NIHR | Clinical Research Network West Midlands

Spring 2019

Edition No. 5

PARTICIPATE

The new Five Year Plan for General Practice

In January, NHS England published its five-year framework for the general practice reform that is needed to implement the NHS Long Term Plan. The context for this was recognition that general practice is the bedrock of the NHS, without which the NHS cannot survive and thrive, and that there is a need to strengthen general practice. This includes its capacity to participate in research.

Among its various goals, is the intention that the NHS should "get better at developing, testing and costing future potential changes before rolling them out nationwide". It is proposed that a new testbed programme will be established with clusters of GP practices in Primary Care Networks developing and testing specific innovations, such as service specifications, QOF indicators or QI modules. It is anticipated that clusters may work with innovators to discover promising approaches and develop prototypes, and presumably this could include academic teams. Each cluster will be commissioned nationally, topic by topic.

Primary Care Networks will also be encouraged to participate in research. The NHS Long Term Plan aims to increase the number of people registering to participate in health research to one million by 2023/24, with Primary Care Networks playing an important part in achieving this goal. Primary Care Networks are seen as means of increasing general practice research participation levels.

What do these changes mean for NIHR CRN primary care specialist teams? This is still unclear, and the plan states that the details of how networks will be helped to develop their research capacity will be worked on over the next year. However, the CRN primary care specialist team in the West Midlands welcomes the opportunity of engaging with the new Primary Care Networks as they emerge, supporting applications to become testbeds, and together creating the infrastructure to support the increased research activity that can follow from this.

In this edition we feature articles on:

- REST, improving antibiotic prescribing for children with ear discharge, see page 3
- Launch of vidibooks, aimed at increasing research awareness and improving patients' understanding about health research, see page 6

Not all studies will run in all areas, or be suitable for all practices – for more detailed information, please contact your local research facilitator, contact details on page 16.

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

- Study – We've Got Your Back
- Study – Cancer: Life Affirming Survivorship Support in Primary Care
- A Patient's Story – CARE 75+

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CRN WM Primary Care: Commercial Research Event

27 September 2019 at The Studio, Birmingham

- Keynote presentations from the Life Sciences Industry, NIHR CRN and regional representatives from General Practices
- Topical breakout sessions
- Networking opportunities with colleagues and partners across the region
- Poster Exhibition

For further information please contact crnwm.primary-care-industry@nihr.ac.uk

ATTACK (Aspirin To Target Arterial Events In Chronic Kidney Disease)

ATTACK 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 diseas. 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 now starting in the West Midlands. Participating practices would receive service support costs to cover their time to help with this important study, and support would be provided.

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

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

NCMH
National Centre for Mental Health

The National Centre for Mental Health (NCMH)

NCMH brings together world-leading researchers from Cardiff, Swansea and Bangor Universities to learn more about the triggers and causes of mental health problems.

Aims

- To improve diagnosis, treatment and support for the millions of people affected by mental ill-health every year
- Tackle stigma

How is this done?

- Engagement with services and their users, the third sector and the wider public to increase understanding of mental illness, and by supporting and undertaking mental health research

How can you help?

Mental health problems can affect anyone regardless of age, gender, race or social background. But together **we can make a difference.**

Current focus

- Bipolar Disorder
- Schizophrenia & Psychosis
- Post Traumatic Stress Disorder (PTSD)
- Perinatal Mental Health Problems
- Schizoaffective Disorder

What is involved?

- 30-60 minute assessment at the participant's home or a nearby clinic
- Personal information & background, family history, physical health and mental health diagnoses, medication history and lifestyle questions
- DNA sample - blood/saliva
- Questionnaire left with participant

If you would like further information, please visit our website: www.ncmh.info, email info@ncmh.info or call 029 2068 8401

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

RENEWEDonline

Background

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

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

What is involved for participants?

Eligible participants are randomised into one of three groups:

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

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

What is involved for practices?

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

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

UNIVERSITY OF Southampton

FUNDED BY NIHR | National Institute for Health Research

For further information, please contact your local research facilitator, details on page 16 or contact the Programme Manager, Jane Barnett, Email: renewed2@soton.ac.uk, phone: 023 8059 1752.

Improving antibiotic prescribing for children with ear discharge - we need your help

Researchers at the Universities of Bristol and Southampton are looking for GPs and Nurse Practitioners nationwide to help recruit 399 children to a study comparing antibiotic treatments for Acute Otitis Media with discharge (AOMd).

Read all about it

the runny ear study

It is believed that nearly all children with AOM or AOMd in the UK are treated with oral antibiotics. It may be that alternative treatments such as an antibiotic eardrop or delayed oral antibiotics could be at least as effective as immediate oral antibiotics for children with AOMd.

With your help we will recruit children aged ≥12 months to <16 years from September 2018 to July 2020. To help you recruit, we are using a cutting-edge, secure electronic platform that automatically integrates with GP electronic medical records to help you through the process and avoid duplicate data entry.

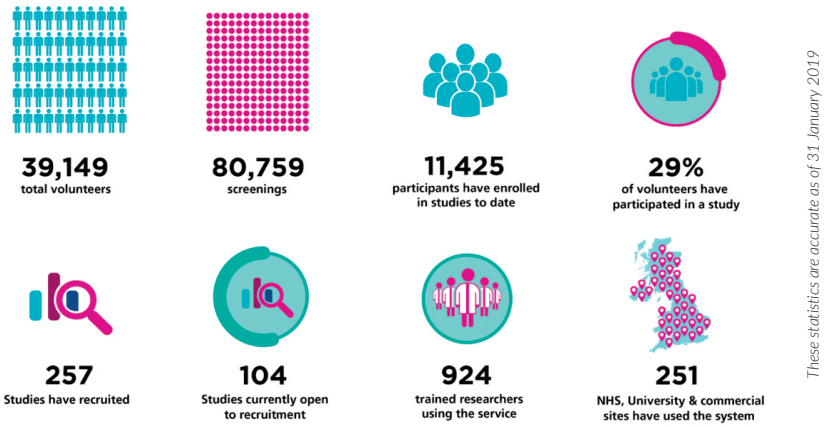
Together we can provide the evidence to improve the treatment of AOMd. Thank you.

If you think your practice would be interested in supporting the first national trial of its kind, please email rest-study@bristol.ac.uk

Join Dementia Research (JDR) www.joindmentiaresearch.nihr.ac.uk is still being widely promoted across the UK and members from the West Midlands primary care Patient Public Involvement and Engagement (PPIE) team continue to actively develop and support new ways of approach to spread the word to a wider audience, and increase the volunteer recruitment rate for the region

As a reminder, the initiative is part of the 2020 Dementia Strategy and provides a platform for members of the public to register their interest in volunteering to participate in dementia-related research. By signing up to the register, volunteers provide their consent to be contacted by researchers whose studies have been downloaded onto the system. Anyone over the age of 18 can sign up. You do not need to have a dementia-related diagnosis. It is also open to family members, carers and friends of those with dementia.

Join Dementia Research in numbers



These statistics are accurate as of 31 January 2019

The aim of the Dementia Strategy is for every newly dementia-diagnosed individual and their carer to be signposted to JDR. The target set is 25% of those diagnosed to be registered, with 10% of the volunteers participating in research. By 2020 a target of 100,000 volunteers to be registered on JDR has been set.

As at 31 January 2019 nationally 39,145 volunteers had signed up, 34,193 do not have a diagnosis, 4,952 do. Within the West Midlands region 48,177 people have a diagnosis. 2,439 volunteers have registered, 2,064 without a diagnosis, 375 with one.

How can you support us?

We would like extend a warm welcome to Karen Cooper, Practice Manager from the Bulkington Surgery on becoming the West Midlands' first Professional JDR Champion within a GP setting. Karen and the surgery already provide dementia support and information to clients, were keen to share research opportunities and will be actively promoting JDR within the surgery.

If you would like to know more about becoming a JDR Champion and have access to up to date information, promotional material and much more please visit the JDR website: https://news.joindementiaresearch.nihr.ac.uk/further-information/help-spread-the-word/champion/

If you would like any further information about JDR, please do feel free to contact your local primary care team member or Jacqueline Smart on jacqueline.smart@nihr.ac.uk

Coventry Dementia Cafe

As part of the Join Dementia Research (JDR) Innovation and Improvement project in primary care, Research Nurse Eleanor Hoverd attended the Coventry Dementia Café in October 2018 to raise awareness about JDR to patients and their carers affected by the condition. The Coventry Dementia Café is held regularly at Queens Road Baptist Church, Grosvenor Road, Coventry and is run by Fiona Coombes, Regional Administrator for the Alzheimer's Society. It provides dementia patients and their carers with the opportunity to share experiences and have an informal chat with those in a similar situation with support provided through offering information and advice.

Eleanor presented an informal talk to a group of 30 - 40 dementia patients and their carers about Join Dementia Research, how to find out further information and register if interested. There were many questions such as "are we getting closer to a cure?" Two people were already taking part in a dementia trial. Interestingly, no one had previously registered with JDR. Leaflets and registration forms were distributed to those interested.

Eleanor says: 'I thoroughly enjoyed speaking to patients and their carers about JDR at the Coventry Dementia Café and propose that we aim to raise awareness about JDR at more dementia cafes around the West Midlands as part of our project. These patients and their carers have a strong desire to improve care and treatment for those suffering with this devastating condition and were keen to find out more about current research evidence on dementia and future research study opportunities. The atmosphere is relaxed and informal and provides a safe environment for people to ask questions.'

WE'VE GOT YOUR BACK

Improving the understanding of back-pain by combining patient generated data with health-records

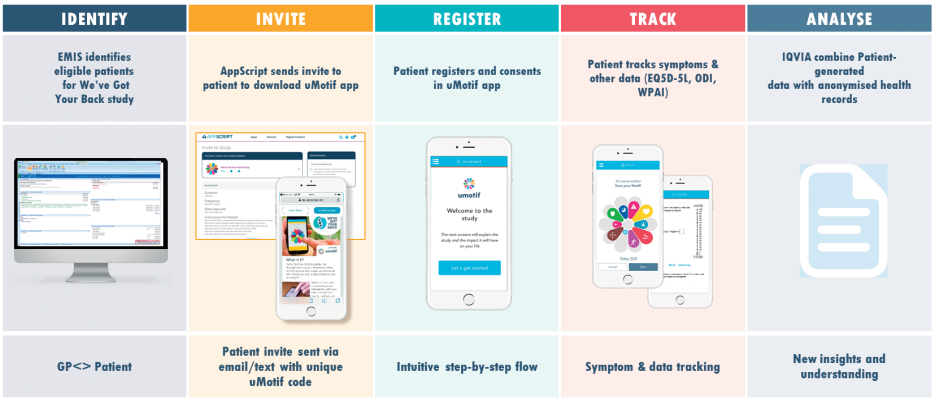
Through collaboration between Leeds University, National Institute for Health Research (NIHR), Clinical Research Network West Midlands, EMIS, IQVIA and uMotif, an innovative smartphone app has been developed to capture real-time, patient reported data which is combined with participants' electronic medical record creating enriched datasets for researchers.

This significantly reduces physician burden and costs through efficient, cost-effective study recruitment and data extraction, as consent and data collection is undertaken through the app. This ground-breaking approach opens opportunities to revolutionise, how we efficiently identify, recruit patients and obtain real-time data from study participants, whilst allowing both patients and clinicians to more effectively manage their illness.

Enrolment occurs via the app. The app delivers study questionnaires at specified times with recorded data seamlessly entered onto the study database. It also allows patients to record real-time data, helping clinicians to develop individualised care-plans with their patient whilst symptom tracking empowers patients to self-manage their condition more effectively.

Simple to Identify, Simple to Invite, Easy to Track

By combining multiple technologies into one seamless flow, a new form of real-world evidence study can be generated



The study team requires 30 practices to participate across the West Midlands. For further information please contact your local research facilitator, contact details on back page.

Increasing representation of Patient Research Ambassadors (PRAs) in Primary Care

Only two out of 100 PRAs in the West Midlands region are volunteering in primary care. 75 are with secondary care trusts, 15 with the Young Persons' Advisory Group and 10 with the CRN West Midlands. Updates indicate only a possible handful of PRAs volunteering in primary care elsewhere in the country. Partly, this is due to establishing how to support PRAs, as each region has a slightly different set-up. Primary care Patient and Public Involvement and Engagement Lead Eleanor Hoverd explains:

'It is vital that we increase representation of PRAs volunteering with us in primary care in order to: engage with GP practices; raise awareness about health research; engage with marginalised groups, study teams; identify areas for research that are relevant and important to patients; increase the visibility of research within general practice and reduce health inequalities through innovation and providing the opportunity to be involved and engaged.

In order to develop a culture of equality between health research professionals and PRAs, the infrastructure must be created to support them. In the West Midlands, we have recently advertised for more PRAs to volunteer with us in primary care over a period of six weeks, which has led to several expressions of interest from patients and the public. Our aim initially, is to establish a small group of PRAs who are interested in volunteering with us in primary care - and it looks like we will achieve that this year.'

Examples of impact thus far include: co-development of a primary care PRA Delivery Plan; providing induction, further training and a NIHR email for PRAs; PRA engagement with a local practice and their Patient Participation Group; building relationships – ensuring PRAs feel part of the team; forming a PRA Working Group to guide the direction of future activities; forming a Join Dementia Research working group to work on an Innovation & Improvement project; matching PRA interests e.g. care homes, equality, diversity & equity work streams; providing JDR training; introducing PRAs in Participate; engagement with study teams; advertising for more PRAs to volunteer in primary care; putting the importance of primary care PRAs on local and national agendas – primary care now has a monthly update slot on the national PRA teleconference.

NIHR INNOVATIONS IN PPIE
Small Grant Awarded in Primary Care: Vidibooks

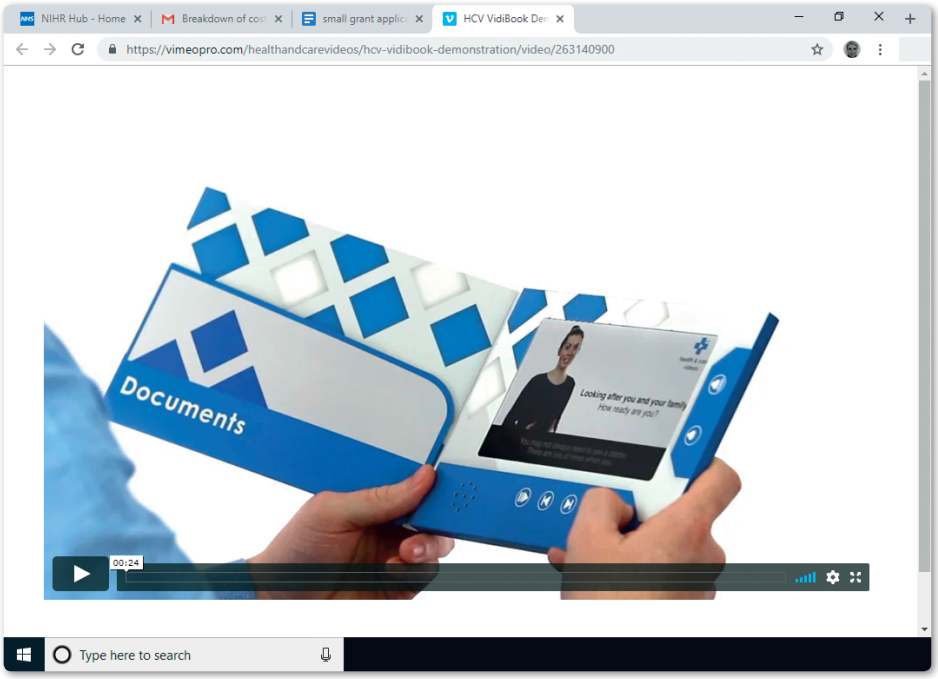
An application was submitted to the NIHR small grant (Innovation in PPIE) competition in 2018 which provides access to resources to support innovative ideas and enable the opportunity to work in different ways.

The primary care PPIE team was successful with its application and used the award of around £2.9k to purchase 30 bespoke vidibooks, in collaboration with Health and Care Videos company, a trading arm of Health and Care Innovations LLP, a partnership with Rocklands Media and NHS Torbay and South Devon NHS Foundation Trust.

The vidibooks aim to increase research awareness and improve patients' understanding about health research through watching four, short videos. They will allow for bite-size learning which has been proven to improve engagement (Growth engineering 2018, Lawson 2018) and improve mobility of information as they can be used in any venue. Vidibooks are fully portable so can be used in different practices, venues and community settings, without the need for WIFI or licences.

Two of the four videos that are proposed to be part of the vidibooks are animated, which can help improve understanding of complex concepts and can also make boring information interesting (Ramon 2018). Choosing short videos benefits a limited attention span (Health and Care Innovations LLP 2018), along with being an excellent marketing tool - which may help in gaining interest about health research (Ramon 2018).

The 30 vidibooks will be distributed between the three primary care localities in the West Midlands (North, South and Central teams) to research active practices, where Research Nurses and Research Facilitators are based, or visit regularly, to raise awareness of research in primary care via a new partnership with Health and Care Videos.



We could cut down on paper leaflets and posters, which has both cost and environmental benefits. Most excitingly, this project has the potential to introduce a new way of sharing and learning that could be a step towards reducing inequalities in access to health research through:

- Increased awareness and access to information about clinical research within primary care, not only for patients, but for staff and Patient Research Ambassadors
- Improvement in the format in which information is shared with patients
- Offering access to health research for patients, in particular those who may prefer not to read, or do not have the ability to read about research
- Increasing patient participation in Join Dementia Research and other studies within the West Midlands
- Stimulating interest from patients and the public in getting involved in research and sharing their stories
- Collaboration with other networks and specialities if the project is successful, as the vidibooks can be made bespoke to suit the needs of various populations

The vidibooks will be launched in Spring 2019

References:

Growth engineering (2018)
http://www.growthengineering.co.uk/why-learning-needs-to-be-bite-sized/

Health and Care Innovations LLP (2018) The advantages of using short videos. 22 July 2018
http://www.healthandcarevideos.com/production/advantages/

Lawson, Maria (2018) 4 Benefits of Bite-Size Learning. Edge2Learn. 22 July 2018
https://www.edge2learn.com/four-benefits-of-bite-size-learning/

Ramon, Ray (2018) How animations can help your business - 7 ways. 22 July 2018
http://www.smallbiztechnology.com/archive/2018/07/how-animations-can-help-your-business-7-ways.html/#.W1S0p9JKjIU

For further information about the vidibook project please contact:
Research Nurse Eleanor Hoverd, email: eleanor.hoverd@nihr.ac.uk

The Children with Cough Cluster Randomised Controlled Trial: CHICO RCT

Respiratory tract infections (RTI) in children are extremely common and there is wide variation in antibiotic prescribing between regions, practices and individual healthcare practitioners. There is growing concern about overuse and misuse of antibiotics, combined with the slowing in development of new antibiotics, which is resulting in proliferation of antimicrobial resistance.

CHICO is a Randomised Control Trial, where GP practices are randomised to use either CHICO intervention or continue their usual practice for all their consultations with children aged 0-9 years presenting with acute cough or respiratory tract infection (RTI). The study does not involve patient recruitment or consenting.

There will not be any deviation from the standard care offered to patients attending consultation at the participating surgeries.

CHICO intervention originated from the five year NIHR programme TARGET, which helps the clinician to decide which children are unlikely to benefit from an antibiotic. Embedded in EMIS WEB, the intervention consists of a prognostic algorithm, and is used as a decision aide in the background, alongside clinical experience. The treating clinician will receive a pop-up on their screen and will have the option to use this aide to assess the risk of hospitalisation. An information leaflet for carers and a personalised letter that addresses parental concerns and treatment strategy are also embedded.

The study is currently recruiting practices from Dudley and Walsall CCGs. Practices need to nominate a member of staff as practice champion who will act as a main contact and monitor the study.

For more information, please contact your local facilitator, Anu Krishna, details on back page.

Alzheimer's Society Memory Walk

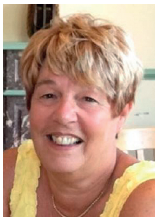
Julie Timmins, Acting Senior Research Nurse, CRN West Midlands - Central

Somi, Azaria, and I attended the memory walk in Sutton Park on Saturday 15 September, Somi's birthday, to promote JDR. It was a beautiful hot summer's day with over 5,000 walkers.

We had a great response to the kiosk and had to fill in paper forms as the queue was so long. Even the jacket potato man provisionally signed up!

After a long eight hours in the sun we were glad to get home and put our feet up. Many thanks to Somi for doing this on her birthday: that's dedication.

Goodbye and Good Luck to Hilary Percival



Hilary joined the Clinical Research Network (formerly PCRN) as a temporary Finance Administrator and was formally appointed in January 2009. She has been responsible for keeping us in the West Midlands on track with EDGE and the Open Data Platform (ODP). Her main role however is the overall management of practice payments. In 2016 all payments to GP practices transferred from the local universities (Birmingham, Warwick and Keele) to the Royal Wolverhampton NHS Trust. Hilary was instrumental in ensuring a smooth transition, ensuring that practices were fully aware of this change and ensured all permissions were in place. In the same year she received an award from the Network for her:

"fantastic attitude towards the changes to the finance and GP practice payment process. Her ideas contributed to the success of this transition".

Much to the irritation of her friends and colleagues, Hilary has been on count down telling us on a daily basis how many days she has left until she no longer needs to get up for work. She never misses an opportunity to tell anyone passing through that she will be retiring at the end of May. In fact she timed her retirement date so that she could be free to watch Wimbledon any day any time. She is an avid tennis player (currently in her mind!) and assures us that she will take this up when she retires.

We will all miss Hilary and wish her well for the future.

THE UCON Trial

Ulipristal acetate versus conventional management of heavy menstrual bleeding (HMB; including uterine fibroids): a randomised controlled trial and exploration of mechanism of action

Menstrual bleeding complaints affect quality of life and comprise a substantial societal burden, including major impact on health care use and costs. In the UK, one million women annually seek help for heavy menstrual bleeding (HMB). Current common treatments for HMB include COX-inhibitors, anti-fibrinolytic therapy, and the levonorgestrel-releasing intra-uterine system (LNG-IUS) recommended by NICE as the first line of medical treatment. The LNG-IUS significantly reduces the burden of heavy menstrual bleed compared to non-hormonal treatments; however women may still experience unpredictable unscheduled bleeding, which may be problematic, with up to a third ceasing use within two years.

Ulipristal Acetate (UPA) is the only selective progesterone receptor modulator (SPRM) to have been licensed for use in clinical practice, though restricted to two cycles of three month pre-treatment of fibroids prior to surgical removal.

The efficacy of UPA was evaluated in two concurrent randomised controlled trials 'PEARL I and PEARL II'. Both trials demonstrated control of HMB in over 90% of women and amenorrhoea in over 70% women. There were no serious side effects or complications associated with UPA; adverse events were limited to minor complaints in these studies.

There is an urgent need to develop safe, simple, acceptable, fertility-sparing medical treatments for HMB and evaluate the use of UPA against current best medical treatment for all women with HMB. The primary objective of the UCON study is to determine if UPA is more effective at reducing the burden of HMB symptoms than LNG-IUS after 12 months of treatment.

The study will be looking to recruit females aged 18 years or over who perceive their bleeding to be heavy or troublesome.

What is involved for practices?

Practices will have option to choose opportunistic recruitment or through search and mail out:

- Search GP database in accordance with inclusion/exclusion criteria as defined in the study protocol
- GP to check the list
- Mail out to potentially eligible patients using DOCMAIL

Practice remuneration

Service support costs: **£57.49** (database search and list checking) or £45 for each patient confirmed as randomised to the study. Research costs: **£12.44** will be paid for mailing using DOCMAIL. The service support costs are pro-rata based on a mailing of 41 patients. This is PIC activity and recruitment and consent will be undertaken by the study team located at Birmingham Women's Hospital.

UCON is funded by Medical Research Council (MRC) and National Institute for Health Research (NIHR) - Efficacy and Mechanism Evaluation (EME) programme (Ref 12/206/52.

The study is currently recruiting from GP practices in CRN West Midlands Central area.

For more information, please contact your local facilitator, Anu Krishna, details on back page.

Clinical Research Network West Midlands VIP Staff Award Ceremony, 11 December 2018

On 11 December 2018 the Clinical Research Network West Midlands (CRNWM) held a VIP Staff Award ceremony at the Everyman Cinema at the Mailbox in Birmingham to celebrate the contributions of staff from all around the Network. There was a lot of competition for these awards and staff in receipt of an award were selected for going above and beyond what was expected of them in their roles.

Many congratulations to Lucy Hughes and the ROST Team.

Lucy Hughes, CRN Primary Care, won the award for Facilitator of the Year. Lucy is also part of the Recruitment Optimisation Support Team (ROST) within and her contribution as part of that team has helped to improve the way in which searches are run in primary care. The ROST Team were highly commended for their work.

Mediterranean diet, Exercise and dementia risk in UK adults (MedEx-UK)

We are currently recruiting GP practices within Birmingham to take part in the MedEx-UK study.

Dementia is a growing problem. There are currently about 850,000 people with dementia in the UK, and this is forecast to increase to over two million by 2051. Researchers want to understand what causes dementia so that they can help prevent or delay it as people age. Although there are some drugs available to treat the symptoms, there is currently no cure, and little is known about how to slow its progression. Over the past ten years, scientists have identified certain factors which are associated with a lower risk of dementia, including eating a Mediterranean diet and taking regular exercise. However, more evidence is required from human studies to show that these factors improve brain function.

This study will be testing if a Mediterranean diet, along with regular exercise, improves brain function (cognition) in individuals aged 55-74 years, at risk of developing dementia. It will look at cardiovascular risk, as this has shown associations with dementia incidence in older ages. MedEx-UK will attempt to change the diet and exercise habits of people over a short period of time (24 weeks). If this is successful, it is hoped that a larger trial could be run in the future.

The study is being run at three UK Universities (Norwich, Newcastle, and Birmingham). At each of these, volunteers will be recruited from GP practices to ascertain whether diet and exercise behaviours can be changed. The aim is to recruit 108 people aged between 55 and 74, who have no diagnosis of dementia but may be at risk of developing it in later life (as identified through cardiovascular health risk factors). Volunteers will be allocated to one of three groups:

- Group 1: Mediterranean Diet & Physical Activity
- Group 2: Mediterranean Diet only
- Group 3: Control

Local research activities

Potential participants aged 55-74 years will be identified through computerised searches of patient records. Those potentially eligible will be contacted directly by the GP practice, provided with brief information regarding MedEx-UK, and directed to an online Participant Information Sheet. Patients will initially be screened using an online questionnaire and then if suitable asked to attend the University of Birmingham for a full screening.

What will it involve for GP practices?

- Identification of potential participants from computer record search (provided by the study team)
- Checking of list prior to mail-out using DOCMAIL

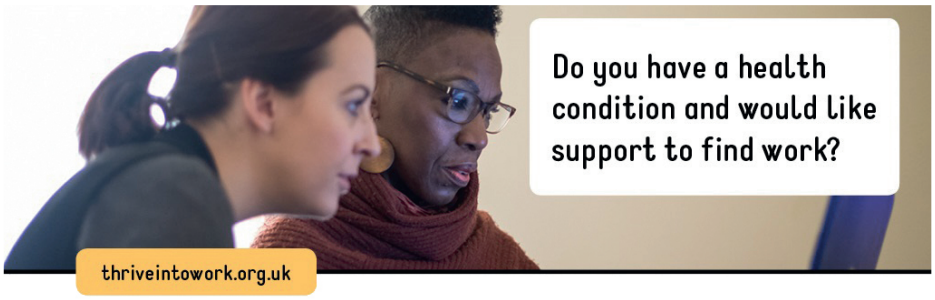
It is expected that each practice will identify approx. 600 potentially eligible patients (with 12 enrolled into the study). These are averages so may be more or less depending on the size of the practice. Research & Service Support Costs are £271.24 (pro rata based on the number of patients identified at the practice). Please note that this study also qualifies as part of the Research Site Initiative (RSI) scheme, as a Level 1 study: £300 payment to participating practices.

This study is sponsored by the University of East Anglia and funded by Alzheimer's Research UK.

If your practice would be interested in taking part or would like to find out more about this study, please contact your local facilitator, Sheila Bailey, details on contacts page.

NEW Research Sites Initiative (RSI) Practices: Moss Grove Surgeries (Kinver and Kingswinford)

The central team would like to welcome Dr Jayesh Patel, and his colleagues at Moss Grove Surgeries in Kingswinford and Kinver, to the RSI scheme. Dr Patel has been very research active over the last few months including taking part in the SupportBack2 trial, where they reached their recruitment target within a month! Moss Grove Surgeries will join the RSI scheme in 2019-20 financial year and we look forward to them being involved in many successful trials in the future.



Thrive into Work Study - GP Pilot

Thrive into Work NHS

Additional Funding for Primary Care Networks and Participating Practices

The Thrive Into Work team, has been working with the Primary Care Network to identify a scheme to increase referrals into the service. There is funding available to support this initiative through the Primary Care Network localities, which is available upon application

Each Primary Care Network, accepted into the scheme, will receive £9,000 and each practice within the Primary Care Network will receive £4.50 per referral.

To secure access to this funding:

1. Each Primary Care Network will be required to identify a lead practice to sign the Service Specification on behalf of the practices in their Network. This will commit the Lead Practice to:
   - Identify a practice where the Employment Specialist can be hosted
   - Agree a network target with the West Midlands Combined Authority (WMCA) and Dudley and Walsall Mental Health Partnership (DWMHT)
   - Agree an operating model for the way in which this work will be embedded within existing schemes or new approaches such as nurse led specialist clinics
2. Each practice will be required to:
   - Allow the Clinical Research network to conduct a search of the practice/ network populations to identify potential trial eligible participants and conduct an initial screen of the generated list to remove patients that may not be suitable for the trial
   - The potential participants will need to be flagged on the clinical system and referred to the Employment Specialist
   - Identify through local knowledge and intelligence any additional patients that may be eligible
   - All relevant members of the practice/Network will receive an initial education session in relation to trial eligibility and protocols
   - The practice will use the electronic-Referral System (e-RS) to refer patients to the Employment Specialist
   - They will agree to Thrive IPS marketing materials being visible and accessible to patients for the duration of the trial; this would include use of TV Screens in waiting rooms
   - Each Network will work with the West Midland Combined Authority representatives and its providers to develop a mutually acceptable process to monitor and manage uptake
   - The practice/Network will contribute to the national evaluation (process and qualitative) of the IPS Programme

If you have any questions regarding this new pilot scheme, please do not hesitate to contact Dr Fozia Ikram-Bashir, Thrive into Work IPS Programme Clinical Engagement Lead, on: 07920 150070.

Princess
Probiotics to Reduce Infections iN CarE home reSidentS

PRINCESS: Probiotics to Reduce Infections iN CarE home reSidentS

Berwood Court Care Home

A massive thank you to Berwood Court Care home, Victoria Hardy and Lucia Crkonova for all their hard work on the Princess Study. The picture shows the team with some appropriate thank you gifts from the study team to show their appreciation.

The study investigated whether administering a probiotic to the residents helped reduce incidents of common ailments in this vulnerable group.

If successful, it would be a cost effective way of significantly improving the quality of life for this group of people.

Join dementia research at Hereford City Library

By Claire Brown, Research Nurse

Join Dementia Research (JDR) has been developed by the NIHR in partnership with Alzheimer Scotland, Alzheimer's Research UK and Alzheimer's Society to allow people to register an interest in participating in dementia research. Those with dementia or memory problems, their carers or anyone who is interested, can sign up. West Midlands wide we have a number of JDR kiosks, to move between sites and enable JDR enquiries using an interactive touch screen. A short animation gives information about the service, and an electronic form requiring just a name and contact details is available. This information is sent securely to the JDR team and the individual is given more information about signing up.

To try to engage more people in Hereford city centre, following a successful International Clinical Trials Day event, it was decided to take a kiosk to Hereford Library and promote JDR. This city-centre library provides a wide range of services to Hereford's 66,000 residents and gave us a great opportunity to reach local people. The Library Manager, Jon, and I decided that as Tuesday was their busiest day, this would be the time to bring the kiosk. Posters promoted the day; electronic versions were shared on screens and via the library's social media.

I decided to wear uniform, as experience from Clinical Trials Day indicated this promoted more discussion and interest from onlookers as it's not something they normally see in the library. The kiosk was set up in the library entrance to catch the eye of passers-by; after a slow start approximately 20 people expressed interest in JDR using the kiosk and a handful more took leaflets from the front of the stand.

I also had discussions about my role and research in general, and encouraged people to ask their GP about what research opportunities were available at their practice.

After a successful day, we decided to leave the kiosk at the library for a short while to allow continued sign up. After a week or so I asked how things were going and how the kiosk was being used. Unfortunately, it appeared that not many people had used it, and that without someone staffing it there wasn't much interest. It will be interesting to see how many people, if any, made autonomous use of the kiosk.

We now have good links to local libraries, which are keen to support and promote future events. The library, which is dementia friendly, really enjoyed being involved and hosting the kiosk. Other local libraries have now asked if they can do the same, so I am planning to take the kiosk to the smaller rural libraries. It would be interesting to hear how other sites have used the kiosks, and whether they have had similar experiences with leaving it unstaffed.

All in all, this was a great opportunity to meet local people, promote discussion, and raise the profile of the Clinical Research Network within the area.

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Hereford Library, Working in Partnership with CRN

By Jon Blackhouse, Library Manager, Hereford Library

Since coming to work in libraries over a decade ago I've seen many changes take place, not just relating to how libraries operate, but also in regards to how we are perceived, and how we as a service perceive our role in the community.

Being situated as we are, we see people from all aspects of life. A common saying amongst staff is that people use us from cradle to grave, morbid as it sounds. It's very true though.

Due to this, and with a clear direction of travel from our Core Libraries Strategy, I actively encourage any potential partnership working. The latest example being to link in with the NIHR Clinical Research Network West Midlands to promote the Join Dementia Research initiative.

All staff at the library are Dementia Friends; it's a subject that affects all of us, not just in our private lives but on a daily basis during work, as we see customers who we have known for years slowly deteriorate. We also have worked with the Alzheimer's Society over the last year to try and help promote the great work they do, so when Claire, a Research Nurse from the CRN, contacted me initially about the possibility of them having a space at the library I jumped at the chance.

The more that we can do, and the more that awareness can be raised, is all for the good. Having links with Claire and being supportive of the great work she is doing can only benefit us all, and from our customers' view point it helps to show that we are more than just a place to get your books from.

Hopefully as more research and understanding take place, we can eventually look at being able to better combat what is such a sad and life affecting affliction.

Primary Care Nurses - Research Challenges

Eleanor Hoverd, Research Nurse, CRN West Midlands Primary Care

In response to a request from Professor Rosalind Bryar, Co-chair of the International Collaboration for Community Health Nursing Research (ICCHNR) a questionnaire entitled *Primary Care Nurses - Research Challenges* was circulated at the end of September 2018, to 498 nurses working in primary care as Practice Nurses, Advanced Nurse Practitioners and Lead Nurses in GP surgeries in the West Midland. Seventy-eight responses were received (15.8%).

Q1 What is your job title?

64% Practice Nurses, 21% various titles, 14% Advanced Nurse Practitioners 1% Director of Nursing.

Q2 How many years' experience do you have as a nurse?

The majority between 31-40 years of nursing experience (45%). 93% of the respondents have more than ten years of nursing experience.

Q3 Please describe your primary care setting

77 are in a GP Practice, one in Respiratory/Cardiac.

Q4 Are you involved in clinical research in the primary care setting where you work?

More than 75% are not involved in clinical research.

Q5 What experience do you have in clinical research?

The majority described their experience of clinical research as: none, minimal, very little or limited. Around 35% have experience of clinical research as part of their nursing role, but the number of projects involved in varies, as does the frequency and level of involvement.

Q6 If you do not already take part in research, would you like to?

A small percentage said they would not like to take part in research. It would be helpful to explore the reasons why, along with the 37% who aren't sure. It may also be useful to see if this is also the case in other countries, do the same barriers exist to not wanting/being unsure about taking part?

Q7 What prevents you from being involved in clinical research in your current role?

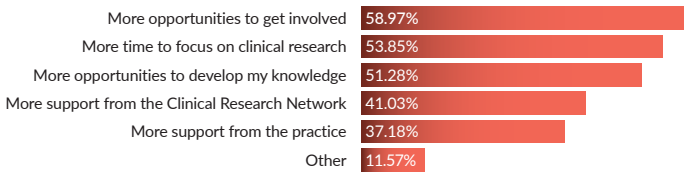
The biggest barrier is lack of time (67%). A large proportion (47.44%) felt more opportunities are needed, but 44.87% are fearful of increasing workload, potentially affecting motivation. Lack of understanding and knowledge are barriers to involvement with a few feeling challenged by lack of support. A very small minority (2.56%) were not interested in clinical research.

Barriers to involvement

Q8 What would enable you to become involved in research in your current role?

Many feel that more opportunities, more time, and chances to develop knowledge would enable participation in research. 41% felt more support from the CRN would help - this would be useful to explore further to identify specific areas for improvement. 37% felt they required more support from their practice. Comments included the suggestion of central co-ordination through training hubs as an enabler.

What would enable your involvement in research?



Q9 Please make any further comments about what, in your opinion, are the challenges that you face as a primary care nurse around any aspect of clinical research.

46% of respondents commented. The pervading view was lack of time for research, due to workload and no protected time. A few mentioned more encouragement and sharing of knowledge/ information may provide better access to research for primary care nurses. A very small number mentioned financial incentive as reward for becoming involved. A couple suggested that nurses are not normally involved in research in the practice.

'Practice nurses have very little time to do research unless they are going to do this as a job given to them by the GP. I think if you have the funds, then you may want to look at a project with nurses to explore this further. . .'

'I feel that visibility is an issue in primary care research in general, which means that it is not hitting the radar of practice nurses. As research nurses we need to be able to provide training or share our knowledge with practice nurses around research. Practices need to provide protected research time, even if just a small amount of time for CRN nurses to facilitate support. Primary Care research always focuses on GPs being the go-to person when new studies become available, but it should be encouraged for nurses to be part of training and information sessions on new studies. Perhaps the ICCHNR could work collaboratively with the CRN primary care teams to encourage the development of practice nurses understanding of clinical research.'

'Would the ICCHNR be able to help with enabling links to marginalised groups, so that participation in clinical research could be more equitable in primary care?'

Brian's Story - The Community Ageing Research 75+ Study (C.A.R.E 75+)

Brian Birch from Staffordshire took part in the CARE 75+ research study which explores how health problems and frailty may develop in later life for a number of reasons. He at first thought the study title seemed interesting and was flattered to be asked to take part as a representative from his community. Brian felt that looking at the variances of health between the differing populations being studied would be beneficial to the medical profession. He was also interested in the prospect of his health being monitored over the next four years to see if any changes occurred over this time period.

Brian stated that the information provided was easily understood and any queries he had were of a social nature, such as how he would have to take part in the study, either at the GP surgery or at home. He preferred that the visits took place at his home.

Brian reported the study to have been a very pleasant experience and he liked the ability to be able to chat to a person in his home. He found some of the questions to be a little ambiguous but the physical measurements were helpful, in as much as he felt he was helping us with our research, he could also monitor his weight and water percentage for example. Brian was also pleased to have his blood pressured monitored and it reassured him that his medication and health were all going in the right direction. He would recommend this study as he found it interesting to participate in. He liked the flexibility of the nurses, who fitted in around his needs and he found there to be no inconvenience in taking part.

Prior to taking part in the CARE 75+ study, Brian had taken part in research, sharing his experience of being a Critical Care patient at University Hospital of North Midlands to approximately 200 people. He added that Research Nurse, Lucy Rosenberg who visited him for the study visits was both very punctual and helpful.

RCGP Midland Faculty's Annual Education, Research and Innovation Symposium 2019

Thursday 23 May 2019, 9am-4.15pm, Keele University

Keele University's Research Institute for Primary Care and Health Sciences is proud to be hosting the 2019 RCGP Midland Faculty Research Symposium which encourages and showcases primary care research, innovative projects and interesting clinical cases from across the West Midlands.

The day aims to inspire and generate enthusiasm for General Practice and research amongst GPs, AiTs, medical students, junior doctors, and allied health professionals from the region.

The day will consist of key note speeches from **Professor Richard McManus** (Oxford University), **Professor Christian Mallen** (Keele University), and **Dr Helen Atherton** (University of Warwick).

There will be breakout groups during the day, where individuals will be able to present their work, poster presentations as well as provide networking opportunities and gain CPD points.

To book your place and find out more, visit the website: keele.ac.uk/rcgp

I Am Research Event

In 2016 Sheena Davidson shared her research story with the Network after participating in a stroke research study. Sheena has such a passion for research that she went on to become a Patient Research Ambassador for the Network. Since starting in the role, she had always been keen to host an event to raise awareness of research among the residents of Pannel Croft Retirement Village in Newtown, Birmingham where she lives.

In the spirit of involvement, staff from the Network and the Village met with Sheena and other residents on a number of occasions to work with them on ideas for an event. This resulted in the I Am Research day at the Village on Friday 1 February. There were presentations, including patient research stories and 20 charity and Network displays featuring information on rheumatoid arthritis, dementia, stroke and eye conditions. The Pannel Croft Community Singers and the Stroke Club Singers were also on hand to entertain attendees.

Feedback from the day was excellent and future events at other retirement villages are planned.

> *"A fantastic idea to host a research event at a retirement village."*

> *"Really good opportunity to learn about research and what is going on in the region."*

> *"Fantastic opportunities to find out information: well organised."*

POWeR
Positive Online Weight Reduction

Aim: Behavioural counselling with intensive follow-up for obesity is effective, but in resource-constrained primary care settings briefer approaches are needed. The aim of the study was to estimate the clinical effectiveness and cost-effectiveness of an internet-based behavioural intervention with regular face-to-face or remote support in primary care, compared with brief advice.

Method: Positive Online Weight Reduction (POWeR+) is a 24-session, web-based weight management intervention completed over 6 months. Following online registration, the website randomly allocated participants using computer-generated random numbers to (1) the control intervention (n = 279), which had previously been demonstrated to be clinically effective (brief web-based information that minimised pressure to cut down foods, instead encouraging swaps to healthier choices and increasing fruit and vegetables, plus 6-monthly nurse weighing); (2) POWeR+F (n = 269), POWeR+ supplemented by face-to-face nurse support (up to seven contacts); or (3) POWeR+R (n = 270), POWeR+ supplemented by remote nurse support (up to five e-mails or brief telephone calls).

Conclusion: Clinically valuable weight loss (> 5%) is maintained in 20% of individuals using novel written materials with brief follow-up. A web-based behavioural programme and brief support results in greater mean weight loss and 10% more participants maintain valuable weight loss; it achieves greater enablement and fewer participants undertaking other weight-loss activities; and it is likely to be cost-effective.

Trial registration: Current Controlled Trials ISRCTN21244703.

Reference: Little P, Stuart B, Hobbs FDR, Kelly J, Smith ER, Bradbury KJ, et al. Randomised controlled trial and economic analysis of an internet-based weight management programme: POWeR+ (Positive Online Weight Reduction). Health Technol Assess 2017;21(4).

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https://www.journalslibrary.nihr.ac.uk/programmes/hta/0912719/#/documentation

Primary Care Clinical Trials Unit
University of Southampton

REFER (REFer for EchocaRdiogram)

Aim: To evaluate the performance of a clinical decision rule (CDR) with or without a natriuretic peptide assay for identifying heart failure in symptomatic patients presenting to primary care.

Method: Prospective, observational, diagnostic validation study and economic evaluation. Participants: Primary care patients aged ≥ 55 years presenting with recent new-onset shortness of breath, lethargy or peripheral ankle oedema of > 48 hours' duration.

The CDR included a clinical element (male, history of myocardial infarction, crepitations at the lung bases and oedema) and N-terminal pro-B-type natriuretic peptide (NT-proBNP) blood test. The reference standard was an expert consensus panel of three cardiology specialists.

Main outcome measure: The main outcome measure was test performance of the CDR and the natriuretic peptide test alone, and in combination, in estimating sensitivity and specificity,

positive predictive value (PPV) and negative predictive value (NPV) for a diagnosis of heart failure. Economic evaluation of a decision tree with a NHS/Personal Social Services perspective determined the cost per quality-adjusted life-year (QALY) gained.

Conclusions: Natriuretic peptide testing alone performed as well as the validated CDR in determining which patients presenting with symptoms went on to have a diagnosis of heart failure. The current NT-proBNP cut-off point of 400 pg/ml used in the UK is too high and means that one in five patients with heart failure may not be appropriately referred for further investigation and diagnosis, but this threshold was cost-effective in the REFer for EchocaRdiogram (REFER) trial. The study found only three patients with heart failure with reduced ejection fraction (HFREF), which might limit the benefits of early detection. The other diagnostic strategies with lower NT-proBNP referral levels become more cost-effective as the proportion of HFREF patients increases. International consensus on the optimal cut-off point for natriuretic peptide testing in patients with symptoms suggestive of heart failure should be sought.

Trial registration: Current Controlled Trials ISRCTN17635379.

Reference: Taylor CJ, Monahan M, Roalfe AK, Barton P, Iles R, Hobbs FDR on behalf of the other REFER investigators. The REFER (REFer for EchocaRdiogram) study: a prospective validation and health economic analysis of a clinical decision rule, NT-proBNP or their combination in the diagnosis of heart failure in primary care. Efficacy Mech Eval 2017;4(3).

Publication: Efficacy and Mechanism Evaluation Volume 3 issue 4 April 2017 ISSN 2050-4365

DOI 10.3310/eme04030

https://www.journalslibrary.nihr.ac.uk/eme/eme04030#/abstract

Medication Review Plus Person-Centred Care

A Feasibility Study of a Pharmacy-Health Psychology Dual Intervention to Improve Care for People Living with Dementia

Ian D Maidment, Sarah Damery, Niyah Campbell , Nichola Seare, Chris Fox, Steve Iliffe, Andrea Hilton, Graeme Brown, Nigel Barnes, Jane Wilcock, Emma Randle, Sarah Gillespie, Garry Barton, Rachel Shaw

Background: *Behaviour that Challenges* is common in people living with dementia, resident in care homes and historically has been treated with anti-psychotics. However, such usage is associated with 1800 potentially avoidable deaths annually in the UK. This study investigated the feasibility of a full clinical trial of a specialist dementia care pharmacist medication review combined with a health psychology intervention for care staff to limit the use of psychotropics.

Methods: West Midlands care homes and individuals meeting the inclusion criteria (dementia diagnosis; medication for behaviour that challenges), or their personal consultee, were approached for consent.

A specialist pharmacist reviewed medication. Care home staff received an educational behaviour change intervention in a three-hour session promoting person-centred care. Primary healthcare staff received a modified version of the training.

The primary outcome measure was the Neuropsychiatric Inventory-Nursing Home version at three months. Other outcomes included quality of life, cognition, health economics and prescribed medication. A qualitative evaluation explored expectations and experiences of care staff.

Results: Five care homes and 34 of 108 eligible residents (31.5%) were recruited, against an original target of 45 residents across six care homes. Medication reviews were conducted for 29 study participants (85.3%) and the pharmacist recommended stopping or reviewing medication in 21 cases (72.4%). Of the recommendations made, 57.1% (12 of 21) were implemented, and implementation (discontinuation) took a mean of 98.4 days. In total, 164 care staff received training and 21 were interviewed.

Care staff reported a positive experience of the intervention and post intervention adopting a more holistic patient-centred approach.

Conclusions: The intervention contained two elements; staff training and medication review. It was feasible to implement the staff training, and the training appeared to increase the ability and confidence of care staff to manage behaviour that challenges without the need for medication. The medication review would require significant modification for full trial partly related to the relatively limited uptake of the recommendations made, and delay in implementation.

Trial registration: ISRCTN58330068. Registered 15 October 2017. Retrospectively registered.

Published: BMC Psychiatry201818:340 https://doi.org/10.1186/s12888-018-1907-4

GP Indemnity for Research

In the past there has been a lot of confusion around the indemnity provision for research in primary care. With the introduction of the Clinical Negligence Scheme for primary Care (CNSGP) clinical negligence arising during the course of research is covered. For example, if the doctor misreads a dose of a trial drug and gives too much of a drug which harms the patient the new scheme would cover this. What the scheme will cover can be found in the link to the following document https://resolution.nhs.uk/wp-content/uploads/2019/03/CNSGP-Scheme-scope.pdf

What is not covered is the risk from the design of the clinical study or if the patient comes to harm from the study despite the protocol being followed with no errors. This risk would be covered by trial sponsor's indemnity. Evidence that the trial sponsor has indemnity is checked by the Clinical Research Network before the study is sent out to practices. This reflects what happens in secondary care.

The progress that the new process brings is excellent news and removes uncertainties around research indemnity and also confirms that additional indemnity cover for research from the MDOs is not required. Thank you for your ongoing support with research delivery in primary care and with this reassurance we can deliver more research in primary care safe in the knowledge that indemnity is provided for the research activity we undertake.

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Changes to the Process for Managing the Excess Treatment Costs Associated with Research

On 1 October 2018 a new model for the management of excess treatment costs related to non-commercial research was implemented by NHS England, National Institute for Health Research, Health Research Authority and the Department of Health and Social Care (DHSC). This will bring about changes to the way that excess treatment costs are paid, which you need to be aware of and may directly involve your practice when you participate in NIHR portfolio research studies that have associated excess treatment costs. The new process means that GP practices may receive the payment that covers the cost of the research intervention the patient recruited into the study by the GP eventually receives. However, if the intervention was delivered by another organisation for example an NHS Trust, the payment will need to be reimbursed to the organisation who incurred the cost of the extra treatment. The organisation will contact the practice to invoice for the relevant amount.

Unfortunately the payment process is mandated by the DHSC and cannot be altered by the Clinical Research Network, nor can we interfere in the process to direct the payments to the provider who actually incurred the costs. This new payment process is being implemented for all studies that involve excess treatment costs and will be the norm going forward.

We will write to you to inform you when you are about to receive a payment, how much the payment will be and which study the payment relates to. Please could you ensure that this money is identified in your accounts as money that will be passing through the practice rather than income generated from research within the practice? We apologise for any inconvenience that this may cause and ask that you direct any enquiries to NHS England via the following generic e-mail address - **supportmystudy@nihr.ac.uk**