PC-CRTU *in Contact*
Issue 16 – Spring 2007

Editorial

Welcome to the first In-Contact newsletter for 2007. Last year continued to be one of opportunities and expansion. With the development of the UK Clinical Research Collaboration (UKCRC), the Primary Care, and the Topic Specific Local Research Networks (LRNs), we envisage that this year will be just as challenging for all of us.

We have now had confirmation that the West Midlands is one of the new Primary Care Research Networks. This strengthens our position in the newly reorganised world of NHS R&D and we are hopeful that this development will not affect the way we work with you. It will make new links for us within the West Midlands (Keele and Warwick) as well as nationally and look forward to the possibility that we are likely to have an even wider portfolio of studies to offer you in the coming years. In terms of the proliferation of new networks, we have just had a call for bids to become a host for the Comprehensive Research Network; these are important to us as they will have a role in enabling continued access to service support costs (re-imbursement for time spent on research). We will keep you informed on these developments and will shortly be writing to you all with further and fuller details as to what the networks are all about and what they will mean to you.

Research Support Facility (RSF)

The Research Support Facility has an ongoing remit to identify and support those who wish to commence an academic career. The primary means of achieving this is to provide training and facilitation for those who wish to secure a fellowship to undertake a PhD. The usual route (after securing funding) is for people to spend half time in clinical practice and half-time in the University undertaking a research project that will lead to a PhD. Please get in touch with one of us if this opportunity interests you.

National School for Primary Care Research

Birmingham, as one of the five top rated departments of primary care in England, is a founder member of the National School for Primary Care Research. This brings new investment to our research and will mean more new studies over the next five years as well as improved infrastructure. We continue to develop our electronic links to practices and have just launched the DESCARTEstudy which involves decision making around the management of sore throat and features simple data collection that can be entirely completed online. Get in contact if you want to try it out!

Studies currently open to recruitment include:

- CP450 study (variability in response to warfarin)
- MMP9 study, evaluating the accuracy of a potential serum marker for colorectal cancer
- DESCARTE: **DE**cision rule for **S**ymptoms and **C**omplications of **A**cute **R**ed **T**hroat in **E**veryday practice
- BALLETS: **B**irmingham **A**nd **L**ambeth **L**iver **E**valuation **T**esting **S**trategies
- Use of medical self-tests by members of the public
- GenPod
- IBS and Pro-biotic Yoghurt Study

Further information about all these studies are included within the newsletter.

Dr Richard McManus
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Professor Sue Wilson
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New studies and studies open to recruitment

The RS3 Study: Redesigning Stop Smoking Services

Lifestyle surveys in recent years have shown marked differences in smoking prevalence between ethnic groups and between genders in the UK. Men with a Bangladeshi background were almost twice as likely to be smokers than men from most other ethnic groups.

Stopping smoking is especially important in these populations because Pakistani and Bangladeshi people are at significantly increased risk of heart disease and stroke when compared to the majority of white British ethnic group, and stopping smoking would reduce the risk of these illnesses by several fold. However, despite evidence that smokers from minority ethnic groups are as ready to quit smoking as their counterparts in the UK population as a whole, they are half as likely as the white British population to use standard NHS Smoking Cessation Services. It is likely that this poor uptake of current services is rooted in cultural beliefs about smoking and its cessation, as well as the practicalities of service access. This is a concern, because people who use stop smoking services are about four times more likely to stop than are people who do this unassisted. The RS3 study aims to tackle some of the main barriers to stop smoking services by redesigning service delivery to be more acceptable to this population. This is a pilot RCT which aims to develop the methods we use to increase service use among Pakistani and Bangladeshi people. It is still in the early stages of development, but we hope to be putting some of our ideas into practice in the next few months, working primarily with the stop smoking services, rather than in general practices.

Anyone wanting any further information about the study should contact: Penney Upton on 0121 414 3026.

Variability in response to warfarin: A prospective analysis of pharmacogenetic and environmental factors (CP450 Study)

There is a great deal of variability in the dosage requirement of warfarin to maintain the international normalized ratio (INR) within a target range. This is increasingly an issue for primary care. Recently, pharmacogenetic and environmental factors have been shown to affect warfarin metabolism and therapeutic dosing regimes. Warfarin is metabolised by the liver enzyme cytochrome P450 isoform CYP2C9. Individuals with genetic variants of the enzyme require either abnormally low or high doses of warfarin to achieve therapeutic anticoagulation. Research also suggests that other genetic and environmental factors such as age, weight, liver disease, vitamin K intake, interacting medications and alcohol intake affect warfarin dose requirements and susceptibility to bleeding complications.

The purpose of the study is to define genetic and environmental factors that determine variability in response to warfarin. The proposed outcome of the study would be the development of a clinically useful and practical algorithm (that takes into account the relevant genetic and environmental factors) that will help clinicians individualise anticoagulant therapy. The potential benefits of this would include improved safety of warfarin with reduced morbidity and mortality, improvement in patient quality of life, improvement in the cost effectiveness of warfarin therapy and improved uptake of warfarin, particularly for atrial fibrillation.

A cohort of 100 patients with Atrial Fibrillation (AF) are being recruited from 40 primary care practices within the West Midlands, Warwickshire, Worcestershire and Hertfordshire. Recruitment for this study closes at the end of April 2007, and we remain severely behind our recruitment targets. We currently have 40 practices participating, although to date only 13 have succeeded in recruiting any patients! Of those, two practices in Hertfordshire have recruited a third of the total 44 patients between them, well done! We are hoping that the West Midlands, Worcestershire and Warwickshire will have a final push to catch up. If the remaining 27 practices can recruit just two patients each over the next four months, we will reach our target.

Forthcoming publication plans include a protocol paper and interim analysis, in the very near future.

For further information please contact Dr Trini Closa León on 0121 414 2954 or email to t.closaleon@bham.ac.uk

SEMAPHFOR – Self-management of heart failure for people with heart failure – open randomisation

Study aim

To compare the clinical effectiveness of a newly developed nurse facilitated, cognitive behavioural self-management programme with usual care from the heart failure nurse, in terms of re-admissions/admissions to hospital, self-management and quality of life.

Recruitment

Potential participants for this trial will be identified by General Practitioners, Heart Failure Nurses, Research Co-ordinators or Consultants.
The Study will consist of:

- Control group who will receive the manual
- Intervention group who will receive the manual plus cognitive behavioural chronic disease management which teaches people to be better self-managers using simple techniques such as goal setting and pacing, facilitated by a Heart Failure Nurse.

Inclusion criteria

- Have a definitive diagnosis of symptomatic heart failure (LVSD) as defined by ECHO, clinical diagnosis or coronary angiography.
- Have NYHA class stratification ie. class 1, 2, 3, 4

If your surgery is based within Solihull PCT and would like to participate, please email: r.hare@bham.ac.uk for more details.

An excellent start to the year for GenPod

GenPod is attempting to determine why some depressed patients fail to respond to antidepressant medication by examining two possible explanations.

Firstly that there may be a genetic component that may affect response to SSRIs and secondly that the severity of the depressive episode may have also had an effect (it has been noted that patients with severe depression have low levels of noradrenalin and respond better to medications acting on serotonin and noradrenalin). Patients are allocated to either an SSRI (Citalopram) or a NaRI (Reboxetine) and grouped according to the severity of their depression. Once the project is complete we will have a fuller understanding of the reasons patients respond to antidepressants and GPs will be able to prescribe medication more precisely.

The project has made a commendable start to the New Year with new team members and GPs increasing our new patient referral rate by 20 per cent. We now have 44 GPs working with us over the Birmingham, Solihull, Walsall and Wolverhampton areas, contributing to the over 460 patients participating throughout the country. Now that figures are improving, it seems assured that the Birmingham University branch will reach its annual target.

In order to keep GenPod recruiting to this high standard it is essential that we continue to have the support of participating GPs. All we ask is that when seeing patients with new episodes of depression, ask if they would like to participate and refer them to the research team if they are willing to assist. Many GPs have reported that participating patients tend to improve quickly compared to non-participants and that most enjoy contributing.

If you would like to know how you can participate in GenPod, if you are already participating but would like a recap or would like some more information please contact Alex Smith on 0121 414 8593 or email smithav@adf.bham.ac.uk.

Birmingham And Lambeth Liver Evaluation Testing Strategies – Ballets Study

This multi-centre study funded by the Health Technology Assessment (HTA), is asking the question – what is the utility of Liver Function Test (LFT) abnormalities in predicting risk of serious treatable disease? The aim is to develop an algorithm to inform GP decision-making within the consultation.

Patients who are flagged as having an abnormal LFT are consented to undergo an abdominal ultra sound scan and an extensive set of blood tests at their surgery. This is carried out by the BALLETS team. We have successfully recruited over 300 patients to date in Birmingham from 4 GP surgeries. However, we have recently had the opportunity to expand the study in the Birmingham area and are therefore currently looking to recruit more surgeries. You need to be a surgery that sends bloods to UHB who are flagging abnormal results.

If you would like to take part please contact Louise Bentham for further details.
Tel 0121 414 6805.

The launch of a Randomised Controlled Trial (RCT) to assess the efficacy of sildenafil citrate in men with erectile dysfunction after pelvic surgery for rectal carcinoma (the ED study).

Colorectal cancer is the second most common cause of death from cancer in the UK.

Surgery remains the treatment of choice but despite careful operative technique up to 70 per cent of male patients have either complete or partial erectile dysfunction. This has major implications with regard to quality of life for many cancer patients. Sildenafil (Viagra®) has been extensively used in the treatment of erectile dysfunction but its effectiveness in patients who have undergone pelvic surgery for rectal cancer remains uncertain. It is well recognised that psychological factors, the presence of a stoma, and the fear of recurrent cancer, have a major influence on erectile dysfunction.

The primary objective of this placebo controlled, flexible dose, RCT is to evaluate the efficacy of sildenafil and assess the extent of improvement in quality of life, sexual function and sexual satisfaction that may be associated with access to therapy. We will commence this study during April 2007. Recruitment of 100 participants will be undertaken at colorectal follow-up clinics held at the University Hospital Birmingham NHS Trust. Research clinics will be held at the Wellcome Trust Clinical Research Facility QEH, where participants will be randomised to receive either oral sildenafil (n= 50) or placebo (n= 50) for a total treatment period of 12 weeks.

Secondary objectives include establishing the prevalence of erectile dysfunction after resection for rectal cancer and assessing the acceptability of Sildenafil.

Prior to recruitment, permission will be sought from participants for us to contact their GP to obtain a list of currently prescribed medication and to check that there are no medical reasons that indicate Sildenafil should not be prescribed.

An intention is that the outcomes from this study will provide information to improve the management of rectal cancer patients.

If you would like further information about this study, please contact:
Professor Sue Wilson (s.wilson@bham.ac.uk)

Ongoing research

Sore throat study

DESCARTE – Evaluating management decisions in sore throat

A bit of a late start but we now have PCT approvals, with 300 x 10 patient packs ready to send out. GP's can start with a pack of 10 then fax in for further supplies. At the time of writing this article over 40 x 10 patient packs have already been sent out. One keen practitioner entered 15 patients in the first 2 weeks! The feedback so far has been very positive – GP's love the web site, which, once data has been ticked into the boxes can then populate the patients notes; we also have paper versions if preferred. We can provide posters and Information leaflets for the waiting area so patients with sore throats are alerted to the study. We are recruiting 16 year olds and over with sore throat symptoms as their main problem.

Unusually this study can be done by any individual GP or all GPs in the practice. If you or your practice are interested and have not previously volunteered to host the study, please ring our Administrators on 0121 414 2845 or myself for further information.

Ros Salter - 0121 414 6505 (r.a.salter@bham.ac.uk)

Use of medical self-tests by members of the public

The Cancer and Screening Team in the Department of Primary Care has a stream of research related to self-testing. Self-testing is where a member of the public buys a test from a shop or over the internet to see if they may have a condition without involving a doctor, nurse or other health professional. Examples include tests for chlamydia, prostate specific antigen and faecal occult blood. Although the range and accessibility of self-tests has increased dramatically over the last few years, there have been very few studies looking at who is using self-tests and why they are being used.

We are currently conducting a study, funded by the Department of Health, to get a precise estimate of the prevalence of the use of any self-test and to determine factors that are associated with using them. So far, we have sent a short questionnaire about the use of self-tests to around 2500 people from general practice lists. The response rate was 65%, and we have interviewed 23 of the respondants. We will now use those interviews to help us design a more detailed questionnaire about why people use self-tests.

After designing the second questionnaire, we will be approaching further general practices to ask them to take part in the study. We would send the initial short questionnaire to samples of adults randomly selected from practice lists, excluding people who it would be inappropriate for us to approach, for example because of a terminal illness, severe mental illness or recent bereavement. People who respond to that questionnaire will then be sent the more detailed questionnaire if they said that they would be willing to receive it.

If your practice is interested in collaborating with this research, please contact Angela Ryan (a.v.ryan@bham.ac.uk) on 0121 415 8015.

IBS & Pro-Biotic Yoghurt Study

We urgently need to involve practices in North Birmingham in a randomised controlled trial to determine the efficacy of pro-biotic yoghurt in the management of Irritable Bowel Syndrome (IBS). Our research office will undertake identification of patients, mailings and appointment bookings and we will provide research staff to run study clinics. If you would like further details please contact Debbie McCahon, Research Manager, Tel: 0121-414-2957. Email: d.mccahon@bham.ac.uk

Development of patient pathways to identify risk of genetic disorder in primary care

This is a collaborative service development and evaluation project between Birmingham University and the West Midlands Clinical Genetics Unit supported by the DoH service development initiatives in genetics.

The aim of this service development initiative is to develop, implement and evaluate pathways for the identification of patients at risk of cardiac, endocrine or renal genetic disorders in primary care and offer them access to new specialist nurse led genetics clinics in secondary care.

The service evaluation has been running for 12 months. 10 general practices within the Heart of Birmingham Teaching PCT and South Birmingham PCT have implemented the new pathways. In addition qualitative interviews and focus groups have been conducted with primary care health professionals to inform the overall service development and identify barriers and facilitators to the development of genetic services in primary care.

The final evaluation data is now being collected and collated for analysis. We anticipate that the outcomes of this project will include recommendations for the provision of a genetic triage strategy for the identification and appropriate referral of at risk patients at a primary care level and provide data to direct future research concerning provision of clinical genetic services.

If you have any queries please do not hesitate to contact Debbie McCahon, Research Co-ordinator, Tel: 0121 414 2957, Email: d.mccahon@bham.ac.uk

MMP9 Studies

MMP9

Increased levels of MMP9 have been found in the blood of people with colorectal cancer and polyps. Two ongoing studies (MMP9 UHB and MMP9 CR-UK) aim to establish the accuracy of MMP9 and determine whether it will be of value in increasing the proportion of colorectal cancers diagnosed at an early stage of disease.

MMP9 UHB
This is a study to assess the value of a new blood test in improving the appropriateness of urgent referrals to colorectal clinics. The study will compare the MMP9 level of people who have been referred to a colorectal clinic with the results of examinations and investigations undertaken at, or shortly after their clinic visit. If a high MMP level does identify people with colorectal cancer or polyps, the test could assist general practitioners in deciding which patients should be referred urgently.

About 1,000 patients were recruited to the study. We are now near to completion of collecting clinical outcomes and data analysis is underway. Completed analyses of symptom profiles, anxiety and quality of life have been presented at the 9th Annual conference of the UK Federation of Primary Care Research Networks, Liverpool (27–28 November 2006) and NCRI Cancer conference, Birmingham (8–11 October 2006).

For further information contact Sally Warmington (s.a.warmington@bham.ac.uk) or Angela Ryan (a.v.ryan@bham.ac.uk) on 0121 414 8589.

MMP9 CR-UK – (Open to recruitment)
The aim of this study is to assess the accuracy and acceptability of MMP9 as a potential screening test for colorectal cancer. All participating patients will provide a blood sample for MMP9 estimation and have a colonoscopy (gold standard screening test for colorectal cancer) at the Wellcome Trust, QEH. Comparison of MMP9 levels and the colonoscopy results will establish the accuracy of the test. To achieve the end points of the study, 700 colonoscopies will be undertaken and to date 432 have been performed.

We are on the home straight now but we still need continued support from GPs to complete the study. General practices agreeing to participate with the study are essential to the process of patient recruitment. The second phase of practice recruitment is complete and 19 practices are involved in the study. However we aim to recruit a total of 29 practices within travelling distance of the QE. Potential participants will be seen at the practice by one of the study research nurses. During the appointment, the research nurse will provide more information about the study, undertake informed consent and book a colonoscopy date.

Any other practices interested in participating should contact either Professor Sue Wilson (s.wilson@bham.ac.uk), or Val Redman v.d.redman@bham.ac.uk) on 0121 414 2688

Heart Failure amongst the minority ethnic communities in Birmingham: The E-ECHOES (Ethnic - Echocardiographic Heart of England Screening) Study

This study has now succesfully started recruiting individuals to document the prevalence of heart failure within the South Asian and African-Caribbean communities. Individuals from these ethnic groups, aged 45 years and above are being invited and screened by researchers within general practices in Heart of Birmingham Teaching PCT. If you have already expressed your interest in participating, don't worry we haven't forgotten you, and will be in touch soon. For further details please contact:

Dr Paramjit Gill
Tel: 0121 414 3758
Email: p.s.gill@bham.ac.uk

National Eden

This project aims to evaluate how differences in the implementation and configuration of Early Intervention Services (EIS) affect key outcomes such as duration of untreated psychosis. We are employing a multiple case study approach because it uses a combination of quantitative and qualitative methods to provide findings that are both descriptive and explanatory in nature. At present, young people with first episode psychosis are being recruited from EIS in Birmingham, Cambridge, Cornwall, Lancashire and Norfolk. We are conducting longitudinal semi-structured interviews and clinical assessments with service users. In addition, we are carrying out further interviews and focus groups with EIS health professionals and their families. Data collection will close in June 2007.

If you would like more information about the study please contact
Professor Helen Lester
Tel: 0161275602
Helen.Lester@manchester.ac.uk

Recruitment completed – under analysis

The Rotavirus Incidence Study

The aim of the Rotavirus study is to estimate the burden of rotavirus in children aged under 5, including incidence rates, seasonal variations and economic costs.

This year long study has now finished. We were notified of 370 patients with diarrhoea of which 280 stool samples were tested by research nurses and 14 were found to be positive.

We would like to thank all the participating practices and the Bank Nurses for their hard work over the last 12 months.

Ros Salter
Tel: 0121 414 6505

The Birmingham Atrial Fibrillation Treatment of the Aged Study (BAFTA)

The Birmingham Atrial Fibrillation Treatment of the Aged Study (BAFTA) has been ongoing since 2000 and aims to determine whether aspirin or warfarin is the best form of stroke prevention in people 75 years old and over who have atrial fibrillation. Patient recruitment targets were exceeded, with 973 patients entering the study. Patient follow-up finished in September 2006, and we are in the process of collecting the final data items from practices.

BAFTA results will be presented at the MidReC annual Research Conference on 3rd May 2007, at City Hospital Postgraduate Centre, Birmingham. All GPs and nurses who were involved in recruitment to BAFTA should have received an invitation to attend this event. It is hoped that the results will be published at the end of May.

Once again, we would like to thank all the staff in the BAFTA practices for their hard work. It is a direct result of the extra effort that everyone has put in that ensured that this trial was so successful.

Kate Fletcher
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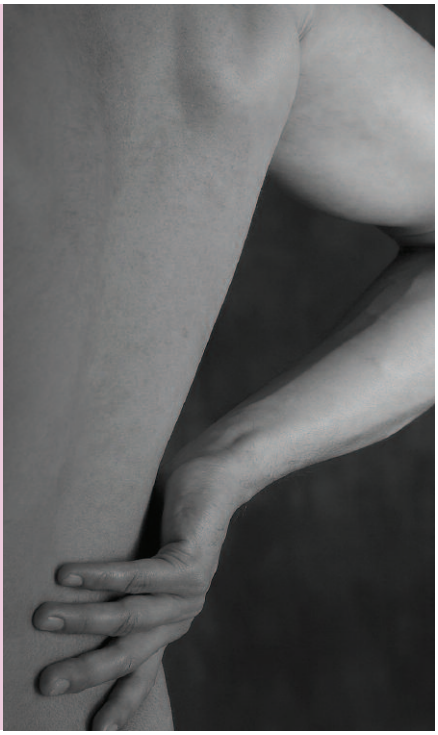
The BeST Study (The Back Skills Training Trial)

The BeST study is looking at the development of Cognitive Behavioural Therapy (CBT) in patients with low back pain in a primary care setting. It is hoped that this will empower patients to manage their own back pain. We are collaborating on this study with The University of Warwick.

The Birmingham team successfully recruited 85 patients and has now completed its involvement with this study. We would like to thank all practices and patients who took part in this study.

Ros Salter
Tel: 0121 414 6505



REDIRECT – summary 2007

The Redirect Trial is a 4-year randomised controlled trial clustered at the practice level, which means that general practices who agreed to participate were randomly allocated to either early detection of first episode psychosis training or 'detection as usual'. All new cases of first episode psychosis referred by intervention and control practices were identified and invited to participate in the study. Baseline and follow-up measurements of clinical recovery and other important outcomes were conducted.

110 practices were recruited into the trial, and GPs enrolled 75 young adults with first episode psychosis.

Evaluation of the education showed that GPs enjoyed it and felt that it improved their knowledge, skills and attitudes around first episode psychosis. The practice attrition rate in the trial has been low, with only one practice dropping out of the trial.

The study has received a significant amount of national and international publicity and the methodology and educational intervention papers have been published in BMC Health Services Research and Medical Education, respectively.

The Redirect Trial has now closed to new referrals and follow-up patient interviews are continuing over the next few months. The Redirect Trial research team thank all who supported and participated in the trial.

Dr Lynda Tait
Research Fellow
Tel: 0121 414 8584

Reported studies

Hypnotherapy and Irritable Bowel Syndrome

Wilson S, Maddison T, Roberts L, Greenfield S, Singh S. (The effectiveness of hypnotherapy in the management of irritable bowel syndrome: a systematic review of the literature). Aliment Pharmacol Ther 2006;24:769-80

Irritable bowel syndrome (IBS) is a chronic disorder affecting 10-20% of the population. It is estimated that a general practitioner in the United Kingdom (UK) sees eight patients with IBS every week and these patients constitute up to 50% of gastroenterology referrals. Conventional therapy leaves up to 25% of sufferers without relief of symptoms and many patients have been reported to turn to alternative therapies. 'Gut directed hypnotherapy' (GDH), a type of hypnosis, is one of the alternative therapies most frequently reported to have a demonstrable beneficial therapeutic impact on IBS symptoms.

The large number of primary studies and reviews suggesting that GDH may have significant value in the management of IBS and the lack of a high quality systematic review, provided the impetus to conduct this systematic review, which addresses the question of whether hypnotherapy is effective in the management of IBS.

An abstract of our results is given below:

Aim: To systematically review the literature evaluating hypnotherapy in the management of irritable bowel syndrome (IBS).

Methods: Electronic databases were searched (Cochrane Library, Medline, CINAHL, AMED, Embase, PsycINFO and the Social Science Citation index), bibliographic references scanned and main authors contacted. No restrictions were placed on language or publication year. Eligible studies involved adults with IBS using single component hypnotherapy. All studies, except single case or expert opinion, were sought and all patient related outcomes eligible.

Results: Out of 299 unique references identified, 20 studies (18 trials of which 4 were randomised, 2 controlled and 12 uncontrolled) and two case series were eligible. These tended to demonstrate hypnotherapy as being effective in the management of IBS. Numbers of patients included were small. Only one trial scored more than 4/8 on internal validity.

Conclusion: The published evidence suggests that hypnotherapy is effective in the management of IBS. Over half of the trials (10 of 18) indicated a significant benefit. A randomised placebo controlled trial of high internal validity is necessary to establish the effectiveness of hypnotherapy in the management of IBS. Until such a trial is undertaken, this form of treatment should be restricted to specialist centres caring for the more severe forms of the disorder.

Vaginal vault smears after hysterectomy for reasons other than malignancy: a systematic review of the literature

Helen Stokes-Lampard, Sue Wilson, Christine Waddell, Angela Ryan, Roger Holder, Sean Kehoe. BJOG 2006; 113:1354-1365.

Approximately half of all vault smears are undertaken in primary care. This study aimed to establish the evidence base to support the value of vault smears after hysterectomy for reasons other than malignancy. The following abstract summarises a paper that was published recently in The British Journal of Obstetrics and Gynaecology, it reports on a systematic literature review conducted within the department. The title has also been accepted by the Cochrane Collaboration.

Background: Vaginal vault smear tests are used to detect persisting neoplasia of the lower female genital tract after total hysterectomy. Recent data suggest their widespread use outide the recommendations of national guidelines and uncertain evidence of their effectiveness.

Objectives: To identify and synthesise all the available evidence on the use and effectiveness of vaginal vault smears and to assess the quality of this evidence.

Search Strategy: 'vault smear' OR 'vaginal vault smear' OR 'cervical vault smear' OR ('Hysterectomy') AND ('Follow up' OR 'Smear'). Selection Criteria: Primary research, women who had a hysterectomy and were followed up by vault cytology.

Data Collection and Analysis: Systematic search of the literature (8 electronic databases), supplemented by contact with experts in the field and a review of bibliographies. Two independent reviewers determined eligibility/validity and extracted data concerning test performance characteristics. Quality was assessed according to established criteria.

Results: 441 unique references, only 19 were suitable for analysis. Quality of studies varied considerably and few were of 'high' methodological quality. Studies were geographically diverse and published over 40 years in 16 journals. From the higher scoring papers there were 11,656 hysterectomies (6,546=benign, 76=CINI/CINII, 5,037=CINIII). Proportions of abnormal vault smears and abnormal biopsies during follow-up increased with worsening histology at hysterectomy ($p<0.0001$ and $p=0.0001$). There was only one report of vaginal cancer subsequent to hysterectomy for CIN and insufficient data to allow for reliable meta-analysis.

Conclusions: Vault smears cause anxiety, consume resources and their value is largely unproven. Inconsistency of study design and limited methodological quality means that the value of vault smears could not be established. High quality, robust research is required to ensure that future guidelines are evidence based.

News from the Birmingham Elderly Thyroid Study (BETS)

This study was concerned with determining the prevalence of sub-clinical thyroid dysfunction in the elderly population and investigating the implications of dysfunction in terms of depression, cognitive dysfunction and atrial fibrillation. After a long period of data validation, coding, analysis and re-analysis, the first two papers from this study have now been published.

The first paper published in Annals of Internal Medicine concluded that there was no clinically relevant association between sub-clinical dysfunction and depression or cognition. This paper has attracted significant interest in the United States where screening is more common than in the UK, and on Christmas day we had a full page in the American Medical News! The second paper published in the Journal of Clinical Endocrinology and Metabolism revealed a community prevalence of sub-clinical dysfunction much lower than that previously reported and also reported new findings in terms of the association between deprivation and thyroid dysfunction. Both of these papers will, we believe, be important in the screening debate. A third paper which explores the relationship between thyroid function and AF looks set to shake this debate further.

Abstracts and references for the two papers are provided below and we will keep you posted with further news.

1. *Roberts L, Pattison H, Roalfe A, Franklyn J, Wilson S, Hobbs F, Parle J.* ***Association between subclinical thyroid dysfunction and depression, anxiety and cognitive function: Evidence from the Birmingham Elderly Thyroid Study.*** *Annals of Internal Medicine 2006; 145: 573-581*

Background: Widespread use of automated sensitive assays for thyroid hormones and Thyroid Stimulating Hormone (TSH) has increased identification of mild thyroid dysfunction, especially in elderly patients. The clinical significance of this, however, remains uncertain and associations with cognitive impairment, depression and anxiety unconfirmed.

Objective: To determine the association between mild thyroid dysfunction and cognition, depression and anxiety in elderly individuals.

Design: Cross-sectional study. Associations explored through mixed model analyses.

Setting: Primary Care, West Midlands, UK.

Patients: 5865 patients aged 65 years and over, with no known thyroid disease, recruited from primary care registers.

Measurements: Serum TSH and free T4 levels were measured. Depression and anxiety scores were obtained using the Hospital Anxiety and Depression Scale (HADS) and cognitive functioning established using the Middlesex Elderly Assessment of Mental State (MEAMS) and Folstein's Mini Mental State (MMSE). Co-morbidities, medication usage and socio-demographic profiles were recorded.

Results: 295 patients met criteria for sub-clinical thyroid dysfunction (127 hyperthyroid, 168 hypothyroid). After controlling for confounding variables, statistically significant associations were demonstrated between anxiety (HADS-A) and TSH (P=0.013) and between cognition and both TSH and free T4. The magnitude of these associations was such that they lacked clinical relevance; a 50mIU/L increase in TSH being associated with a 1 point reduction in HADS-A and a 1 point increase in MMSE being associated with increases of 50mIU/l in TSH or 25pmol/L in free T4.

Limitations: Low participation rates, low prevalence of sub-clinical thyroid dysfunction and other unidentified recruitment biases mean participants may not be representative of the elderly population.

Conclusions: This study controls for the confounding effects of co-morbidities and medication and confirms, in a large generalisable sample, the lack of association between sub-clinical thyroid dysfunction and depression, anxiety and cognition.

2. *Wilson S, Parle JV, Roberts LM, Roalfe AK, Hobbs FDR, Clark P, Sheppard M, Gammage M, Pattison H, Franklyn J.* ***Prevalence of subclinical thyroid dysfunction and its relation to socioeconomic deprivation in the elderly: a community-based cross-sectional survey.*** *The Journal of Clinical Endocrinology & Metabolism 2006; 91: 4809-4816*

Context: Population-based screening has been advocated for subclinical thyroid dysfunction in the elderly because the disorder is perceived to be common, and health benefits may be accrued by detection and treatment.

Objective: The objective of the study was to determine the prevalence of subclinical thyroid dysfunction and unidentified overt thyroid dysfunction in an elderly population.

Design, Setting, and Participants: A cross-sectional survey of a community sample of participants aged 65 years and older registered with 20 family practices in the United Kingdom.

Exclusions: Exclusions included current therapy for thyroid disease, thyroid surgery, or treatment within 12 months.

Outcome measure: Tests of thyroid function (TSH concentration and free T4 concentration in all, with measurement of free T3 in those with low TSH) were conducted.

Explanatory variables: These included all current medical diagnoses and drug therapies, age, gender, and socioeconomic deprivation (Index of Multiple Deprivation, 2004).

Analysis: Standardized prevalence rates were analyzed. Logistic regression modelling was used to determine factors associated with the presence of subclinical thyroid dysfunction.

Results: A total of 5960 attended for screening. Using biochemical definitions, 94.2% [95% confidence interval (CI) 93.8–94.6%] were euthyroid. Unidentified overt hyper- and hypothyroidism were uncommon (0.3, 0.4%, respectively). Subclinical hyperthyroidism and hypothyroidism were identified with similar frequency (2.1%, 95% CI 1.8–2.3%; 2.9%, 95% CI 2.6–3.1%, respectively). Subclinical thyroid dysfunction was more common in females ($P < 0.001$) and with increasing age ($P < 0.001$). After allowing for co-morbidities, concurrent drug therapies, age, and gender, an association between subclinical hyperthyroidism and a composite measure of socioeconomic deprivation remained.

Conclusions: Undiagnosed overt thyroid dysfunction is uncommon. The prevalence of subclinical thyroid dysfunction is 5%. We have, for the first time, identified an independent association between the prevalence of subclinical thyroid dysfunction and deprivation that cannot be explained solely by the greater burden of chronic disease and/or consequent drug therapies in the deprived population.

Range of Self-Tests available to buy in the United Kingdom: An internet survey

Ryan A, Wilson S, Greenfield S, Clifford S, McManus RJ, Pattison HM.

The following is taken from a paper published in the Journal of Public Health (2006; 28(4): 370-374).

Introduction: To inform the design of the study to describe the prevalence of the use of self-tests, we undertook a systematic internet search to identify self-tests that are available to buy by members of the UK public.

Methods: In April and May 2006, we used popular search engines to search the web for self-tests that could be purchased and used by a member of the UK public without involving a doctor, nurse or other health professional. The entire web was searched, rather than just UK sites, to ensure that tests that are sold from other countries to UK customers were also identified. We reviewed the descriptions of the first 20 sites returned from each search and then explored relevant sites and collected details of any relevant tests.

Results: We collected details of 167 self-tests, which were advertised by 19 retailers, nine of which were based in the UK. Some self-tests were sold by more than one retailer, and there were 104 unique tests. These tests relate to 24 named conditions, including cancers (eg. tests for faecal occult blood and prostate specific antigen), chronic conditions (eg. tests related to diabetes and cardiovascular disease) and infections (eg. tests for urinary and sexually transmitted infections). Self-tests related to male and female infertility and allergies were also available. The self-tests required a variety of samples, including urine, stool and blood samples. Where a blood sample was needed, this was a finger prick sample obtained using a lancet. The samples were processed in the home with results available in minutes or sent to a laboratory for processing with results returned by email or post after several days. Prices per self-test and condition ranged from less than £1 to £76.

Conclusions: This study demonstrates the potential for self-testing for a wide range of conditions by members of the UK public and supports our current study to determine how many people are using self-tests and their reasons for using them. Further work is also needed, however, to assess the impact of self-test use on individuals, the population and health services.

The effects of exercise in women with postnatal depression (pnd)

Abstract

Background and aims: The consideration of novel adjunctive interventions for the treatment of PND is timely for several reasons. The recent United Kingdom (UK) Confidential Enquiry into Maternal Deaths (2000-2002) reported that psychiatric disorders contribute to 12% of all maternal deaths, there is some reluctance to take antidepressants among postnatal women and because the availability of psychological and counselling based treatments is often limited. There is also growing acceptance of exercise as a useful treatment option for depression among general populations with NICE advocating that depressed patients be advised about the benefits of exercise. It seems possible that participation in regular exercise may also have a positive effect in the management of postnatal depression. The aim of this study was to examine the feasibility and acceptability of an exercise intervention in depressed postnatal women who had given birth in the previous 12 months.

Method: Women were identified from GP practice records, health visitor clinical judgement, referral from the QE Psychiatric Hospital Mother and Baby Unit, or by self-referral. Following informed consent participants were randomised to an exercise consultation intervention over 12 weeks (two sessions plus two support telephone support calls) that focussed on promoting feasible exercise such as pram-walking or usual care. Main outcomes were the amount of mild, moderate and vigorous exercise and self-efficacy for exercise. Levels of depression using the Edinburgh Postnatal Depression Scale (EPDS) were obtained, but the study was not powered to show a difference in this outcome. Intervention participants also completed an intervention evaluation questionnaire related to their experiences.

Results: 25/262 (9.5%) general practices approached provided lists of eligible patients. The most successful route of recruitment of eligible patients was via referral from the specialist Mother and Baby Unit (9/28(32.1%)), followed by invitation letter from patients' GP (24/93(25.8%)). After 12 weeks there were no significant differences in levels of exercise participation between the groups, but the intervention group reported significantly higher self-efficacy for exercise compared to usual. Depression scores did not differ. Responses from the open-ended intervention evaluation questionnaire indicated that participants felt they had experienced some mental health benefits from participating in the exercise intervention.

Conclusion: The recruitment of eligible patients into this pilot trial was low, raising issues of generalisability. Further work regarding optimum methods of recruitment in this difficult to research population are required prior to a substantive trial. The higher self-efficacy for exercise in the intervention group suggests the intervention was successful in promoting the belief in participants that they could achieve regular participation in exercise. However, exercise participation over the 12-week period was not increased; this may be because the intervention was not sufficiently intensive to change participants exercise behaviour.

Research team

Dr Amanda Daley
Professor Christine Macarthur
Dr Heather Winter
Dr Richard McManus
Ms Chloe Grimmett

We would like to thank all the practices that helped us with this project. We would also like to thank the staff at the Mother and Baby Unit, particularly Mary McGuinness for their help and support with this study.

For further information contact Amanda Daley (a.daley@bham.ac.uk).

Research opportunities

Research Development Fund

The Pan Birmingham Primary Care Nursing R&D Group Research Development Fund has been established through donations from PCTs in the Birmingham area and the University of Birmingham Research Support Facility.

Pan Birmingham Primary Care NURSING Research & Development Group

Purpose

The purpose of the Fund is to provide small grants to primary care nurses seeking to increase their research expertise.

A small grant may be awarded for one of the following reasons:

- To fund small scale research studies that would potentially result in publication
- To fund feasibility/pilot work for studies that have the potential to form the basis of an application for larger scale research funding from another source
- To provide bursaries to facilitate attendance at a conference where the applicant has been invited to present completed research
- To meet specifically identified research skills training needs of an individual by enabling them to undertake appropriate training
- To support the dissemination of research findings

Criteria

Small scale research studies and feasibility/pilot studies: a maximum of £1,000 to cover material costs and expenses.

Conference bursaries: a maximum of £500 to cover registration fees and expenses.

Training bursaries: a maximum of £500. Funding will not be provided for the purpose of undertaking a first degree or Masters programme.

Dissemination of research findings: to encourage the development of nursing through the dissemination of nursing research, financial assistance may be provided to special interest groups.

Eligibility

Primary care nurses living or working in the Pan Birmingham area.

Application process

Applications must be made in writing (1000 words maximum), stating the reason for the application and the basis of the amount of funding being applied for. The application should also state how the grant will increase the research expertise of the applicant(s).

Applications can be made at any time. All applications will be peer reviewed.

The application should be sent to the Chair of the Group at the address below. General queries may also be sent to the Chair.

Angela Knight Jackson, Balsall Heath Health Centre, 43 Edward Rd, Birmingham B12 9LP
Email: Angela.Jackson@hobtpct.nhs.uk
Telephone: 0121 446 2300

Applicants will be informed of the outcome within three months of the application being received.

Payment

The Fund is administered by the University of Birmingham and payment will be made through the University on receipt of an invoice or expenses claim using appropriate documentation.

Eyelid Research Project

Are you an academic GP registrar in search of a project?

The PCCRTU has been approached by Teifi James, a consultant Ophthalmologist in Halifax who has developed a re-useable eyelid warming device for the treatment of cysts, styes, chalazion, and blepharitis. It has also proved to be helpful in some dry eye patients. He is interested in funding a comparative study of efficacy and compliance with self administered ad hoc home made warm compresses versus his EyeBag product.

A recent RCT at Central Middlesex Eye Dept (Vikki Lee) looked at meibomian cyst management and found that 48% resolved within 3 weeks using homemade hot compresses. There is scope for looking at how many hospital eye referrals for meibomian cysts could be avoided if the eyebag is used appropriately.

He is unable to offer to design any study due to his personal and financial interest, but is in a position to provide the EyeBag product free and in appropriate quantities to bona fide researchers. Further information about this product can be viewed on the website: www.eyebagcompany.com/

If you are interested in taking this up further, please contact Mr Teifi James, FRCP., FRCS., FRCOphth, Consultant Opthalmic Surgeon and MD., The Eyebag Co. Ltd or mobile: 07966 660240

Report from the Inaugural Conference: Shaping the Future of Primary Care

The Pan Birmingham Primary Care Nursing R&D Group is a group of highly motivated individuals who have come together to promote and support Birmingham primary care nurses interested in research. Supported by the University of Birmingham Research Support Facility, their enthusiasm resulted in local PCTs providing funding to support an Inaugural Conference in June last year.

Pan Birmingham Primary Care NURSING Research & Development Group

The Conference was held at the City Hospital Post Graduate Centre in Birmingham and attended by 110 delegates, mainly nurses, working in practice, research, educational and management roles.

The programme comprised, parallel sessions, workshops, poster presentations and plenary presentations from the following keynote speakers:

- George Castledine (Professor of Nursing at UCE in Birmingham)
- Kate Gerrish (Professor in Nursing Practice Development at Sheffield University and Chair of the RCN Research Society)
- Ann McMahon (RCN Research and Development Adviser)
- Angela Knight Jackson (Chair of the Pan Birmingham Primary Care Nursing R&D Group).

Planning is now underway for this year's Conference. It will be held on June 25th at the Austin Court Conference Centre (near to the NIA). Keynote speakers include Professor Tony Butterworth from the University of Lincoln and Professor Ros Bryar from City University, London.

The Conference will also provide a showcase for locally undertaken primary care nursing research. For further information on how to submit an abstract or book a place either contact Beverley Hancock (b.hancock@bham.ac.uk) or visit the R&D Consortium, website: **www.southbirminghampct.nhs.uk/_services/RandD/researchGroup.htm**

Primary Care Dermatology Training

This course is suitable for general practitioners, nurses and other professionals with an interest in primary care dermatology. A range of learning methods will be used including seminars and group work. Also included are sessions at the Birmingham Skin Centre, City Hospital and at local general practices that provide dermatological expertise within the community.

The five day course is accredited by the University of Birmingham for 20 credits at masters level. These credits can be used towards the MSc in Primary Care and are transferable to other masters courses at this university or elsewhere. The module can also be taken as a stand-alone short course and is open to all interested professionals.

Fees: £700.00
Course dates: 3–7 September 2007
Venue: University of Birmingham
To book a place contact:
Deborah Bird, Postgraduate Course Secretary
Dept of Primary Care and General Practice
University of Birmingham, Edgbaston
Birmingham B15 2TT
Tel: 0121 414 2677
Email: d.bird@bham.ac.uk

MidReC Management Group

We would like to say thank you to Dr Craig Munro for volunteering to join the Group. Craig is a GP at Cape Hill Medical Centre, Smethwick and will join the other members listed below:

Professor Brendan Delaney, Academic lead and GP, University of Birmingham and Laurie Pike Health Centre, Aston
Professor Richard Hobbs, MidReC Director and GP, University of Birmingham and BelleVue Medical Centre, Edgbaston
Dr Richard McManus, Clinical Director MidReC and GP, University of Birmingham and Greenridge Surgery, Yardley Wood
Dr Harj Dau, GP, Tudor Practice, Sutton Coldfield
Dr Isabel Draper, GP, Whitehall Medical Practice, Rugby
Dr Karim Ladha, GP, The Dovecote Surgery, Oldbury
Dr Martin Wilkinson, GP, The Harlequin Surgery, Shard End
Mrs Pat Marsh, Practice Nurse, Ridgacre House Surgery, Quinton
Mr Barry Clark, User and Chaplain based at Selly Oak hospital
Mrs Ros Salter, R and D Manager, University of Birmingham

In addition to the above, we have representatives from Practice Managers throughout the West Midlands serving on this group.

If you would like to find out more, please contact any of the above members or alternatively contact Sheila Bailey, Administrator on 0121 414 2845

Academic training opportunity

A new scheme has been launched by the National Coordinating Centre for Research Careers Development. It is for funding for fully trained GPs to undertake an MSc/MPH or similar academic training – see **www.nccrcd.nhs.uk/intetacatrain/iatipf.** for details of the scheme. If you are interested, please speak to Dr Paul Aveyard on (0121) 414 8529 here at the University of Birmingham.

Annual Research Conference 2007

Equalising health opportunities through research

Date for your diary
MidReC, The Royal College of General Practitioners (Midland Faculty) and R&D for Birmingham and Solihull PCT Consortium are holding their annual research conference on

Thursday, 3 May 2007

City Hospital Postgraduate Centre
Dudley Road, Birmingham

The Annual Research Conference is an opportunity to hear about local research taking place by local researchers.

The programme will include:

- Presentations on local research and audit projects
- Informative posters (including audits)
- Practice Innovations
- Educational/Training projects
- The 'New' Research Networks
- Research Approval Clinic – research and ethics approval process queries answered

Booking forms can be obtained from:
Sheila Bailey, PC-CRTU Administrator, Primary Care Clinical Research and Trials Unit, Department of Primary Care and General Practice, University of Birmingham, Primary Care Clinical Sciences Building, Edgbaston, Birmingham B15 2TT.
Email: s.m.bailey.20@bham.ac.uk
Telephone 0121 414 2845.

Places are limited and will be allocated on a first-come, first-served basis.

PLEASE BOOK EARLY

PC-CRTU CONTACTS

Richard Hobbs Director
Richard McManus Clinical Director
Sue Wilson Trials Director
Ros Salter R&D Manager

Andrea Roalfe Statistician
Beverley Hancock Research and Training Facilitator
Jo-Anne Miles Research Co-ordinator
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