

October 2009

INSIDE THIS ISSUE:

<i>Lung-Search Study</i>	2
<i>The Counterpoint Study</i>	2
<i>Patient Identification Centre</i>	3
<i>NIHR Portfolio Studies</i>	4
<i>NIHR CRN Training Courses</i>	5
<i>Interesting Events</i>	5
<i>Contact Details</i>	6

Could your practice identify eligible patients to participate in research projects?

If yes....

Why not become a PIC?

See how inside

DENTAL STUDIES IN SET UP

The Primary Care Research Network Northern & Yorkshire (PCRN N&Y) is working with two dental studies being set up in the Northumberland, Tyne & Wear (NTW), area:



DRN140 - Periodontitis and type II diabetes (NIHR CRN ID No: 4678) is a co-adopted study being offered to GPs in Gateshead and Newcastle. The Chief Investigator is Professor Philip Preshaw from the University of Newcastle School of Dental Sciences. The study is interventional and involves

dentists identifying patients (aged 30-55 years) with both periodontitis and type II diabetes, introducing them to the study and referring them onto the dental school for further periodontal treatment and further investigations.

FICTION – Filling Children’s Teeth: Indicated or Not?

A co-adopted multi-site National Institute for Health Research Health Technology Assessment (NIHR HTA) funded study to assess the benefits of three different methods for treating dental decay in primary teeth.

The pilot is due to commence in Newcastle from January 2010. The main study will open to Newcastle and Leeds in the summer of 2010 (with an accrual target of 1,800).

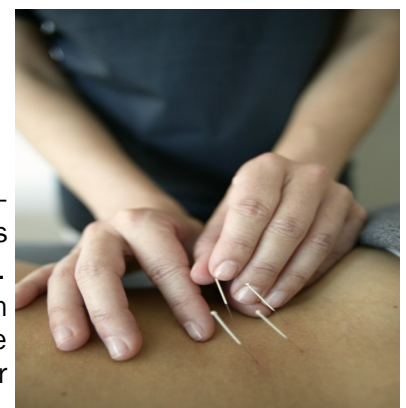
For more information or to express your interest in either of the above studies please contact Louise Warner Clinical Trial Coordinator, PCRN N&Y by email louise.warner@nyren.co.uk or contact the PCRN N&Y office.

ACUBACK- ACUPUNCTURE FOR BACK PAIN

A MIXED METHODS OBSERVATIONAL STUDY EVALUATING PATIENT MES AND THEIR DETERMINANTS

This is an opportunistic, observational, cohort study. The purpose of the research is to improve the understanding of the psychological mechanism (factors and process) involved in treatment for back pain, using acupuncture as a model. The study requires GPs to identify eligible patients, explaining study and option of acupuncture to patients; handing out study leaflet/information packs to those fitting the inclusion criteria – we estimate approximately 10 minutes extra per consultation.

The study will be open to all GPs within the PCRN N&Y areas of Co. Durham & Tees Valley, Northumberland, Tyne & Wear and West Yorkshire. For more details please contact the PCRN N&Y Clinical Trial Coordinator for your area (contact details on back page).



Lung-SEARCH

A randomised controlled trial of surveillance for the early detection of lung cancer in a high-risk group.

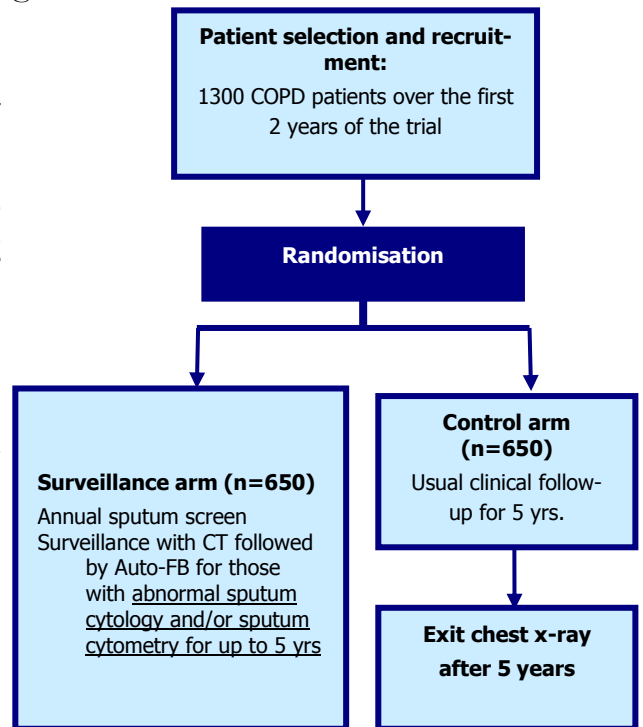
Picking up lung cancer early may improve the patients' prognosis. Over the first 2 years of this lung cancer screening trial we are looking to recruit, 1,300 patients with mild to moderate COPD. The Study Team can pay you £250 for helping us in finding possible patients.

We would ask you to identify possible patients and send them out study information and asking if they are interested in taking part.

The Chief Investigator of the trial is Professor Stephen Spiro. The Principle Investigator is Nial Keaney who is based at the Sunderland Royal Hospital.

This trial is only open to GPs in Sunderland.

Trial Flow Chart



For the inclusion criteria or more details please contact Louise Warner at the PCRN N&Y office.

NEW STUDIES
OPEN TO
RECRUITMENT IN
THE NTW AREA

If you are interested in taking part in either of these studies, please contact:

Dr Louise Warner
Clinical Trial Coordinator
for
Northumberland,
Tyne & Wear,
at the
PCRN N&Y office

THE COUNTERPOINT STUDY

Counteracting the problem of insulin production caused by triglycerides

Type 2 diabetes has until now been regarded as permanent and progressive. Recent studies have shown that major weight loss can return the body to near-normal and improve or reverse diabetes. This is very important for health. We need to test whether intensive dieting really does decrease the pancreas and liver fat content, and whether this explains the improvement and in some cases, the reversal of diabetes.

Who is eligible? Men and women with type 2 diabetes who are overweight (but with

waist circumference < 150cm) and between 25-67 years old.

What does it involve?

The study involves 8 weeks of intensive dieting with meal replacement drinks called OPTIFAST to cause weight lost. Tests to measure changes in liver and pancreas fat content using MRI, and your body's response to insulin will be carried out at intervals during the study. The tests will be conducted at the Newcastle Magnetic Resonance Centre, based at the Newcastle General Hospital.

If you are interested and would like to know more, please contact Dr Ee Lin Lim, e.l.lim@ncl.ac.uk or Dr Louise Warner, CTC,

PATIENT IDENTIFICATION CENTRE (PIC)

WHAT IS A PATIENT IDENTIFICATION CENTRE (PIC)?

A PIC is a practice or clinic that is responsible for identifying eligible patients to participate in research projects using specific inclusion/exclusion criteria. The PIC retains responsibility for the healthcare of the patient outside of the research, but the research site takes on the duty of care for them in relation to the study.

WHY ARE PICS BEING IDENTIFIED NOW?

The **NHS Constitution** states that *“the NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them”*.

THE NHS OPERATING FRAMEWORK STATES:

- *“the NHS must play its full part in supporting health research”;*
- *“all providers of NHS care will need to increase their participation in research”.*
- *“the national ambition is to double the number of patients taking part in clinical trials and other well-designed research studies within five years”.*

In order to achieve these objectives the NIHR networks need to identify sites to take on the role of a PIC. It is worth noting that you are still able to have full involvement in other studies.

HOW MUCH WORK IS INVOLVED IN BEING A PIC?

- If a study is being conducted in your PCT your practice will be sent a study summary with details of the inclusion/exclusion criteria. You would need to build a search using these criteria and then have the resulting patient list checked by a clinician to confirm that the patients are suitable for the research project. Staff from the PCRN can assist with this.
- All the eligible patients remaining on the list would be sent a letter informing them of the research and inviting them to participate. Staff from the PCRN can assist with this.

IS THERE ANY PAYMENT FOR THE WORK INVOLVED?

At present, a payment per referred patient enrolled onto a research trial is made to a PIC. This payment covers the work involved and currently is assessed on a ‘study by study’ basis.

If you are interested in becoming a PIC site please complete the slip below and fax it to the PCRN N&Y office

Fax to: 01642 615700

PATIENT IDENTIFICATION CENTRE (PIC)

EXPRESSION OF INTEREST

GP Practice Name: _____

Email Address: _____

Telephone Number: _____

NIHR CRN PORTFOLIO STUDIES

Currently recruiting and open to new sites in PCRN N&Y

(Co. Durham & Tees Valley (CDTV), Northumberland, Tyne & Wear (NTW), West Yorkshire (WY),
North & East Yorkshire/North Lincolnshire (NEYNL))

The following is a sample of studies recruiting in the PCRN Northern and Yorkshire area. You can find more information about these and other studies by visiting our website www.nyren.co.uk, the portfolio

DRN 023 ASCEND - A Study of Cardiovascular Events in Diabetes. A randomised 2x2 factorial study of aspirin versus placebo, and omega-3 fatty acid supplementation versus placebo, for primary prevention of cardiovascular events in people with diabetes (NIHR CRN ID: 2257)			
Recruitment Target	Funder	Project End Date	Recruiting:
10,000	British Heart Foundation	31/12/2009	All PCRN N&Y

EUDRAGENE - the pharmacogenetics of selected adverse drug reactions (ADRs): identifying possible cases of ADRs through primary care databases and hospitals across the UK (NIHR CRN ID: 4412)			
Recruitment Target	Funder	Project End Date	Recruiting:
5000	NIHR	01/01/2017	All PCRN N&Y

AESOPS - The effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care (NIHR CRN ID: 3796)			
Recruitment Target	Funder	Project End Date	Recruiting:
500	NIHR	31/01/2010	CDTV, NEYNL, NTW, WY?

REEACT - The Randomised Evaluation of the Effectiveness and Acceptability of Computerised Therapy Trial (NIHR CRN ID:4115)			
Recruitment Target	Funder	Project End Date	Recruiting:
600	NIHR	31/05/2011	In set up in NEYNL, NTW, Durham

ABC - (A bipolar cohort study) Bipolar 2 Disorder Cohort (NIHR CRN ID: 5668)			
Recruitment Target	Funder	Project End Date	Recruiting:
180	MRC	30/04/2010	In set up in NTW, CDTV

Lung-Search - A randomised controlled trial of surveillance for the early detection of lung cancer in a high-risk (NIHR CRN ID: 5668)			
Recruitment Target	Funder	Project End Date	Recruiting:
1,300	Cancer Research UK	26/02/2010	NTW

AcuBack Observational Study - Acupuncture for back pain: a mixed methods observational study evaluating patient outcomes and their determinants (NIHR CRN ID: 4857)			
Recruitment Target	Funder	Project End Date	Recruiting:
500	Arthritis Research Campaign	30/04/2010	NTW, CDTV, WY

If you are interested in or would like further information about any of the studies mentioned above, please contact the PCRN N&Y Clinical Trial Coordinator for your geographical area—see back page for contact details

NIHR CRN Training Courses are *free of charge* and can be **booked online** via the Learning Management System (LMS) on the NIHR CRN CC Website

Local courses from October 2009	Date	Location
Information Governance Foundation/Advanced	-	Online
Good Clinical Practice (GCP) Training/GCP & the EU Directive	-	Online
Valid Informed Consent	22/10/09	Leeds
Introduction to GCP: A practical guide to ethical & scientific quality standards in clinical research	29/10/09 11/11/09	Newcastle Leeds
Fundamentals of Involving Patients & Public As Partners in Clinical Research Activities (PPI)	10/11/09	Leeds
Mastering the Trial File: Understanding Essential Documents	24/11/09	Leeds

[Click here](#) to see list of course on NIHR CRN website or for **general enquiries** please contact the NIHR CRN CC Training Team by email to training@ukcrn.org.uk

North East Mental Health Research

Friday 23rd October 2009

This one-day conference is specifically designed for **Researchers, potential Researchers, Trust Senior Managers, Service Users and Carers.**

The aim of the conference is to inform existing and future researchers about the MHRN and to celebrate our success so far

Registration is free

For further **information** or to **book** your place, please contact:

Alissa Harrison, MHRN North East Hub, Psychiatry Dept., Royal Victoria Infirmary, Newcastle upon Tyne
Telephone: 0191 2824427 Email: alissaemma.harrison@ntw.nhs.uk

A joint Event between Diabetes Research Network and the Comprehensive Local Research Networks across the region

Wednesday, 11 November 2009

The Garter Room, Lumley Castle, Chester-le-Street, Co. Durham

“I have a research idea, how do I get started?” How the Diabetes Research Network can help you to initiate and support your Clinical Research

This is a **free** event sponsored by the Diabetes Research Network

To **book** a place on the conference go to www.necdrnpiconference.eventbrite.com and follow the instructions online, or via the North East & Cumbria Diabetic Research Network

NTW CLRN Roadshows

The Northumberland, Tyne and Wear CLRN is organising a range of **roadshows** across the region. These events aim to promote an understanding of the clinical research environment and showcase the CLRN and partner NIHR Clinical Research Networks. This is seen as an opportunity to engage further with local NHS staff and academics so that they can understand more fully the range of opportunities available through the CLRN to undertake and lead health and social care research to improve patient care and NHS services.

20 October 2009	12:00—14:00	Freeman Hospital
11 November 2009	11:00—13:00	St Nicholas Hospital
10 December 2009	12:00—14:00	Northumbria House, Cobalt Business Park
12 January 2010	12:00—14:00	Hedley Court, Orion Business Park
1 February 2010	12:00—14:00	Pemberton House, Sunderland Enterprise Park
18 February 2010	12:00—14:00	Wansbeck General Hospital
9 March 2010	12:00—14:00	Sunderland Royal Hospital

Lunch/refreshments will be provided at each event. Each event is accredited with 2 CPD points by the Federation of the Royal Colleges of Physicians of the UK

You can book your place at www.clnroadshow.eventbrite.com

WELCOME TO TWO NEW MEMBERS OF THE PCR N&Y TEAM



1st Floor, East Wing
Wellington House
Falcon Court
Preston Farm Industrial Estate
Stockton-on-Tees
TS18 3TS

Tel: 01642 615 600
Fax: 01642 615 700

General Email:
enquiries@nyren.co.uk

www.nyren.co.uk

NELLIE NKHOMA, CLINICAL TRIAL COORDINATOR



Nellie is originally from Malawi where she was born and was educated. After obtaining her BSC in 1997, she moved from public sector and joined the University of North Carolina Research Project (UNC Project) as a Research Nurse/Supervisor where the main interest was in HIV/STD.

Nellie emigrated to the UK in 2001 and worked for BUPA for a short period before joining the South Tees NHS Trust.

Although Nellie enjoyed her job in secondary care, her interest has remained in research. Nellie has been involved in setting up a study in the hospital. She has been seconded to the PCR N for six months and is hoping to learn a lot about research in primary care whilst working within the PCR N.

The team is delighted to have Nellie on board.

JOHN HODGSON, CLINICAL TRIAL COORDINATOR

John graduated from Bradford College of Health in 1995 as a registered General Nurse and continues to be a registered member of the NMC. He is currently studying for a BSc degree with the Open University.

John started his career as a Staff Nurse, moving on to Research Nurse based within hospitals. He has come to the PCR N with plenty of research and clinical trial experience, not least having worked for the last two years as a Stroke Researcher with the Yorkshire

Stroke Research Network.

In his spare time John enjoys running - having completed several half marathons and many 10km runs. We are very happy to have him join our team.



*Interested in a
trial or study?*

IF YOU HAVE ANY QUERIES, ARE INTERESTED IN PARTICIPATING IN A CLINICAL TRIAL OR STUDY MENTIONED IN THIS NEWSLETTER, OR WOULD LIKE TO KNOW WHICH STUDIES ARE BEING CARRIED OUT IN YOUR GEOGRAPHICAL AREA PLEASE DO NOT CONTACT THE STUDY TEAM — INSTEAD PLEASE CONTACT A CLINICAL TRIAL COORDINATOR OR THE PCR N&Y OFFICE.

Clinical Trial Coordinator	Geographical Area	Email Address
Mrs Nellie Nkhoma	Co. Durham/Teesside	nellie.nkhoma@nyren.co.uk
Dr Louise Warner	Newcastle, Tyne & Wear	louise.warner@nyren.co.uk
Mr John Hodgson	West Yorkshire	john.hodgson@nyren.co.uk
Dr Gareth Dovey	York/Hull/North Lincolnshire	gareth.dovey@nyren.co.uk