most appropriate setting for the type of illness being studied. At the outset it was completely unknown how the trial was going to run. There were some initial concerns around gaining ethical approvals and some uncertainties around whether patients would want to be involved. However, the ethics board was very supportive of our requirements, and we concluded with results that clearly demonstrate the appropriateness of pharmacies as a research setting."

As outlined by Professor Birring, not only did the community-based approach maximise access to the target patient population, it also meant that study participants more closely resembled the broader population seeking cough medicines. This led to the generation of real-world data - more accurate and applicable results

in terms of how effective the medicine is in the 'real-world' as opposed to a controlled clinical trial setting.

The recruitment success of Rococo was also in part down to support provided by the NIHR Clinical Research Network. Sinead Collinge, Industry Operations Manager for the West Midlands Clinical Research Network, explains how her team supported the study:

"The NIHR contributed significantly to efficient site identification and selection. We have a number of pharmacies in the area that are 'research-ready'. By this we mean that they either have Royal Pharmaceutical Society 'Research Ready' status or they are already engaged in clinical research and have worked with the NIHR Clinical Research Network previously."

The Royal Pharmaceutical Society runs a 'Research Ready' accreditation scheme for pharmacies in the UK. It requires a pharmacy to have a dedicated research lead and for all staff to have undertaken Good Clinical Practice (GCP) training which is mandatory for employees who will help to deliver a study. There are currently over 100 pharmacies registered. Sinead continues:

"Having access to research ready pharmacies really helps when it comes to getting a study up and running in a pharmacy setting. The staff already understand the principles that make the study run smoothly, such as how to collate, store and submit the data. But

in addition these pharmacies really understand the unique benefits that delivering research in the community can bring. They are always willing to contribute to studies, in fact, the problem we often have is that we don't have enough studies to offer them."

Julie Shenton is the Lead Pharmacist and Continuous Improvement Lead for West Midlands LCRN. Julie is a strong advocate for clinical research and explains more about what advantages community pharmacies have to offer when delivering clinical research:

"Community Pharmacies are more accessible than other healthcare providers. People with long term conditions see the pharmacist more frequently than they see their GP, which means we have a different level of access to those patients. But also there are more pharmacies than GP surgeries and hospitals and we have longer opening hours. Plus people can just pop into a pharmacy without an appointment. I think there is a statistic that says about 96% of people can get to a pharmacy either by foot or public transport in less than 20 minutes.

"We can also access harder to reach patient populations and different patient populations to GPs. For example, some people might not know if they need to visit a GP and may instead visit a pharmacy for advice about what they believe to be minor ailments. So it may be that we can access a patient population at a different stage of their disease progression. Community pharmacies certainly have a lot to offer and we'd like to see more researchers tapping into that resource."

Results

Rococo closed to recruitment April 2015 with good data completion, having recruited 163 participants. The study results demonstrated that, although there was little change in cough severity, the OTC cough medicine 'Unicough' was associated with greater reductions in acute cough symptoms than a simple linctus generally prescribed by GPs.

Aim: Depression is usually managed in primary care, but most antidepressant trials are of patients from secondary care mental health services, with eligibility criteria based on diagnosis and severity of depressive symptoms. Antidepressants are now used in a much wider group of people than in previous regulatory trials. The clinical effectiveness was investigated of sertraline in patients in primary care with depressive symptoms ranging from mild to severe and tested the role of severity and duration in treatment response.



Method: The PANDA study was a pragmatic, multicentre, double-blind, placebo-controlled randomised trial of patients from 179 primary care surgeries in four UK cities (Bristol, Liverpool, London, and York). It included patients aged 18 to 74 years who had depressive symptoms of any severity or duration in the past two years, where there was clinical uncertainty about the benefit of an antidepressant. This strategy was designed to improve the generalisability of our sample to current use of antidepressants within primary care. Patients were randomly assigned (1:1) with a remote computer-generated code to sertraline or placebo, and were stratified by severity, duration, and site with random block length. Patients received one capsule (sertraline 50 mg or placebo orally) daily for one week then two capsules daily for up to 11 weeks, consistent with evidence on optimal dosages for efficacy and acceptability. The primary outcome was depressive symptoms six weeks after randomisation, measured by Patient Health Questionnaire, nine-item version (PHQ-9) scores. Secondary outcomes at two, six and 12 weeks were depressive symptoms and remission (PHQ-9 and Beck Depression Inventory-II), generalised anxiety symptoms (Generalised Anxiety Disorder Assessment seven-item version), mental and physical health-related quality of life (12-item Short-Form Health Survey), and self-reported improvement. All analyses compared groups as randomised (intention-to-treat).

Results/conclusion: 655 patients were recruited and randomly assigned - 326 (50%) to sertraline and 329 (50%) to placebo. Two patients in the sertraline group did not complete a substantial proportion of the baseline assessment and were excluded, leaving 653 patients in total. Due to attrition, primary outcome analyses were of 550 patients (266 in the sertraline group and 284 in the placebo group; 85% follow-up that did not differ by treatment allocation). No evidence was found that sertraline led to a clinically meaningful reduction in depressive symptoms at six weeks. The mean six-week PHQ-9 score was 7.98 (SD 5.63) in the sertraline group and 8.76 (5.86) in the placebo group (adjusted proportional difference 0.95, 95% CI 0.85-1.07; p=0.41). However, for secondary outcomes, evidence was found that sertraline led to reduced anxiety symptoms, better mental (but not physical) health-related quality of life, and self-reported improvements in mental health. Weak evidence was observed that depressive symptoms were reduced by sertraline at 12 weeks.

Importance: Sertraline is unlikely to reduce depressive symptoms within six weeks in primary care but we observed improvements in anxiety, quality of life, and self-rated mental health, which are likely to be clinically important. Our findings support the prescription of SSRI antidepressants in a wider group of participants than previously thought, including those with mild to moderate symptoms who do not meet diagnostic criteria for depression or generalised anxiety disorder.

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Research Design Service

In an increasingly competitive research environment, securing funding to conduct health and social care research can be difficult and time consuming. The National Institute for Health Research (NIHR) Research Design Service provides expert advice and support to researchers developing research funding applications.

How we can help

We could help your team with:

- designing a research study
- research methods (qualitative and quantitative)
- identifying suitable sources of funding
- involving patients and public in research design
- identifying potential academic, clinical and lay collaborators
- identifying and refining the research question
- medical statistics
- health economics
- advice on common pitfalls
- interpreting feedback from funding panels

Who we can help

We can help you if you are:

- developing grant applications for applied health or social care research
- applying for personal fellowships
- writing applications to national, open, peer-reviewed funding streams

We support a broad range of people, including doctors, nurses and allied health professionals; patients and service users; academics and NHS and social care managers. Our priority is to support applications to NIHR research funding streams. We also support applications to Research Councils and other open, national, peer-reviewed funding programmes.

Why choose us

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Collaboration: We can help you to identify possible gaps in your research team and collaborators who can add value to your research, including health and social care clinicians, policy makers, academic researchers and patients and the public.

Tailored support: We can offer support tailored to the needs of your research team. Advice is available at face-to-face meetings, by telephone or email, at research clinics or as feedback from panel review meetings.

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