Clinical Research Network
West Midlands

NHS
National Institute for
Health Research

Summer 2017 **Edition No. 1**

PARTICIPATE

Welcome to your new look Participate

Welcome to the first West Midlands wide primary care research update for general practices, pharmacies, GPs, practice nurses, CCGs, study teams and all those interested in research across the whole of the West Midlands. Previously there have been separate newsletters for south, central and north areas, but with the three Clinical Research Network (CRN) primary care teams increasingly working as one we felt it was time for a single newsletter. However, the middle pages will continue to have a local focus.

With the 'Five Year Forward View' the NHS is again going through a significant period of change. In primary care, not least in general practice, new models of care are being developed and set-up: GP Federations, primary and acute care systems (PACs) and multispecialty community providers (MCPs), super practices, super partnerships, etc.

Currently much of the way the CRN supports practices to participate in research is at individual practice level, e.g. each practice has a named CRN research facilitator and is individually remunerated in the Research Site Incentive Scheme. This may need to change to reflect the new models being set up across the West Midlands.

We would very much like to hear from practices, and those developing and setting up these new models, on how we could support the research delivery by working at the level of the new models, in addition to working directly with practices. For example, a GP federation might agree to pool the research support resources its research active practices receive, and the support we are providing, with all federation practices working together to deliver research; or a super practice might set up a 'hub and spoke' model with spoke practices referring patients to research clinics at a hub practice.

We are open to any ideas you have on this, please let your local primary care CRN contact know or contact me at m.porcheret@keele.ac.uk or on 01782 734861.

The call for applications for the 2017 RCGP/CRN Awards, which recognise excellence and innovation in delivering NIHR by research active NHS GPs and general practices, will be announced soon. There will be a practice award and a First5 award. Further details on the RCGP website or see page 11.

In this newsletter we feature articles on:

- PACT: will treating asthmatic children according to genetic status improve their quality of life and asthma control? (page 4)
- STILTS2: assessing the genetic basis of thinness; identification of genes that contribute to thinness may provide further insights into the regulation of body weight and obesity resistance (page 3)
- ARCHIE: aims to determine the effect of giving the antibiotic co-amoxiclav to 'at risk' children within five days of them becoming ill with flu or influenza-like illness (page 4)

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

Points of Interest

- Study - Pact
- Study – Stilts2
- Results – Start2Quit
- CRN – RCGP and CRN Awards 2017

Contents

i-WOTCH

IMPROVING THE WELLBEING OF PEOPLE WITH OPIOID TREATED CHRONIC PAIN

Funding Acknowledgement: This project is funded by the National Institute for Health Research, Health Technology Assessment (project number 14/224/04). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA, NIHR, NHS or the Department of Health.

Seeking GP practices to host i-WOTCH study on opioid withdrawal for chronic pain

We are currently recruiting GP practices across the whole West Midlands region, to take part in the I-WOTCH study. Clinical Research Network nurses will identify eligible participants by initially searching and screening GP lists from those that are recruited to the study. Eligible patients who provide consent will be randomised into either the active arm (behaviour-change group educational intervention with associated handouts, an educational DVD, mindfulness and relaxation CDs plus an opioid information booklet and trained I-WOTCH nurse support package) or control arm (usual care plus the opioid information booklet and relaxation CD). The support programme aims to improve the everyday functioning of people living with chronic non-malignant pain and gradually reduce their opioid use. All participants in both groups will receive questionnaire packs at baseline, four, eight and twelve months. Our primary outcome measure is activities of daily living and main secondary outcome measure is opioid use. Other outcome measures include pain, sleep, quality of life and resource use.

Strong opioids are increasingly being prescribed for chronic non-malignant pain including expensive transdermal preparations. However there are limited data supporting the effectiveness of long-term use with adverse effects often outweighing the benefits of long term opioid treatment for pain. We have recruited and trained nurses and lay facilitators to co-deliver the I-WOTCH intervention with the nurses providing tailored tapering advice at one-to-one sessions and follow-up phone calls. The group course includes sessions about pain, opioid education, acceptance, and non-drug self-management techniques including stress management, pacing, relaxation, mindfulness, recognising unhelpful thoughts, and overcoming barriers.

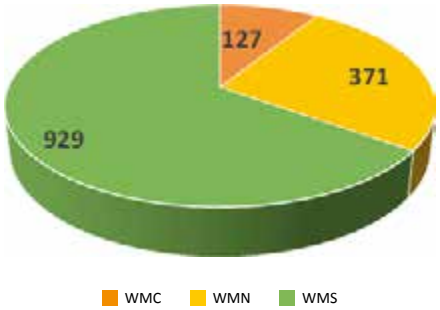
If your GP practice is interested in the study or for more information, please contact your local facilitator, please see page 12.

This national study draws to a close in September 2017, and we wish to express our thanks to all the West Midlands practices who have contributed to its success.

The **CANDID** target recruitment is 20,000 with a further 2,000 required per cohort for validation by the end of September or until the figure is reached whichever is sooner.
Total recruitment is 21,287 – nationally an additional 900 colorectal patients and 1,813 lung patients are required.

Please continue to recruit. Thank you.

CANDID RECRUITS – WEST MIDLANDS AS AT MAY 2017



CONGRATULATIONS!
A very special thanks to a number of practices reaching outstanding recruitment to the study; our top ten in the West Midlands are:

CANDID
CANcer DIagnosis Decision rules

PRACTICES	NUMBER OF RECRUITS
The Atherstone Surgery	145
The New Dispensary Warwick	114
Sherbourne Medical Centre Leamington Spa	112
Plas Ffynnon Medical Practice Oswestry	76
Spring Gardens Group Medical Practice Worcester	71
Parkside Medical Practice Brownhills	52
Eve Hill Medical Practice Dudley	49
Corbett Medical Practice Droitwich Spa	48
Bennfield Surgery Rugby	46
Mansion House Surgery Stone	45

For any of you interested in the qualitative work that was carried out before the main study started there have been a couple of papers published:

Mansell G, Shapley M, van der Windt D, Sanders T, Little P. Critical items for assessing risk of lung and colorectal cancer in primary care: a Delphi study. *The British Journal of General Practice.* 2014;64(625):e509-e515. doi:10.3399/bjgp14X681001.

McLachlan S, Mansell G, Sanders T, et al. Symptom perceptions and help-seeking behaviour prior to lung and colorectal cancer diagnoses: a qualitative study. *Family Practice.* 2015;32(5):568-577. doi:10.1093/fampra/cmv048.

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

ALL HEART

(Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease) is a major multi-centre trial of allopurinol up to 600mg daily versus no treatment added to usual therapy in patients aged 60 years and over with ischaemic heart disease. The aim is to establish whether allopurinol improves cardiovascular outcomes in this population.

Suitable patients are identified in primary care by their GPs; those that respond favourably attend an appointment with a research nurse. Patients will be randomised to either allopurinol or no drug to be given in addition to their usual medications. Allopurinol will be started at 100mg daily for two weeks, then titrated to 300mg daily for two weeks, then titrated to 600mg daily if tolerated. Patients will then be followed up for a period of around four years to count the number of heart attacks, strokes and cardiovascular deaths that occur.

Participating practices will receive a fee for completing the database search, in addition to per patient payments.

Recruitment is going well in the West Midlands. Would your practice be interested in helping us with this important study?

Many thanks to the 66 practices who have already signed up, and have recruited 380 patients to date.

For further details, pleases contact your local research facilitator, details on page 12. More details can also be found on the trial website: www.allheartstudy.org

STUDY INTO LEAN AND THIN SUBJECTS

Image courtesy of Grant Cochrane at FreeDigitalPhotos.net

STILTS2 assesses the genetic basis of thinness.

Identification of genes that contribute to thinness may provide further insights into the regulation of body weight and obesity resistance, which may lead to rational preventative and therapeutic strategic for weight disorders.

How will the practice be involved?

- The practice will run a search to identify potentially eligible patients at the practice (using disease specific read codes)
- GPs will be asked to screen the list of potentially eligible patients
- The practice will send out invitation letters and information packs
- If a patient is interested they respond to the study team who will send out a saliva kit for DNA collection and a simple questionnaire to record eating/exercise behaviours

Main inclusion criteria

- Age 18-65 at time of recruitment
- BMI<18kg/m2
- No known history of eating disorders, renal, liver or gastrointestinal disease

If you would like further information, please contact your local facilitator, details on page 12

UNIVERSITY OF BIRMINGHAM

HEAT

Helicobacter Eradication Aspirin Trial

Helicobacter eradication to prevent ulcer bleeding in aspirin users: a large simple randomised controlled trial

Principal Investigator Birmingham region: Prof. Richard Hobbs.

Locations: ~400 GP practices in Birmingham and Black Country, Worcestershire, Coventry and Warwickshire, Shropshire, Staffordshire, Herefordshire, Stoke, Telford and Wrekin, Wolverhampton, Sussex & Surrey, Nottingham, Durham, Southampton, and Oxford.

Enrolment Period: 2012 – June 2016

Participants: Men and women aged 60+, infected with *H. pylori,* who are using aspirin <326mg daily

Other Information: This trial has been preceded by a successful pilot study, funded by the MRC. Practices will be reimbursed for their time.

Use of aspirin for cardiovascular prophylaxis is widespread and increasing. The main hazard is ulcer bleeding. This is usually associated with H. pylori infection. It is important to determine whether this can be reduced or prevented by *H. pylori* eradication. The trial hypothesis is that aspirin does not itself cause peptic ulcers, but that it promotes bleeding of ulcers caused by *H. pylori*. Given the scale of aspirin use, its continuing increase and its contribution to ulcer bleeding, how to deal with this problem is arguably the most important question with regard to current iatrogenic medicine.

Intervention and Clinic: Suitable patients will be identified by their surgery, using an automated search, and then asked to attend an appointment with a University Research Nurse or Practice Nurse (relevant training will be provided) to consent to the trial and take a *H. pylori* breath test. Those with a positive result will be randomised to receive a one week course of either eradication treatment or placebo, supplied by the trial centre. No follow-up visits for the patients are required, but any hospital admissions for ulcer bleeding will be recorded over a period of 2-3 years by the trial centre.

Further Information: if you would like to find out more, please contact your local facilitator, details on page 12.

PACT - Testing the Delivery of the Best Asthma Treatment Based on Genetics

A study by researchers from across the UK, funded by Action Medical Research, is aiming to discover whether treating asthmatic children according to their genetic status can improve their quality of life and asthma control.

One in every 11 children in the UK has asthma. When asthma is well managed, children can lead full and active lives. Unfortunately, not all asthma is well controlled. There is evidence that the routinely used controller medication salmeterol is ineffective in 1 of 7 cases. Previous work by Professor Somnath Mukhopadhyay from Brighton and Sussex Medical School suggests that certain gene variations are linked to poor asthma control in children.

As a result, working with general practitioners, PACT is designed to assess the effectiveness of prescribing children, whose asthma is inadequately controlled, either salmeterol or montelukast according to their beta2 receptor genetic status compared to standard asthma management regimes. Participants' genotype status is established from self-administered saliva tests.

PACT is novel as no hospital visits are required with all outcome data being completed by participants online at three monthly intervals for one year. This design allows participants to complete their quality of life and asthma control questionnaires at their convenience, with associated costs reduction.

At the end of the study, all participants and GPs will receive gene test and study results.

Healthcare professionals can find out more about the study at www.pactstudy.org.uk or by calling the Tayside Clinical Trials Unit on 01382 383932.

If your practice would like to take part, or would like further information, please get in contact with your local research facilitator, details on page 12.

ARCHIE - The early use of Anti-biotics for 'at-risk' Children with Influenza

Study Summary

Children with underlying medical conditions such as asthma, diabetes and cerebral palsy are 'at risk' of becoming more unwell from bacterial infections if they get flu. ARCHIE is a double-blind randomised placebo-controlled trial which aims to determine whether giving the antibiotic co-amoxiclav to 'at risk' children within five days of them becoming ill with flu or influenza-like illness might:

1. Help stop them from developing bacterial infections and becoming more unwell
2. Help them get better more quickly
3. Affect how well antibiotics work against similar infections in future

Practice Involvement: We are looking for practices to

- Identify and flag potentially eligible patients via a database screen prompt
- On presentation of an eligible patient during the winter season to call the ARCHIE recruitment hotline to inform central trial office if family happy to be contacted (approx. 5-10 min call)

A CRN nurse will then attend the patient at home for consent, baseline, randomization and study medication dispensing. The CRN nurse will carry out follow up including medical notes review. The practice may be asked to give additional information if their participant has an SAE.

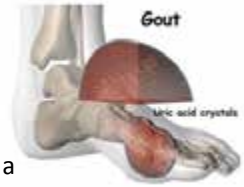
Patient Involvement: In addition to the child completing a five day course of study medication a nose and throat swab will be taken. Family will be asked to complete weekly diary for a month after study entry.

Recruitment Status: Seasonal from October to April.

Funder: NIHR's Programme Grants for Applied Research Programme.

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

FAST



FAST (**F**ebuxostat versus **A**llopurinol **S**treamlined **T**rial) is a major multicentre clinical trial evaluating long term cardiovascular safety of febuxostat in comparison with allopurinol in patients with chronic symptomatic hyperuricaemia (gout). This is a very simple study, with a very low workload for participating practices.

So far, more than 100 practices in the West Midlands are taking part, and patient recruitment has commenced, with over 5,000 patients taking part nationally. Thank you so much to those of you who are on board, and we look forward to expanding this exciting trial to any other practices who may be interested.

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

Participating practices will receive a £500 fee for completing the database search, in addition to £5 per month per patient for the duration of the trial. All medication will be prescribed by the trial sponsor, and so there will be no prescribing costs to GP practices.

For further details, please contact your local research facilitator, details on page 12. More details can also be found on the trial website: www.fast-study.co.uk

The Role of GP Receptionists: A Research Study

Michael Burrows, Ian Litchfield, Nicola Gale and Sheila Greenfield

The roles of the GP receptionist are varied and essential to the smooth running of the practice. As well as undertaking administrative and clerical duties to ensure the various office systems continue to support the delivery of care, such as filing, maintaining medical records and making appointments, they also undertake functions more directly related to patient health, such as booking appointments, communicating test results and managing repeat prescriptions. However the complexities of primary care are increasing and these responsibilities are placed on staff without formal training, whether in data protection and information governance or appropriate styles of communicating with patients. This gap between training and the implication of the role has clinical consequences for patients and medico-legal concerns for practices. Funded by the Health Foundation, this research aims to explore in greater detail the parameters of the roles of the GP receptionist in modern healthcare. It will explore the scope of their current activities and will ultimately identify areas that might benefit from targeted support. Further details can be found in our published protocol.

Getting involved

We are currently actively recruiting participants and would like to encourage receptionists across the West Midlands to complete our questionnaire. This will take only a few minutes to complete and includes questions about the nature of current responsibilities, and their interactions with colleagues and patients. The questionnaire can be accessed via the following link https://bham.onlinesurveys.ac.uk/gp_receptionist-survey_v1. The second phase of our work involves speaking with patients and a broader cross-section of staff to gather a range of perspectives on the role.

If your practice is interested in being involved in either phase or if you would like any further information about our work please contact Michael Burrows; Mjb538@bham.ac.uk or on 07528 528868.

Chronic Headache Education and Self-management Study (CHESS)

CHESS Chronic Headache Education and Self-management Study

A multi-centre, randomised controlled trial evaluating an education and self-management support programme for people living with chronic headaches (headache ≥ 15 days/month for ≥ 3 months). The programme is led by Professor Martin Underwood at the Clinical Trials Unit, University of Warwick.

We plan to recruit around 700 people aged ≥18 years living with chronic headaches from across the Midlands and North-east London.

What will it involve for participants?

All participants will be asked to:

- Provide written consent and complete postal questionnaires at baseline, 4, 8 and 12 months
- Complete an electronic diary of headache frequency, duration and severity (smartphone app or paper version) weekly for 6 months and monthly until the end of the study at 12 months
- Complete a telephone interview with a research nurse to classify their headache

If your practice is interested in taking part in the study or you would like any further information regarding CHESS please contact your local research facilitator, details on page 12.

Participants will be randomised to either:

a. *Usual GP care plus a group headache education and self-management support programme*
   Participants will attend a two day education and self-management course held at a venue close to their practice; followed by a one-to-one consultation and up to eight weeks of telephone support with a nurse
b. *Usual GP care plus relaxation CD*
   Participants will receive standard treatment and sent a relaxation CD

What will it involve for GP Practices?

- Identification of potential participants from computer record search
- Checking of list before mail-out
- Mail-out of study invitation letters (via Docmail)
- Access to patient records for data collection of consultations, health service activity, and medication use related to headaches at 12 months

This project is funded by the National Institute for Health Research – Programme Grants for Applied Research (project number RP-PG-1212-20018). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or Department of Health.

Funded by NHS National Institute for Health Research

BrIT - Brains In Transition

It is possible to identify young people at risk for psychotic illnesses such as schizophrenia through a combination of symptoms and personal or family history. Around 20% of such people develop psychosis within 12 months of being identified. There are differences in the brains of at risk cases when compared to similar participants not at risk and these differences get greater with the onset of psychotic illness. We don't yet know, however, when in the progression these changes occur. They may come before (and somehow cause) the increase in symptoms, implying that trying to prevent these brain changes could prevent the illness. The Brains in Transition (BrIT) study (funded by the Medical Research Council) will investigate the course of brain changes across the transition from being at risk for psychosis to the development of a psychotic illness, and determine if those changes can be used to predict outcome and improve early detection.

Participation in the study involves assessments of symptoms and functioning, as well as brain scans (MRI). Participants are followed for one year and receive £20 in recognition of their time and expenses each time they take part.

Practice involvement

- Conduct a search to identify potentially eligible patients
- GP to check patient list
- Conduct a mail-shot inviting potentially eligible patients

GP practices taking part will be eligible to receive payment via service support costs to cover the time spent identifying and mailing out to eligible patients. £225.26 has been calculated for this study. This figure is based upon activities to be performed by the practice; it is an approximation only and may be adjusted in line with the amount of patient recruitment and the level of CRN support received. GP practices will be informed in writing of a patient's participation in the study.

The study is currently recruiting in West Midlands central area.

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

CONDUCT - COllectioN Devices to reduce Urine ConTamination

This study aims to investigate whether use of urine collection devices (UCD), compared to urine collection with standardised instructions, reduces the proportion of contaminated urine specimens. The effectiveness and acceptability of two urine collection devices that aim to reduce contaminated urine samples in women presenting with symptoms of urinary tract infection. A three arm trial in UK primary care.

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

RAte control Therapy Evaluation in permanent Atrial Fibrillation

Atrial fibrillation is increasingly common and an important cause of poor quality of life and heart failure in older patients. The RATE-AF trial is designed to evaluate the use of rate control therapy to benefit patient-reported quality of life and improve heart function.

The trial is recruiting permanent AF patients newly in need of rate control therapy, with current symptoms of breathlessness aged 60 years or older. RATE-AF is funded by the NIHR and will assess patients over a one-year period, based at the Queen Elizabeth Hospital and the University of Birmingham: http://www.birmingham.ac.uk/rateaf.

What is involved for patients?

- Randomisation to digoxin or bisoprolol for rate control, with Consultant Cardiologist-led study visits at baseline, 2-weeks, 6-months and 12-months
- Questionnaires on quality of life, heart function assessment with ultrasound, heart rate recorder and walking test
- Taxi fares to the hospital paid for all visits

What is the benefit for GPs?

- Direct access to the AF team, with patient appointments usually within 48-72 hours
- Includes all components of clinical care that would usually require referral (consultations, echocardiography, ambulatory ECG and follow-up)

For further information, please contact your local research facilitator, details on page 12. YouTube video: search "rate af"

How can we optimise medication management in older people?

Medication related adverse events have been estimated to be responsible for 5,700 deaths and cost the United Kingdom £750 million annually. Polypharmacy is particularly common in older people; due to this and increased vulnerability to side-effects, this burden falls disproportionately on older people. The MEdication Management in Older people: REalist Approaches BAsed on Literature and Evaluation (MEMORABLE) project uses an innovative realist synthesis and is led by Dr Maidment, Senior Lecturer in Clinical Pharmacy at Aston University. The research is funded by the NIHR and collaborators include the Universities of Oxford and Sheffield, and Wollongong University in Australia.

MEMORABLE aims to understand how, why, for whom and in what contexts interventions, to improve medication management in older people on complex medication regimes residing in the community, work. Based on this, we aim to develop the framework for an effective intervention on what staff, patients and carers believe is likely to be effective. Therefore a key part of the research involves interviewing these groups.

If you are interested in being interviewed, or would like more information please contact Sally Lawson on s.lawson2@aston.ac.uk or Dr Ian Maidment on i.maidment@aston.ac.uk

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

Previous research has shown that a hormone releasing coil, fitted inside the womb, is effective in reducing the impact and symptoms of heavy menstrual bleeding. Other medical treatments, including the contraceptive pill and non-hormonal treatments also reduce bleeding, but not as well as the coil. Ulipristal has been found to quickly reduce bleeding in women with large, non-cancerous growths in the womb, known as fibroids. It is not known whether this drug is effective in reducing the impact of heavy menstrual bleeding in women who do not have fibroids, or have small, insignificant fibroids. It is also unclear how ulipristal stops menstrual bleeding and its effect on the womb lining.

The aim of the study is to test the hypothesis that ulipristal acetate (UPA; Esmya®), is more effective than the levonorgestrel releasing intrauterine system (LNGIUS, Mirena®) for the long term treatment of HMB. Furthermore, we aim to understand the mechanism of action of UPA on the endometrium and its effects upon the vasculature and structure of the uterus.

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?

A database search as defined in the study protocol; GP to check the list; mail out to potentially eligible patients using DOCMAIL.

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)

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

An exploration of parents' perceptions and experiences of using e-cigarettes in homes with children (PPEC)

The study aims to explore parents' perceptions and experiences of using e-cigarettes in homes with children. This study is considered a Patient Identification Centre (PIC) study but will contribute towards meeting the Research Site Initiative (RSI) scheme criteria

Practice involvement:

- Display posters advertising the study
- GP, nurse and/or receptionist to identify potential participants and hand out a brief study information leaflet

Study duration: 1 May 2016 to 31 December 2017.

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

Eve Hill Medical Practice

RCGP/CRN AWARDS 2016

We were delighted to get a commendation from the RCGP/CRN awards team in 2016. We had worked hard in the practice to establish a 'research culture' and make research a core business activity. Many of the studies that the NIHR offered us were very well aligned to our own interests and had immense benefits for our patients too. Patients are often very happy to be invited into a research study, and will comment that they value being part of something that could help other patients or advance medical knowledge. There are so many research active practices within the West Midlands who are also working very hard and recruiting patients to NIHR studies and we would strongly encourage them apply. Completing the application was quite straightforward and in fact it was a useful to collate all our research activity and be able to summarise it. Even though we did not outright win, the press coverage that we got after our commendation gave us a real boost!

What are the indications for Prescribing ANtiDepressAnts that will lead to a clinical benefit

The aim of **PANDA** randomised controlled trial is to investigate the severity and duration of depressive symptoms that are associated with a clinically important response to selective serotonin reuptake inhibitors, (SSRI) in people with depression.

Practice involvement: Identify participants using both opportunistic (refer the patient to the study team) and database search, confirm the list and mail out.

Patient involvement: After the initial interview of c. two hours, participants are randomly allocated to one of the two study treatments: sertraline or placebo, will be on the treatment for 12 weeks and will have further interviesw with a researcher either at home or GP practices at 2, 6 and 12 weeks.

Trial medication: The study team will post the medication either to the practice or to the home address.

The PANDA trial is sponsored by **University College London**. We are looking for practices from **Dudley, Sandwell and Walsall Area**.

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

A randomised controlled trial to encourage smokers to seek help to quit

A personalised invite can encourage more people to quit smoking through Stop Smoking Services

Smoking remains the leading cause of ill health and mortality, at an estimated cost to the NHS of about £6 billion. Stop Smoking Services (SSSs) in England offer intensive advice and support to smokers motivated to quit, and smokers attending have a higher chance of succeeding in a quit attempt than if they attempted to quit alone. However the proportion of smokers using the SSS has been less than 5%, and the number is falling each year. In the Start2quit trial we developed an intervention to persuade and motivate more smokers to seek, or accept, help to quit.

Smokers tend to underestimate their own personal risk. Therefore the intervention consisted of a personal risk information letter that told people about their own risk if they continue to smoke, using information from a screening questionnaire and from medical records. We combined this with an immediate offer of treatment and personal invitation to a no-commitment 'Come and Try it' taster session to find out more information about the service and what it involves. These sessions lasted approximately 1 hour were run by advisors, already trained to give smoking cessation advice, and also trained to lead sessions according to a standard protocol.

We assessed whether this intervention would encourage more people to attend the first session of an SSS course compared with a control group who received a standard generic letter advertising the local SSS. We also assessed whether this intervention would increase quit rates, defined as 7-day abstinence at the 6-month follow-up.

Complete data of attendance at the SSS was collected for each participant from SSSs at the end of the 6-month follow-up period, and submitted by SSS staff using NHS monitoring data. Additional data were obtained by telephone interview or postal questionnaire 6-months after the date of randomisation for each participant.

The trial was conducted over 4 years, between January 2011 and December 2014. Eighteen SSSs and 99 practices within the SSS areas were recruited by the Primary Care Research Network (PCRN). All smokers aged 16 and over were identified from medical records in participating practices. After screening by GPs and eliminating duplicate addresses, 112,216 patients were invited to participate. Smokers returning the completed questionnaire and giving consent (4,384 / 4.1%) were allocated at random to the intervention group (2636) or to the control group (1748). A total of 3372 (76.9%) completed the interview or postal questionnaire at the 6-month follow-up (76.7% in the intervention group and 77.3% in the control group).

We attempted to select more practices in areas of high deprivation, determined by the practice postcode converted to an Index of Multiple Deprivation (IMD) score (the Government's official measure of multiple deprivation at small area level. Consequently 54.6% of practices were located in areas of higher deprivation (i.e. within the two highest quintiles of IMD scores). The practices list sizes ranged from 2,205 to 26,000, and the proportion of smokers identified in each practice ranged from 4.8% to 39.7%.

The average age of participants was 49, 51% were male, 51% were living in areas of high deprivation (IMD quintiles 4 and 5), and 32% were living in a household with another smoker. Participants smoked on average 16 cigarettes per day, 68% smoked within 30 minutes of waking. A high proportion (42.5%), were planning to quit sometime in the next 6 months, but not within the next 30 days.

Results

Significantly more people in the intervention group than in the control group attended at least one session of a 6-week SSS course (17.4% vs 9.0%), meaning that receiving a personal letter and invitation to a taster session, rather than receiving a standard letter, more than doubles the odds of attendance. We adjusted the results to account for other factors that might influence attendance, e.g. gender, age, and dependence, and the intervention group still had more than twice the odds of attending. The number of people who completed the 6-week course was also more than doubled in the intervention group (14.5% vs 7.0%).

In addition, significantly more people in the intervention group than in the control group had quit smoking (stopped for at least 7 days and validated by a saliva sample) at the 6-month follow-up (9.0% vs 5.6%), which means that the chances of quitting after receiving this letter and invitation are increased by 61%.

Of the 739 participants in the intervention group who attended a taster session, 338 went on to attend the SSS, and another 120 in the intervention group attended the SSS although they did not attend a taster session. Abstinence rates were highest at 28.7% in those who attended a taster session and also attended the SSS.

For more information contact the PI Dr Hazel Gilbert hazel.gilbert@ucl.ac.uk

Comments from people who attended the tasters sessions suggested that the sessions gave new information and encouraged smokers to look at things in a different way. They were pleased that the advisors did not exert any pressure on the attendees to sign up, and the attendees felt relaxed ('very good. Without trying to 'preach' or exert undue pressure'), and comments also confirmed that some smokers are not aware of the service and what is offered, e.g. 'nice to know that such a service exists'.

Coventry SSS

The Coventry practices were representative compared of the total sample in terms of deprivation, and showed that we were successful in reaching our target population.

There were large differences in recruitment in SSSs, ranging from 2.3% to 6.7%.

Recruitment in Coventry was low overall, but largely due to two practices in particular. This reflected the pattern in other areas, where there were large variations between practices within SSSs. The characteristics of the Coventry sample were very similar to the total in all respects, although the proportion of males was higher at 58%.

Overall SSS attendance also varied between SSSs from 23.1% to as low as 2.1%, and validated 7-day abstinence from 13.4% down to 2.1%. SSS attendance in Coventry SSS was slightly lower than overall attendance, but completion of the course was high, and abstinence rates are comparable with the total. Our criteria for validation are rigorous, and therefore 7-day validated abstinence rates are conservative. Non-validation of 7-day abstinence does not confirm relapse or continued smoking in a participant.

Implications for healthcare

A programme of proactive recruitment can be effective in raising awareness of the SSS, and consequently increasing the service uptake. Personal risk information may prompt more smokers to attempt to quit and the taster sessions offer an opportunity to promote the services in the form of introductory sessions to emphasise their approachability and empathy.

A cost effectiveness analysis suggested that the tailored letter plus the taster session may be more costly during the trial period. However, quitting smoking yields huge health care cost savings and health benefits over the long-term through the reduced risk of smoking-related diseases, such as lung cancer, heart disease, COPD and stroke. The long-term results suggest that over a lifetime horizon, the intervention is more effective and less costly than the generic letter.

PRACTICE	IMD QUINTILE	LIST SIZE	% SMOKERS IDENTIFIED	TOTAL INVITATIONS SENT	NUMBER RECRUITED	RECRUITMENT RATE (%)
Holbrook Health	4	11500	14.96	1408	34	2.4
Westwood	2	5400	14.80	638	12	1.9
Jubilee Healthcare	4	8960	19.80	1284	37	2.9
Phoenix	3	5764	4.79	244	12	4.9
Springfield	4	7500	8.99	572	25	4.4
Jubilee Health Centre	5	8298	16.69	912	18	2.0
Total		**47422**	**13.3**	**5395**	**138**	**2.7**

	START2QUIT SAMPLE		COVENTRY SSS SAMPLE	
	INTERVENTION N=2635	CONTROL N=1748	INTERVENTION N=85	CONTROL N=53
Attended taster session	739 (28%)		17(20.0%)	
Attended SSS	458 (17.4%)	158 (9.0%)	12(14.1%)	4(7.5%)
Completed 6-week SSS course	382 (14.5%)	123 (7.0%)	11(12.9%)	1(1.9%)
Validated 7-day point-prevalent abstinence	236 (9.0%)	97 (5.6%)	7(8.2%)	4(7.5%)
Validated prolonged 3-month abstinence	150 (5.7)	60 (3.4)	4(4.7%)	2(3.8%)
Self-reported 7-day point-prevalent abstinence	424 (16.1)	187 (10.7)	14(16.5%)	4(7.5%)

Funding: National Institute for Health Research HTA Programme

Publications: Gilbert H, Sutton S, Morris R, Petersen I, Galton S, Wu Q, et al. Effectiveness of personalised risk information and taster sessions to increase the uptake of smoking cessation services (Start2quit): a randomised controlled trial. The Lancet , 2017:389(10071): 823–833. http://dx.doi.org/10.1016/S0140-6736(16)32379-0

Gilbert H, Sutton S, Morris R, Petersen I, Wu Q, Parrott S, et al. Start2quit: a randomised clinical controlled trial to evaluate the effectiveness and cost-effectiveness of using personal tailored risk information and taster sessions to increase the uptake of the NHS Stop Smoking Services. Health Technol Assess 2017;21(3) https://dx.doi.org/10.3310/hta21030

HOW CAN WE BEST HELP PEOPLE TO LOSE WEIGHT IN PRIMARY CARE?

WRAP
Weight Loss Referrals for Adults in Primary Care

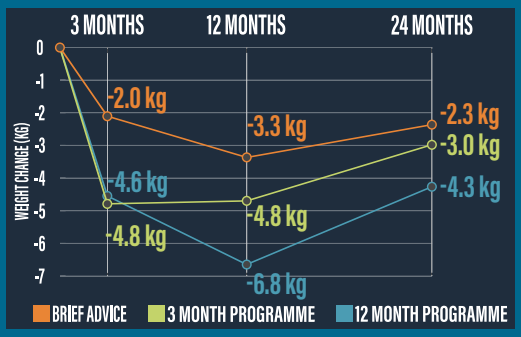
The WRAP study – Weight loss Referrals for Adults in Primary Care – examined if a behavioural weight loss programme, in this case WeightWatchers®, is better than brief advice, and how long a programme should last – 3 or 12 months?

It compared the costs and potential future health benefits of these programmes.

THE STUDY

1,267 participants were randomly assigned to receive either brief advice, or a referral to a weight loss programme for either 3 or 12 months.

Their weight was measured at 3, 12 and 24 months.



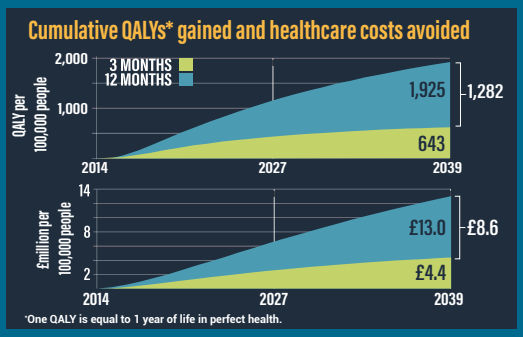
HOW MUCH WEIGHT DID PEOPLE LOSE?

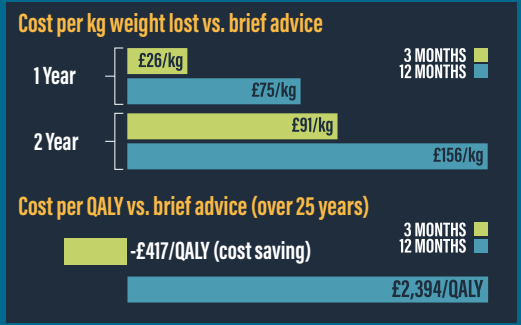
GP referral to a weight loss programme led to significantly more weight loss than brief advice.

The longer programme led to greater weight loss at 12 and 24 months.

WHAT IS THE EFFECT ON FUTURE HEALTH?

We assumed people regained all the weight they lost by year 5. Despite this, modelling suggests the weight loss programmes lead to greater health benefits and lower NHS costs over the next 25 years compared to brief advice. The longer programme is predicted to have much greater benefits.





ARE LONGER PROGRAMMES COST-EFFECTIVE?

The health economic analysis shows that a 3 month programme is likely to be *cost saving* relative to brief advice alone.

The 12 month programme is more expensive, but the greater health benefits mean it is very cost-effective by usual clinical standards*.

*NICE threshold for cost-effectiveness of £20,000/QALY

Reference: Extended and standard duration weight-loss programme referrals for adults in primary care (WRAP): a randomised controlled trial. Ahern *et al.* The Lancet, 2017. DOI: 10.1016/S0140-6736(17)30647-5.

Royal College of General Practitioners and Clinic Research Network Awards: to recognise NHS general practices and First5®GPs who are active in research

Introduction

Since its inception in 2006, the NIHR has significantly increased the scale of clinical research in the NHS, particularly through the Clinical Research Network. The enthusiastic engagement of NHS clinicians is an essential condition for sustaining and building on this success, particularly given the many competing demands on clinician time and resources.

These awards are for members of the Royal College of General Practitioners (RCGP) and recognise outstanding contributions and innovations of NHS general practices and First5® GPs to the conduct of NIHR Clinical Research Network Portfolio studies in a primary care setting.

Eligibility

General practice applications must be submitted in the name of a current Fellow or Member of the RCGP and general practices must be contributing to NIHR Clinical Research Network Portfolio studies (but not exclusively).

First5® GPs must be a First5® member and have contributed to NIHR Clinical Research Network Portfolio studies in a general practice/primary care setting.

"The standard of applications was exceptionally high. The award winners are making an outstanding contribution to clinical research within primary care."

Dr Imran Rafi *Chair, RCGP Clinical Innovation and Research Centre*

Applications

Applicants are required to outline their contribution to NIHR Clinical Research Network Portfolio studies with particular weight being attached to:

- the range and number of clinical research studies on the Portfolio
- how they engaged with patients to inform them of new opportunities to participate in clinical research studies
- their contribution and innovative methods used in the successful delivery of clinical research studies

Applicants should set out how they would use the prize money to increase their contribution to NIHR Clinical Research Network Portfolio studies in future. This may be in the form of support for a personal development plan.

The closing date for entries is 12 noon on 25 August 2017.

Further information including eligibility criteria is available on the NIHR website http://bit.ly/RCGPCRNawards

Interested in becoming a GP Registrar and First5® GP Research Champion?

As part of a national initiative, we are seeking to employ early career GPs for up to eight hours/month to link with the CRN primary care teams based at Birmingham, Keele and Warwick universities. This offers a great opportunity to share your enthusiasm for primary care research with GP registrars and First5® GPs in your area. Each champion will work with members of the CRN team to raise registrars' and First5 GPs' awareness of opportunities to participate in primary care research (especially research delivery in day-to-day practice), and of applying to schemes such as the Academic Clinical Fellowships, post-CCT academic fellowships and In Practice Fellowships.

For further information, please contact Michaela Handley, email michaela.handley@nihr.ac.uk phone 01902 447198

Local Contacts

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

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Research Facilitator	**Aman Johal**	amanpreet.johal@warwick.ac.uk	02476 574127

Meet your West Midlands CRN Patient & Public Involvement and Engagement (PPIE) Team

Local patient and public involvement teams are coming together in primary care to share ideas about improving research awareness and implementing new initiatives recommended by the NIHR, to improve access to clinical research.

PPI should form the cornerstone of all clinical research and our local teams are working hard to enhance its role within primary care and shape future developments. To find out who your local CRN primary care team is, please see our list of contacts.

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