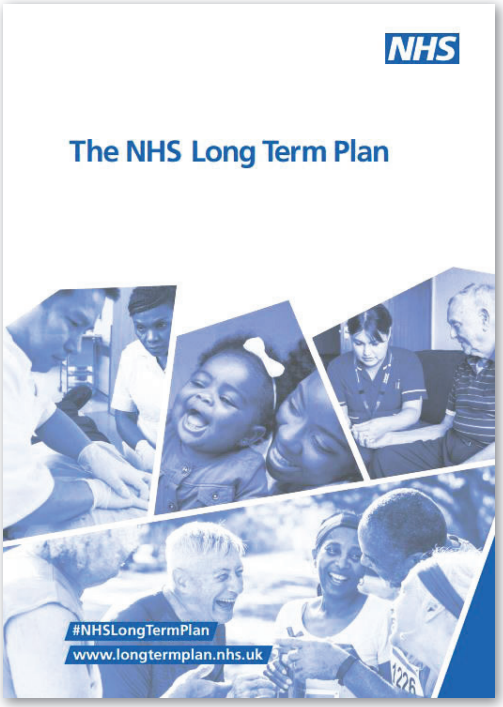
NIHR | Clinical Research Network West Midlands

Autumn 2019 Edition No. 6

PARTICIPATE

Primary Care Networks (PCNs)



One of the objectives in the NHS Long Term Plan is to increase the number of patients registering to participate in research across the NHS to one million by 2023/24. It states that research is essential to improving patient wellbeing, and emphasises how research engagement will drive quality improvement, professional development and also generate income for the practice.

The Clinical Research Network (CRN) in the West Midlands provides a well-established infrastructure for supporting the delivery of research within Primary Care across the region, with an excellent track record for facilitating GP practices to participate in research. Over the last ten years we have developed close working relationships with a considerable number of practices, and, with the recent introduction of PCNs, we are keen to both maintain existing relationships and also to embrace the opportunities presented by this new model for widening participation in research. The CRN is well placed to assist PCNs to develop a research strategy for GP practices and, in the longer term, to embed research in everyday practice which will both benefit patient care, and provide a robust income stream.

If you would like further information or would welcome an informal discussion, please contact either sue.elwell@nihr.ac.uk, Research Manager, or david.shukla@nihr.ac.uk, Clinical Research Specialty Lead for Primary Care.

In this edition we feature articles on:

- The ATTACK Trial, looking at whether the addition of low-dose aspirin to usual care reduces the risk of major vascular events in people with chronic kidney disease who do not have pre-existing cardiovascular disease, see page 2.
- IQVIA MRES (Medical Research Extraction Scheme) which specialises in clinical research, clinical trials and providing analytical solutions to healthcare and life sciences organisations. In the UK, they have collected and supported the research use of non-identified patient data for over 20 years, see page 4.

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

- Study - SupportBack2
- Study - Increasing Physical Activity in Older People with Joint Pain
- Patient Research Ambassador

Contents

Supporting Self-Management of Low Back Pain

SupportBack 2

Image by Wolfgang Claussen from Pixabay

Low back pain (LBP) is one of the most common and costly problems seen in GP surgeries. Internet interventions may provide a new and efficient way of supporting and encouraging patients to become more active in self-management of LBP.

The aim of this study is to determine if an internet intervention called SupportBack, provided both with and without guidance from a physiotherapist over the telephone, is effective in reducing LBP-related disability when compared to usual primary care alone.

806 Primary Care patients with current LBP will be recruited through their GP practices for a Randomised Controlled Trial comparing three groups:

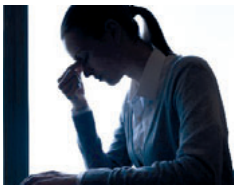
1. Usual care
2. Usual care + internet intervention
3. Usual care + internet intervention + telephone Physiotherapist support

SupportBack provides advice and reassurance, and encourages physical activity over a six-week period. Tailored online materials support gradual goal setting, facilitate monitoring of back-related activities and provide personalised feedback. Telephone physiotherapist support will address concerns, provide reassurance and encourage uptake and compliance with activity goals.

Participants will be followed up at six weeks, three, six and 12 months. Questionnaires will explore how LBP is affecting their daily activities, their level of pain intensity and other LBP-related issues. A GP medical records review will be performed at 12 months which will record health care service use. LBP related costs will be calculated. In-depth qualitative interviews will be conducted with up to 30 trial participants across the three groups to explore their experiences of SupportBack and the care they have received over the trial period.

If you would like further information, please contact your local research facilitator, details on back page

Knowledge, Attitudes and Practice of GPs and Practice Nurses in the West Midlands Regarding Female Genital Mutilation and Cutting: (FGM/C West Midlands)



We are inviting GPs and practice nurses in the West Midlands to take part in the FGM/C West Midlands study, run by the Research Institute for Primary Care and Health Sciences, Keele University in collaboration with Clinical Research Network West Midlands.

In brief, being part of this study will involve completing a **very short** online survey related to your knowledge, attitudes and practice regarding FGM/C.

You can access the survey and participant information sheet, explaining the study in more detail and how you can take part, via this link: https://form.jotformeu.com/90553645158361

** **The survey will take no more than five minutes to complete** **

Thank you for considering taking part in the FGM/C West Midlands study.

Recruitment status: 1 September - 30 November 2019
Sponsor: Keele University
Funder: National Institute for Health Research (NIHR) Research Professorship

Keele UNIVERSITY

If you would like to know more about this study, or have any questions and wish to speak to the researcher(s), please contact Dr Tom Shepherd via t.a.shepherd1@keele.ac.uk or 01782 734824

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

ATTACK

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 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 130 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, email: jennifer.dumbleton@nottingham.ac.uk, phone: 0115 823 1053

Increasing Physical activity in Older People with joint Pain

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 (iPOPP) 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 1085 patients. Each practice will provide approximately 20 participants.

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 (HCA) 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

Option 1 – Practice Health Care Assistant

Allow the practice HCA to attend two full days training at Keele University. Practices will be paid for practice HCA consultation time and for allowing the HCA to attend the training. If you are signed up to the CRN RSI scheme, this study will be paid at Grade Two, £700.

Option 2 – HCA provided by the study team

If you are signed up to the CRN RSI 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 participate in research which can be reported as part of appraisal and revalidation and give their patients the chance to be involved in research.

Arthritis Research UK

Keele UNIVERSITY

Participant identification began in spring 2019. If your practice is interested in taking part, or would like further 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

Improving Antibiotic Prescribing for Children with Ear Discharge

We are recruiting!

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...

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 over a recruitment period of 22 months (starting in July 2019). 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.

We need to recruit 72 children by the end of this year. Please get in contact if you think your practice would be interested in supporting the first national trial of its kind, email rest-study@bristol.ac.uk

The National Centre for Mental Health

NCMH National Centre for Mental Health

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 and Psychosis; Postpartum Psychosis; PTSD; Schizoaffective Disorder

What is involved?

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

Enhancing The Health Of NHS Staff

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.

eTHOS 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 in autumn 2019. We aim to recruit 480 participants across 3 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
  a. attend the staff health clinic and receive assessment for their musculoskeletal, mental and cardiovascular health (or lifestyle advice for those <40 years)
  b. 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
- We will notify you of any test results and potential actions that you may wish to consider
- We 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

IQVIA MRES (Medical Research Extraction Scheme)

The Clinical Research Network West Midlands is pleased to announce that we are working with IQVIA to support practices to sign up to the Medical Research Extraction Scheme.

About

IQVIA specialises in clinical research, clinical trials and analytical solutions to healthcare and life sciences organisations. In the UK, they have collected and supported the research use of non-identified patient data for over 20 years. They have partnered with EMIS Health to offer your practice the opportunity to contribute non-identified data to the research and patient insights programme.

How to join

Joining is a one-time, straightforward process, after which non-identified data is regularly collected automatically from EMIS Web with no impact on day-to day activities.

Benefits for your practice

Your practice would benefit from a quarterly payment of six pence per patient (based on NHS list size).

Data

The data available for research will not include any identifying information on healthcare professionals or patients. IQVIA uses a wide variety of privacy-enhancing technologies and safeguards to protect individual privacy while providing insights that can help drive health policy changes leading to improved outcomes for patients. For more details, visit: https://www.iqvia.com/locations/uk-and-ireland/medical-research-data

These insights include approved scientific research studies for many uses such as epidemiology, drug safety and risk management, public health research, drug utilisation studies, outcomes research and health economics research. You can access the complete IQVIA bibliography at http://www.rwebibliography.com

Approvals

The use of IQVIA™ Medical Research Data extracted from the GP software systems for the purpose of medical research and of supplying the data to external researchers for scientifically approved studies under Data Sharing Agreements has been approved by the NHS Health Research Authority (NHS Research Ethics Committee ref 18/LO/0441).

If you want to know more about the IQVIA data collection programme and take part in the journey to improve patient outcomes, please contact CRN MRES Lead, Saif Uddin, email: saif.uddin@nihr.ac.uk

Trial of Primary Care Based Collaborative Care for People with a Diagnosis of Schizophrenia or Bipolar

Currently recruiting practices in Birmingham and Solihull

PARTNERS2
working together to change mental health care

What are we aiming to do?

Evaluate a new intervention of collaborative care, specifically designed to support the emotional, social and physical health of people with a diagnosis of schizophrenia or bipolar, by placing a specialist mental health worker (care partner) within general practice to work with your staff and your patients for a period of 12 months.

Why do we need your help?

- People with long-term mental health conditions are increasingly discharged back to primary care
- People with a diagnosis of schizophrenia and bipolar die up to 25 years earlier than people without, and are amongst the most socially excluded in our society
- General practice is well placed to support mental and physical health needs but with support from secondary care specialist mental health workers
- We need to test whether collaborative care can improve outcomes for patients, and deliver a positive experience for practitioners

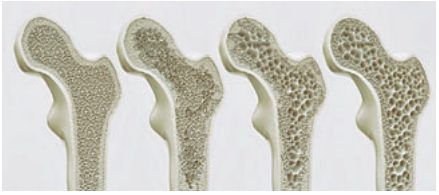
What will it involve for GP practices?

- Lead GP and Practice Manager to attend a site set up visit
- Lead GP to screen and sign off the patient list
- Practice staff to phone patients who do not respond to the rapid invite letter
- Provide a room in order to deliver the study over a ten month period
- GP to report any Serious Adverse Events

The CRN will provide support with search and mailings (including rapid invites), as required.

If your practice would be interested in taking part or would like to find out about this study, please contact Lucy Hughes, local research facilitator, contact details on the back page

Commercial Research Success Story: GP Practices Deliver to Time and Target on Commercial Osteoporosis Study



Seven GP Practices across the West Midlands acted as research sites for an Amgen Osteoporosis study assessing frailty and incidence of osteoporosis diagnoses in women aged over 70. These seven practices included both new, and experienced, commercial research sites across the West Midlands, some being selected within six months of initiating their commercial research training with the CRN Primary Care Industry team.

Practice involvement in the study included undertaking study training, identifying and recruiting patients and submitting the research data to the study team. As a result of careful consideration of study set up at the practice and clearly defined roles and engagement with the CRN, the practices were able to recruit their required patient target within the study recruitment period. This is a fantastic achievement for these practices.

Recruitment to time and target, and efficient study set up, are key factors that commercial sponsors seek when selecting sites for their studies. Additionally, recruitment to time and target is a High Level Objective for the CRN and reaching this target is essential for repeat business from academic and commercial sponsors.

The Primary Care Industry Team can support practices and practice groups to become involved with commercial research by providing training and ongoing support with study expressions of interest, set up and delivery of commercial studies.

The benefits of taking part in commercial research include:

- Access to new treatments which are not routinely available
- The opportunity to contribute to the development of treatments which may improve patient outcomes
- Staff development – opportunity to gain new and different research experience
- Build and develop reputation and relationships with commercial companies
- Source of additional income

Amgen osteoporosis study results

The primary objective was to assess the proportion of women aged over 70 years at increased risk of fragility fracture and not receiving osteoporosis medication. The initial findings for this study have now been published and they found that 55% of women over 70 years old are at risk of fragility fractures with 75% not treated for osteoporosis. Insufficient osteoporosis diagnosis appears to be an important barrier to treatment; future strategies need to increase awareness and facilitate the diagnosis of increased fracture risk to improve primary care management of osteoporosis.

If your practice would be interested in engaging with commercial research, please contact crnwm.primary-care-industry@nihr.ac.uk

CHICO: Caring for Children with Coughs Randomised Control Trial

Respiratory tract infections (RTI) in children are extremely common and there is wide variation in antibiotic prescribing between regions, practices and individual healthcare practitioners. Antimicrobial resistance is a national and global threat to health. Due to this, the NHS England target is to reduce inappropriate antibiotic use by 50% by 2020/21

Background

TARGET Programme (2010 – 2015)
TARGET investigated the care provided to children presenting in Primary Care with respiratory tract infections (RTIs). This focussed on what were the parents' information needs, and on influences on clinical decisions surrounding antibiotic prescribing.

Outcome: The TARGET programme had two important findings (amongst others) that led to the development of the CHICO intervention:

1. Identified predictive signs and symptoms of hospitalisation risk
2. Carer and clinician interviews revealed differences in priorities for both groups that often led to communication being at cross-purposes about the seriousness of the illness

CHICO objectives

To investigate the clinical effectiveness of implementing the findings of the TARGET programme in children aged 0-9 years presenting with cough and RTI.

CHICO intervention: The CHICO intervention is embedded within EMISweb and consists of a prognostic algorithm, an information leaflet for carers, a personalised letter that addresses parental concerns and treatment strategy.

What do practices have to do?

Start: Baseline questionnaire to determine the practice's characteristics (e.g. number of sites, staff, patients, demographics). Confirmation that practices want to take part and will participate in a teleconference (approx. 15-30 minutes). The University of Bristol team will randomly allocate practices to usual care or intervention arm on a 1:1 basis.

Usual care: Practices will continue as per usual practice for 12 months.

Intervention:

1. Import the CHICO intervention (approx. 30-60minutes)
2. Distribute short user guide and self-directed training materials to staff, and encourage staff to use the intervention
3. Use the intervention in consultations for 12 months
4. Run a search once a month to count the number of intervention uses (approx. 10-15minutes)

End: All practices will be given a new questionnaire to capture any changes in characteristics since baseline.

The study also requires your CCG's approval; we have received approvals from the following CCGs:

1. Birmingham and Solihull CCG
2. Dudley CCG
3. Walsall CCG

FUNDED BY NIHR | National Institute for Health Research
University of BRISTOL

For further Information, please contact Anu Krushna or Sophie Bench, details on back page

The Experiences of Setting up a Community Peer Support Group that Promotes the Health and Mental Well-Being of Individuals with Multiple Sclerosis (MS)

Objectives: To understand the experiences of setting up a community physical activity (PA) support group that promotes the health and wellbeing of individuals with multiple sclerosis (MS)

Design: A hermeneutic phenomenological methodology with a subtle realist paradigm

Setting: In person at the University of Birmingham or via Skype.

Participants: A purposive sample of six individuals with MS (five female, one male) was included. Eligibility criteria was a) attended previous PA ice breaker event, b) >18 years and c) >3 years since diagnosis

Intervention: Event bringing together individuals to discuss PA for newly diagnosed MS patients. Following this event, they chose to stay in contact and create their own support group.

Main outcome: Demographic details taken include age, gender, time since diagnosis and type of MS. The main outcome measure was a semi-structured interview with various sub-sections. Thematic analysis identified the main concepts and ideas from the interviews, and wider literature was integrated to enhance data reliability.

Results: Four major themes and nine sub themes arose from interviews. This included
(1) Formation of the group social identity
(2) Feeling empowered by the group to change
(3) The group environment, and
(4) Psychological readiness

Conclusions: The peer led group provided a unique support environment with many perceived benefits. There is a need for policy, education and clinical practice providers to consider the value of peer support for individuals with MS.

Authors: Martin, E., Clarke, H., Pelton, T., Chapman, L., Soundy, A*.
*Corresponding author

To read the full article, please use the link in e-Participate.

Food provision, cUlture and Environment in secondary schooLS (FUEL) study

What are the School Food Standards?

National School Food Standards are nutrient-based food standards and are a legal requirement for most state schools. There has been little research exploring the impact of School Food Standards on school food provision and pupil food intake in secondary schools.

Aims of the project

Our aim is to compare secondary schools legally required to meet the National School Food Standards with those that are not. We will explore the dietary intake and dental health of pupils, the food provided in schools and support for healthy eating, and the level of implementation of the School Food Standards.

What's involved in the study?

Pupils, parents, school governors and key staff members will be asked to complete questionnaires about their views on school food provision, the eating environment, the food curriculum and the implementation of the National School Food Standards. Additionally, pupils will be asked about their general and dental health and dietary intake.

Why is this research needed?

Adolescents aged 11-18 years in the UK consume three times the recommended amount of their total energy intake from free sugars. Excess sugar consumption is a major contributor to increased energy intake, obesity, and poor dental health. Nearly a third of adolescents have excess weight and almost half of 15 year olds have dental caries.

School recruitment began in September 2019. Please email fuelstudy@contacts.bham.ac.uk to find out more or follow the study on Twitter @FuelStudy.

Julie Timmins

Congratulations to Julie Timmins, who has been appointed as Primary Care WM Senior Research Nurse for the Central locality. Julie is based at River Brook Medical Centre, Stirchley.

If you would like to contact Julie, please email: julie.timmins@nihr.ac.uk

The tribulations of trials: Lessons learnt recruiting 777 older adults into REtirement in ACTion (REACT), a trial of a community, group-based active ageing intervention targeting mobility disability

Withall, J., Greaves, C.G, Thompson, J.L., de Koning, J., Bollen, J., Moorlock, S., Fox, K.R, Western, M., Cross, R., Ladlow, P., Zizi, V. Guralnik, J.M., Rejeski, W.J, and Stathi, A

Background: Challenges of recruitment to randomised controlled trials (RCTs), and successful strategies to overcome them, need to be clearly reported to improve recruitment success in future trials. REtirement in ACTion (REACT) is a multi-centre RCT recruiting older adults at high risk of mobility disability to a 12-month group-based exercise and behaviour maintenance programme.

Methods: The recruitment target was 768 sedentary participants with functional limitations, scoring four to nine (inclusive) on the Short Physical Performance Battery (SPPB).

Recruitment methods included: a) invitations mailed by General Practitioners (GPs); b) invitations distributed via third sector organisations (community groups and sheltered housing facilities); and c) a public relations (PR) campaign. Yields, efficiency and costs for each method were calculated.

Results: Over a 20-month recruitment period 25,559 invitations were issued; 88% of participants were recruited via GP invitations, 5.4% via the PR campaign, 3% via word-of-mouth and 2.5% via third sector organisations. The mean recruitment cost per participant was £77.59, with £26.54 per recruit paid in Service Support Costs to GP practices by the Clinical Research Network. The total sample randomised was 777 (33.9% men) sedentary, community-dwelling, older adults (mean age 77.55yrs (SD 6.79), mean SPPB score 7.37 (SD 1.56)). The sample was 95.11% white (n=739) and spread across Index of Multiple Deprivation quintiles: Q1 11.07%, Q2 20.21%, Q3 20.46%, Q4 20.08% and Q5 28.19%, where Q1 is most deprived.

Conclusions: The REACT study successfully recruited to target, with randomised intervention and control groups well-balanced in terms of baseline characteristics; however predicted response rates and recruitment timescales required adjustment. Targeted efforts are needed to achieve more ethnically diverse cohorts. The Clinical Research Network is an effective mechanism for recruiting via General Practitioners. Written invitations from General Practitioners were the most efficient method for recruiting community-based older adults at risk of mobility disability.

NOAH – AFNET 6: A trial to investigate the benefit of oral anticoagulation in Atrial High Rate Episode (AHRE) patients

Oral anticoagulation provides efficient stroke prevention in patients with atrial fibrillation (AF) which is documented by an ECG. But it is not known whether oral anticoagulation is also indicated in the case of atrial high rate episodes (AHRE) recorded on an implanted device. The NOAH – AFNET 6 trial, conducted by the Atrial Fibrillation Network (AFNET), evaluates the potential benefit of oral anticoagulation in this patient group.

Patients suffering from ECG-diagnosed AF receive an antithrombotic therapy for stroke prevention consisting of vitamin K antagonists (VKAs) or non-vitamin K antagonist oral anticoagulants (NOACs). However, a large proportion of AF episodes remain undiagnosed (silent AF), and many of these patients present with a stroke as the first clinical sign of AF. An earlier initiation of anticoagulation could prevent such events. Continuous monitoring of atrial rhythm by implanted devices could close this diagnostic gap. Modern insertable cardiac devices provide automated algorithms alerting to the occurrence of atrial high rate episodes (AHRE). These episodes often, but not always correspond to short atrial tachyarrhythmias, an early subclinical manifestation of AF.

Prof. Paulus Kirchhof, Birmingham, chief investigator of NOAH – AFNET 6 explains the background of the trial:

'There is clinical evidence that the stroke rate is increased in patients with AHRE. However, the increase of stroke risk in these patients is lower than in those with ECG-diagnosed AF. On the other hand, anticoagulation therapy creates a risk for major bleeding complications. Often there is no temporal relationship between AHRE and stroke. And the IMPACT study did not find any stroke reduction in AHRE patients treated with intermittent anticoagulation. Consequently, we do not know whether the risks of oral anticoagulation outweigh the benefits in patients with AHRE.'

Reflecting this evidence, the current ESC guidelines for the management of AF recommend that patients with AHRE detected by an implanted device should undergo further assessment for overt AF by ECG monitoring. In patients with AHRE and without overt AF, patient characteristics, e.g. the stroke risk score, and patient preferences should be considered to decide whether anticoagulation is needed or not.

Prof. Kirchhof comments:

"Due to recent discussions, several physicians prescribe oral anticoagulants routinely to all of their AHRE patients. Unless there is clear evidence that the patient has AF, this is an off-label use of anticoagulation. Hence, we need the NOAH – AFNET 6 trial to assess whether anticoagulation is beneficial in patients with atrial high rate episodes. Please manage your AHRE patients according to the recommended procedure and include all eligible patients into this controlled trial!"

NOAH – AFNET 6 is a prospective, parallel-group, randomized, open, double-blind, multi-centre trial to evaluate the potential benefit of oral anticoagulation therapy in patients with AHRE, but without overt AF. The trial will test whether treatment with the NOAC edoxaban is superior to current therapy to prevent stroke, systemic embolism, or cardiovascular death in this patient group. The pan-European trial will enrol over 2,600 patients in more than 200-250 study centres in 18 European countries, with adequate experience in the follow-up of insertable cardiac devices in clinical routine. Patient recruitment started in June 2016 and just over 1,000 patients have been enrolled so far. There are currently 20 active centres in the UK.

The study participants will be randomised to receive either edoxaban or standard therapy consisting of antiplatelet therapy or no therapy depending on the cardiovascular risk. (Fig. 2)

Selection criteria

Patients are eligible for NOAH, if they meet the following criteria:

- Pacemaker, defibrillator or insertable cardiac monitor implanted for any reason capable of AHRE detection, implanted at least 2 months prior to randomisation
- AHRE (≥ 170 bpm atrial rate and ≥ 6 min duration) documented by the implanted device via its atrial lead and stored digitally
- Age ≥ 65 years
- In addition, at least one stroke risk factor leading to a CHA2DS2VASc score of 2 or more

Patients are not suitable for NOAH – AFNET 6, if they have:

- a history of overt AF or atrial flutter or
- a clear contraindication for oral anticoagulation or
- a clear need for oral anticoagulation or
- an indication for long-term antiplatelet therapy other than acetylsalicylic acid (ASA), especially dual antiplatelet therapy (DAPT) with ASA and clopidogrel, prasugrel, or ticagrelor

For GPs that wish to discuss patients that are considering participating in NOAH, please contact the hospital research team in the first instance; their contact details can be found on the GP letter. For further information on this trial, please contact Sabina Yasin, email: S.Yasin@bham.ac.uk

Fundamentals of Clinical Research Delivery

By Jon Davies, Research Nurse, CRN West Midlands (CRN WM) and Good Clinical Practice (GCP) Facilitator

Last year the National Institute of Health Research (NIHR) released a new training course called "Fundamentals of Clinical Research Delivery", which members of the CRN Primary Care GCP Facilitator Working Group have recently amended to make more relevant to Primary Care.

Fundamentals training is intended for members of staff who will not have freedom to act in a research study.

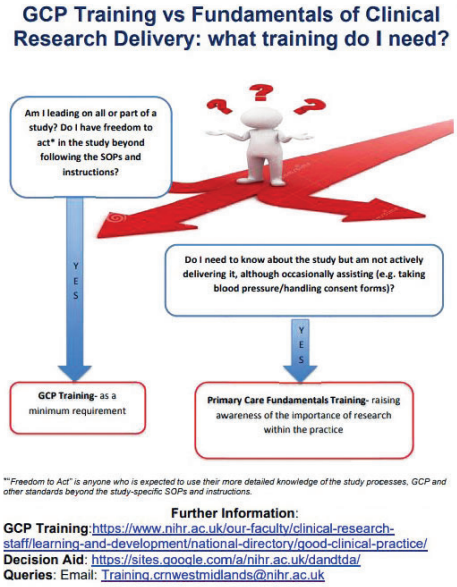
In other words, it is for staff who will only be peripherally involved or occasionally assisting in a study, e.g. Health Care Assistants or Practice Nurses (PNs) who are performing routine clinical procedures for research purposes and, as such, do not need full study or GCP training. Primary Care Fundamentals is an approximately two-hour course delivered in-house, and certificates are provided.

Fundamentals does not replace full GCP training for staff who will have freedom to act in a research study, e.g. lead study GPs or PNs, and this will depend on the type of study as directed by the study Sponsor.

Fundamentals has further been amended in primary care as a research awareness course to make it more relevant to non-clinical practice staff who work in research active practices, e.g. receptionists, administrators etc. This course takes one hour, is delivered in-house, and certificates are provided.

The Primary Care research courses provided by the CRN WM are as follows:

- Full Primary Care GCP training (either in-house or online)
- GCP Refresher (in-house or online)
- NIHR Fundamentals for Primary Care training (in-house only)
- Primary Care Research Awareness Training (in-house only)
- Informed Consent training (in-house)



If you wish to find out more please ask your local research facilitator or research nurse who should be able to assist you, details on back page, contact the CRN Workforce Development team or Jon Davies direct on jonathan.davies@nihr.ac.uk

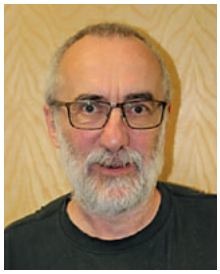
Join Dementia Research (JDR) Event at Holmcroft Library

By Geoff Robson, Patient Research Ambassador

On 5 June, a JDR event was held at the Holmcroft Library in Stafford. In preparation, posters were displayed at the library, in local retail outlets and at two local GP surgeries among others, and a radio interview was held with Stafford FM. The event was led by Jackie Smart (Research Facilitator) assisted by Geoff Robson (Patient Research Ambassador – pictured).

Although they talked to a few people in the Library, and gave out forms to them, the overall response was disappointing and frustrating with no one attending who had seen the posters or heard the interview. It remains a challenge to raise public perception of the JDR initiative, even though this forms part of the government's 2020 Dementia Strategy.

Welcome to John Bentley, Patient Research Ambassador



John writes: "I have been working with the Clinical Research Network for a couple of months. I chose to get involved because I am a firm believer in the NHS, where I worked for 37 years. In addition, I had experience as a carer for my mother in law until her death, and latterly as a patient.

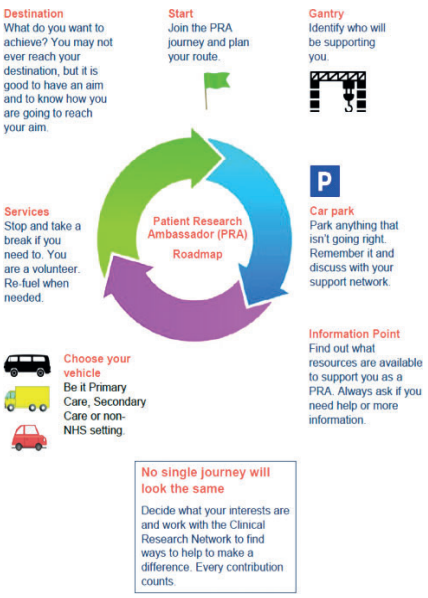
"God bless the NHS: it certainly came to my aid when I tried to kick heaven's door in. Following a brain haemorrhage and a stroke, I am now partially sighted, but my life was saved by the interventions devised through research and development. I am not blind to the failings of the system, or delivery, and any opportunity I can see to make a difference by improving care for others is well worth grasping. I am confident that there will be opportunities to have my say, share my experience, and use my brain.

"NHS and social care staff do a sterling job under increasingly difficult circumstances. Anything we can do to encourage, develop creative solutions, and share good practice must be of benefit to all."

Patient Research Ambassadors (PRAs)

Why it is vital to have more PRA representation in Primary Care:

- To engage with GP practices
- To raise awareness of health research in general practice
- To engage with marginalised groups
- To engage with study teams
- To co-produce research
- To identify areas for research that are relevant and important to patients
- To increase visibility of research within general practice
- To reduce health inequalities through innovation and opportunity to be involved



Are you a patient who is interested in being more involved? Are you a health professional who has dealt with a motived and engaged patient who might be interested in helping the CRN with their patient engagement?

For further information, please contact Eleanor Hoverd, research nurse, email: eleanor.hoverd@nihr.ac.uk

JDR at Waverley House

By Claire Brown, CRN Research Nurse

Staff at Waverley House

As part of the CRN's ongoing mission to promote Join Dementia Research (JDR) in the West Midlands, we recently started a new collaboration with Waverley House, a care home in Leominster owned by Shaw Healthcare, which provides specialist nursing care for people with dementia and residential care for over 65s. The Deputy Manager, Samantha Turner, is passionate about improving the lives of people with dementia and is keen to support JDR promotion in Herefordshire.

We discussed a range of ideas about how Waverley could help to publicise JDR and decided firstly to motivate staff with the knowledge needed to confidently signpost service users to JDR. Samantha and I showed the JDR promotional video and promoted the NIHR JDR learning tool at their monthly staff team meeting, discussing the importance of equal access for all to participation in dementia research and the role they can play.

To promote JDR to residents, relatives and visitors to the home, Samantha has set up a display in the main entrance, with posters, leaflets and registration forms and kiosk, allowing people passing through to register their interest. Additionally, the promotional video is on their welcome area screen, and social media platforms. It is planned to discuss JDR at the next residents' meeting and at relatives' meetings.

Looking to the Future

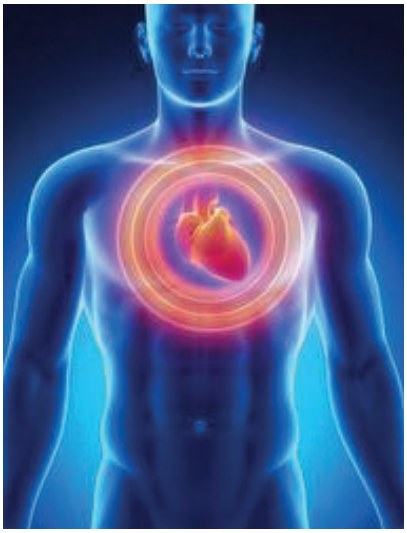
The response to JDR from Samantha and her team has been overwhelmingly positive, and has opened up many further opportunities; they have also signed up to Enabling Research in Care Homes and are keen to participate in future research. We await registration figures, but are hoping to see a steady rise in signups as the promotion continues.

Moving forward, we are in discussions with Shaw Healthcare, with over 90 care homes, about how they can help with promoting JDR nationally. They have already begun distributing the JDR videos, and with Waverley leading by example, it is hoped that other homes within the organisation will soon follow suit.

Samantha says, "Claire and I trained together many years ago and went off on different career paths, but I always knew we would join together again, and what better way than through this exciting collaboration. I am touched that Claire thought to contact us at The Waverley and I am so glad she did. It has sparked a new area of interest for me personally and professionally, and I am now in the process of becoming a Join Dementia Research Professional Champion. Here at The Waverley, we provide person-centred nursing, residential and day care for those suffering with Dementia, and therefore really understand and appreciate how important dementia research is in order to increase knowledge and improve future care and treatment.

"There are many ways that I feel I/we can help to promote JDR at the Waverley. We have many external visitors to the home, including Healthcare Professionals from different organisations, some who have already taken an interest and asked for Claire's details and they feel they can help. I am more than happy to help promote the service not only to our residents, staff and visitors, but also more widely through SHAW Healthcare, and within the local community that both Claire and I grew up in."

Euroaspire V/Aspire-3-Prevent Survey



The Euroaspire V/Aspire-3-Prevent Survey of Cardiovascular Disease Prevention and Diabetes has recruited a total of 558 participants. Data was collected in the West Midlands, East Midlands, Yorkshire, London, Kent and Sussex, South West Peninsula and Oxfordshire.

Congratulations to all involved, and special thanks to CRN West Midlands, with a total of 345 recruited.

In undertaking this research we describe the status of primary prevention in relation to the standards set in national guidelines. This valuable knowledge reveals gaps in the care we provide for patients with hypertension, dyslipidaemia and diabetes in terms of their lifestyle, risk factor management and use of cardio-protective medications. With this knowledge practitioners can make more focussed efforts to improve care and reduce the risk of having a heart attack or stroke; this work should lead to improvements in care and ultimately save lives.

Trust	Recruitment Site	Recruits
NHS Shropshire CCG	Cambrian Medical Practice	54
NHS Shropshire CCG	The Caxton Surgery	40
NHS Stafford and Surrounds CCG	Stafford Health and Wellbeing	35
NHS South Worcestershire CCG	Spring Gardens Group Medical Practice	32
NHS Shropshire CCG	Plas Ffynnon Medical Centre	28
NHS Herefordshire CCG	The Mortimer Medical Practice	27
NHS Birmingham and Solihull CCG	Hall Green Health	24
UHCW NHS Trust	University Hospitals Coventry & Warwickshire NHS Trust	22
NHS South Warwickshire CCG	Castle Medical Centre	20
NHS Birmingham and Solihull CCG	Kingsfield Medical Centre	19
NHS Redditch and Bromsgrove CCG	New Road Surgery Bromsgrove	13
NHS Birmingham South and Central CCG	River Brook Medical Centre	11
NHS Birmingham and Solihull CCG	The Wand Medical Centre	8
NHS Dudley CCG	Eve Hill Medical Practice	7
NHS Birmingham and Solihull CCG	River Brook Medical Centre	5
Total		**345**

Our congratulations and thanks go to all the practices involved for their hard work on recruitment, and to everyone in the CRN who has supported them.

Agnieszka Adamska, Royal Brompton Hospital Campus, Imperial College London, email: a.adamska@imperial.ac.uk
Tel. 0044 (0)20 759 43400

AF Garfield
global anticoagulant registry in the field

Aim

The relationship between outcomes and time after diagnosis for patients with non-valvular atrial fibrillation (NVAF) is poorly defined, especially beyond the first year.

Methods and results

GARFIELD-AF is an ongoing, global observational study of adults with newly diagnosed NVAF. Two-year outcomes of 17,162 patients prospectively enrolled in GARFIELD-AF were analysed in light of baseline characteristics, risk profiles for stroke/systemic embolism (SE), and antithrombotic therapy. The mean (standard deviation) age was 69.8 (11.4) years, 43.8% were women, and the mean CHA2DS2-VASc score was 3.3 (1.6); 60.8% of patients were prescribed anticoagulant therapy with/without antiplatelet (AP) therapy, 27.4% AP monotherapy, and 11.8% no antithrombotic therapy. At two-year follow-up, all-cause mortality, stroke/SE, and major bleeding had occurred at a rate (95% confidence interval) of 3.83 (3.62; 4.05), 1.25 (1.13; 1.38), and 0.70 (0.62; 0.81) per 100 person-years, respectively. Rates for all three major events were highest during the first four months. Congestive heart failure, acute coronary syndromes, sudden/unwitnessed death, malignancy, respiratory failure, and infection/sepsis accounted for 65% of all known causes of death and strokes for <10%. Anticoagulant treatment was associated with a 35% lower risk of death.

Conclusion

The most frequent of the three major outcome measures was death, whose most common causes are not known to be significantly influenced by anticoagulation. This suggests that a more comprehensive approach to the management of NVAF may be needed to improve outcome. This could include, in addition to anticoagulation, interventions targeting modifiable, cause-specific risk factors for death.

Publication: https://academic.oup.com/eurheartj/article/37/38/2882/2336152?searchresult=1

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Changes to the Research Sites Initiative Scheme

After running its current format for several years, the Research Sites Initiative (RSI) scheme is now being reviewed. With the changing primary care landscape, with practices merging and new Primary Care Networks emerging, we need to ensure that any future scheme is fit for purpose and can work with all GP practices, whatever the list size.

The requirements for signing up to the scheme have changed with the introduction of the new guidelines on Good Clinical Practice training and the ongoing review of the Research Ready accreditation scheme. With these changes in mind the CRN is looking to refine the RSI scheme payments to put the emphasis on taking part in studies rather than the other basic requirements.

Our proposal is to make the initial payment on a per patient accessed basis, linked to list size, with an additional per study payment that continues to reflect the difficulty of the study and the practice work involved, but at a higher rate than currently.

Overall, we expect practices to see a similar level of funding for a similar level of activity.

In January 2020, we will be inviting practices to be part of the RSI scheme; for many practices research is part of core business and they sign up to the scheme each year, but we are always keen to hear from new practices who would like to learn more about research, the benefits to their patients and the practice and more information about the initiative scheme we run.