NIHR | Clinical Research Network West Midlands

Summer 2020 Edition No. 7

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@nihr.ac.uk

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

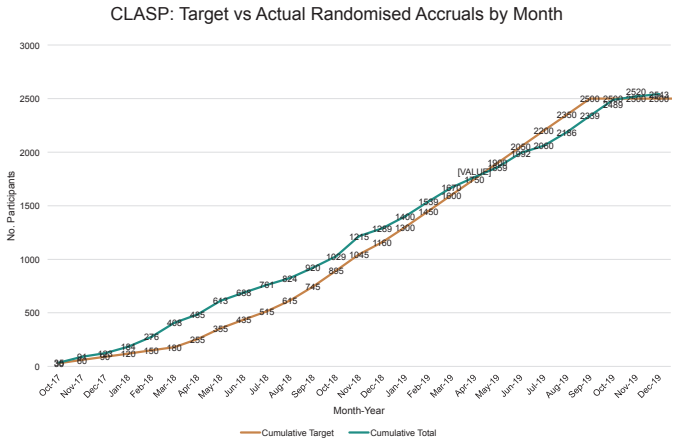
Contents

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.l.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?

Keele UNIVERSITY

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

University of Nottingham
UK | CHINA | MALAYSIA

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 SystmOne. 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.

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)

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 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@nihr.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@nihr.ac.uk

Care Companion

A free resource developed with carers for carers

Care Companion is a free, easy to use, online resource developed to support carers across Coventry and Warwickshire. It's available 24/7 and personalised to the individual carer's situation. Carers can access it now at www.carecompanion.org.uk

"It's great to see innovative solutions for social good being created in the local area. The social care sector is increasingly an area of concern that needs to be addressed. Solutions like this app will hopefully assist carers in lieu of Government investment. I was happy to help the team get a meeting with the Minister for Social Care and I will continue to support them."

Matt Western, MP for Warwick and Leamington

Caring is an increasingly vital role in society

There are approximately 6.8 million unpaid, informal carers in the UK, providing care and support to friends and family, enabling them to continue living in the community rather than in residential care facilities. This informal care is worth £130 billion to the national economy and £1.1 billion locally; values that could never be met by existing health and social care budgets in this country.

Carers rarely have any training for the role they take on and face numerous challenges responding to the changing, and often complex, physical, social and emotional needs of the person they care for. In order to do this they must seek out and verify relevant information and support, often with little guidance.

Caring can be a lonely and isolating experience. In addition to the needs of the person they care for, carers must also manage their own health and social needs. Carers need to be adequately supported to maintain their resilience and ability to cope with the demands placed on them. Lack of support for carers contributes to unplanned hospital admissions, prolonged hospital stays and delays in discharging patients.

Care Companion – a new way to support carers

Carers registering with Care Companion set up a profile containing key information about themselves and the person they care for, such as their age, location and the cared-for person's medical conditions. Care Companion then offers six key features:

- RESOURCE LIBRARY: Personalised up-to-date resources and information tailored to the details provided in the profile. All resources are verified by the content management team and checked for lay accessibility by the carers panel before being added to the library
- DIARY: For appointments, recording test results, and the carer and cared-for person's day-to-day experiences and observations. This can be shared with health and social care providers on screen at appointments or as a PDF. Tags can be added to allow the carer to find entries on a particular topic quickly and easily
- MOOD MONITOR: Linked to the diary, a selection of emoticons offer a quick one click way to monitor the carer and cared-for person's mood and well-being
- ADDRESS BOOK: For creating, browsing, and adding important numbers and addresses for resources and support. Useful resources can be imported from the resource library for quick access. Carers can also create their own entries
- NOTIFICATIONS: For setting reminders and ticking them off when complete. The system can also generate suggestions based on information in the carer and cared-for person's profile
- GLOSSARY: Index of words carers may come across during appointments and in resources

Care Companion is available now

There are already hundreds of carers across Coventry and Warwickshire accessing Care Companion – don't let yours miss out!

If you would like a member of the Care Companion team to visit your practice, clinic, team or community groups, either to speak to staff or directly to carers, please email carecompanion@warwick.ac.uk. We can also have a team of volunteers who can support your carers to start using Care Companion and a wide range of promotional materials available both electronically and by post – drop us an email for more details.

Practice Praise

Firstly, we would like to mention the practices that have undertaken the search and DocMail for the PMR-IS study:

- **Alcester Health Centre**
- **Spring Gardens Medical Group**
- **The Marches Surgery**
- **Winyates Health Centre**
- **Priory Gate Practice**
- **Stanmore House Surgery**
- **Haresfield Surgery**
- **Castle Medical Centre**

In addition, **Stanmore House Surgery** has also started NCMH, thank you for your prompt responses and enthusiasm for engagement in research.

Hillview Medical Centre for enthusiastically taking on board STREAM as the first practice in our locality to achieve the metrics for the study, and also for agreeing to run the STATUS QUO study, the only practice doing this in our locality.

Forrest Medical Centre: our thanks and appreciation go to Matt Grant, Practice Manager, for all his assistance on numerous occasions when he has advised on, and corrected, searches on VISION. He has always been very approachable and helpful on this and all other IT related issues.

Revel Surgery: ten members of staff have engaged with JDR and completed the online learning tool. This is the most of any surgery in West Midlands South.

Congratulations, we would like to thank you all for your commitment and enthusiasm.

Welcome to research

Wyre Forest Health Partnership and **Wyre Forest Network of Independent Practices:** both organisations have expressed an interest in CRN research studies and in getting involved.

And finally . . .

A special mention to Dr Hetherington from **Winyates Health Centre** for over four years of commitment and dedication to the BARACK-D study, which completed last month. Patients were seen every three months over three years and Dr Hetherington had to keep a close eye on blood results and adverse events in order to ensure the safety and wellbeing of patients throughout the study.

Eat Well, Feel Well, Stay Well
STREAM

Screen and treat for malnutrition

An intervention developed for use by healthcare professionals who work in Primary Care to identify older people (75 and over), who live in their own homes and who may be at risk of malnutrition, based on diagnostic criteria. The effect of this intervention, as compared with usual care, will be assessed to see what impact it has had on the participants' quality of life and on their level of infections over 18 months.

The aim is to recruit 1,110 at nutritional risk participants from 110 practices nationwide. These participants will complete a baseline questionnaire and, if they are from an intervention practice and meet the diagnostic criteria, will have a face-to-face screening appointment at the practice. Postal questionnaires will be at six, 12 and 18 months, and all the at nutritional risk participants will be invited to attend a face-to-face follow up with a research nurse at 18 months. In addition, a random sample of 450 participants that are not at nutritional risk at baseline, will be followed up at 18 months.

Practice involvement

- Database search and mail out
- Randomisation into either:
  1) **Intervention** practices (Eat well, feel well, stay well intervention (dietary advice and support) plus targeted oral nutritional supplement for a minority of individuals according to the protocol)
  2) **Usual Care** practices
- Intervention practices – a practice nurse or health care assistant will see participants for an initial face-to-face appointment and follow the care pathway developed for this trial. Further brief follow-ups may be required depending on the patient's needs/nutritional risk
- Notes review at 18 months
- Optional interview with researcher about experiences in the study

Recruitment status: December 2019 – October 2020
Sponsor: University of Southampton
Funder: NIHR Programme Grants for Applied Research

If you would like further information, please e-mail stream@warwick.ac.uk

Which Patients miss Booked Appointments with the General Practice and why?

Missed general practice appointments have substantial time and cost implications for the NHS, exacerbating the increasing demands placed on GPs and primary care. The Unit of Academic Primary Care at Warwick University is conducting a systematic review of published studies, to find out which patients are more likely to miss general practice appointments, how often appointments are missed and the reasons that they are missed.

26 studies met the criteria to be included in the review, and we assessed their quality, and extracted the data from them. The majority (n=14) of included studies were conducted in the US, and the majority of the studies were analyses of patient medical records. 19 of the studies included a rate of missed appointments. The results of the studies showed that between 3.3% and 48.1% of appointments were missed.

Reasons for patients missing appointments included forgetting the appointment, being too ill to attend, weather difficulties, transport barriers, feeling better since making the appointment, family or work commitments and appointments not being with the preferred GP. Patients were more likely to miss an appointment on a Monday than other days.

Patients most likely to miss appointments were those that were younger, and those that had a mental health diagnosis or a long-term condition. Patients with low socio-economic status or those living in deprived areas were also more likely to miss appointments. Patients who were in receipt of Medicaid or who were self-paying for medical care were more likely to miss appointments.

It is anticipated that the findings from this review will help to provide a better understanding of why patients miss primary care appointments, and help to inform strategies for reducing these.

CRN West Midlands 2019 VIP Awards Nurse/ Facilitator of the Year

Warm congratulations go to Eleanor Hoverd, Research Nurse, who received four separate nominations in the category, and who was a worthy and popular winner of this award.

When not fulfilling her role as a research nurse, Eleanor is particularly active in Patient and Public Involvement and Engagement, where she is the lead for Primary Care in the West Midlands.

Genetic Links to Anxiety & Depression

The GLAD study is a project set up to explore risk factors in individuals who have experienced depression and/or anxiety, including those with a diagnosis of bipolar disorder, OCD or related disorders, at any time in their lives.

It aims to better understand depression and anxiety in order to find and develop more effective treatments. The GLAD study is also part of the NIHR BioResource, which is a library of information about people's health aiming to support research in both physical and mental health.

Are you:

- Aged 16+
- Living in the UK
- Experiencing clinical levels of depression and/or anxiety, or have experienced these in the past

Participating

To take part in GLAD, potential recruits follow an easy to use sign up path:

1. Register on www.gladstudy.org.uk and read the information sheet
2. Provide consent using the online form
3. Complete an online questionnaire to check eligibility
4. Send a saliva DNA sample using the freepost envelope which will be provided

Participants are free to withdraw from the study at any stage.

For more information please visit www.gladstudy.org.uk/faqs, email gladstudy@kcl.ac.uk, phone 0800 634 4504 or ask your local research facilitator, details on back page.

A Cross-Sectional Survey of General Practice Health Workers' Perceptions of their Provision of Culturally Competent Services to Ethnic Minority People with Diabetes

Research led by **Dr Peter Zeh**, Honorary Clinical Research Fellow Warwick Medical School and Assistant Professor in Adult Nursing Coventry University, consisted of a survey of all Coventry GP surgeries.

Existing evidence show that people from the black or ethnic minority (BME) groups are susceptible to diabetes due to physiological, environmental and lifestyle factors, insulin resistance and genetic predisposition, and often experience poorer health outcomes. Onset of diabetes in these groups (especially in those of South Asian and African-Caribbean origins) is five to ten years earlier than in white Europeans and more often presents with complications, such as cardiovascular disease, at diagnosis, leading to premature mortality.

In Coventry, a medium-sized industrial and ethnically-diverse UK city typical of many in the developed world, low health literacy and language barriers hamper access to diabetes care for BME populations, leading to poorer self-management. Effective therapeutic relationships between diabetes patients and healthcare professionals are difficult to develop when cultural competence (not currently mandatory in UK healthcare training education) is absent, as an understanding of the patients' cultural background can promote provider-patient engagement and facilitate patients' understanding of their diabetes and care management.

For further details about this study, please contact: p.zeh@warwick.ac.uk or ac5432@coventry.ac.uk

Analysis of this study revealed that:

- 32% of Coventry GP staff spoke a second language relevant to the practice's BME population
- GP staff from BME groups were 1:5 compared to 1:10 in the city's population
- 56% GP practices provided highly culturally-competent diabetes services for patients from BME backgrounds
- 100% GP practice staff received regular formal training on diabetes care
- No GP practice staff received formal/structured cultural competence training

Dr Zeh said: 'Health care organisations should make structured cultural competence training mandatory in order to improve the provision of culturally-competent services as the exacerbating refugee and economic migration of national populations around the world is likely to continue. This may include on some occasions employing appropriately skilled and trained refugees/immigrants in various healthcare specialties to support the health of the same migrant populations.'

This study has been published in Primary Care Diabetes Journal: https://www.primary-care-diabetes.com/article/S1751-9918(18)30245-6/pdf and the findings used to develop the White Paper 'Current Challenges in Diabetes Care and How to Address Them' which sets out plans to improve diabetes care pathways. Furthermore, Insights for Diabetes Excellence, Access and Learning (iDEAL) (www.idealfordiabetes.com) has used the findings to write up a position statement on 'Safety and accuracy in self-blood glucose monitoring with accompanying individualised education.'

Recommendations from this publication have led to a new ongoing collaborative research project, partly funded by THE ROYAL WOLVERHAMPTON NHS TRUST 'Pilot intervention to investigate the delivery of culturally competent diabetes care in the West Midlands.'

Effectiveness and Cost-Effectiveness of a Self-Guided Internet Intervention for Social Anxiety Symptoms in a General Population Sample: Randomized Controlled Trial

Social anxiety is one of the most common sources of mental distress in the population, and many people with symptoms do not seek help for what represents a significant public health problem. We aimed to evaluate the effectiveness of a self-guided cognitive behavioural internet intervention for people with social anxiety symptoms in the general population. Six weeks after the intervention, participants had reduced symptoms compared with the control group, and this difference persisted at 12 months.

For people with social anxiety symptoms who are not receiving other forms of help, this study suggests that the use of an online self-help tool based on cognitive behavioural principles can provide a small improvement in social anxiety symptoms compared with no intervention, although dropout rates were high. You can read more here: https://www.jmir.org/2020/1/e16804/

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

Geoff Robson

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.

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@nihr.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

doi: 10.1016/j.pec.2014.12.013 Epub 2015 Jan 15

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.

Arthritis Research UK

Keele UNIVERSITY

 View Full Text: http://dx.doi.org/10.1136/bmjopen-2017-017073

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 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.

Publication: https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(19)30366-9/fulltext

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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.

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We could help your team with:

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- involving patients and public in research design
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- interpreting feedback from funding panels

Who we can help

We can help you if you are:

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- applying for personal fellowships
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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.

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