



THE NOTTINGHAM CLINICAL TRIALS UNIT

Annual Report 2010



The University of
Nottingham

UKCRC
Registered
Clinical
Trials Units

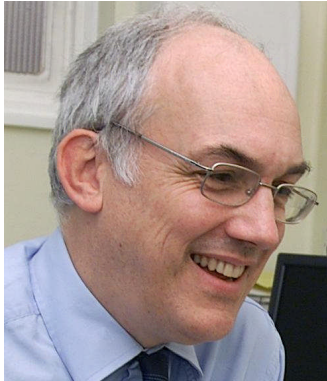


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CLINICAL TRIALS UNIT

Welcome from the Director



Welcome to our third annual report (2010). We continue to expand with 25 staff, and 26 ongoing trials.

Our new director, Professor Lelia Duley took up her post in March 2011. Professor Duley was previously Professor of Obstetric Epidemiology, Centre for Epidemiology and Biostatistics, University of Leeds and Bradford Institute of Health Research. She was the chief investigator of two landmark studies, the Eclampsia and MAGPIE trials (Lancet 1995 and 2002), and has just been awarded an NHS HTA programme grant to study the immediate care of pre-term babies. It is a pleasure to welcome her to the Trials Unit.

One of her first tasks in 2011 will be to oversee the move to new premises on C floor of QMC between East and South block. By the time you read this we will probably be there.

I'm also delighted to welcome two new statisticians, Justin Fenty and Samir Mehta to join Professor Min Yang. This is now a really strong section of the unit, which will help us power forward.

Finally, I can't resist reminding you of the five new trials awarded in the last year. Two drug trials, one of aspirin and fish oil to prevent bowel polyps, and one of a treatment for irritable bowel disease, a trial of rehabilitation to help people with arthritis get back to work, a trial of a heel cast to help heal diabetic foot ulcers and finally a trial of a treatment to improve the gait of patients with stroke.

What a varied life we lead! I'm already sad handing over to Prof Duley!
Jim Thornton

CLINICAL TRIALS UNIT

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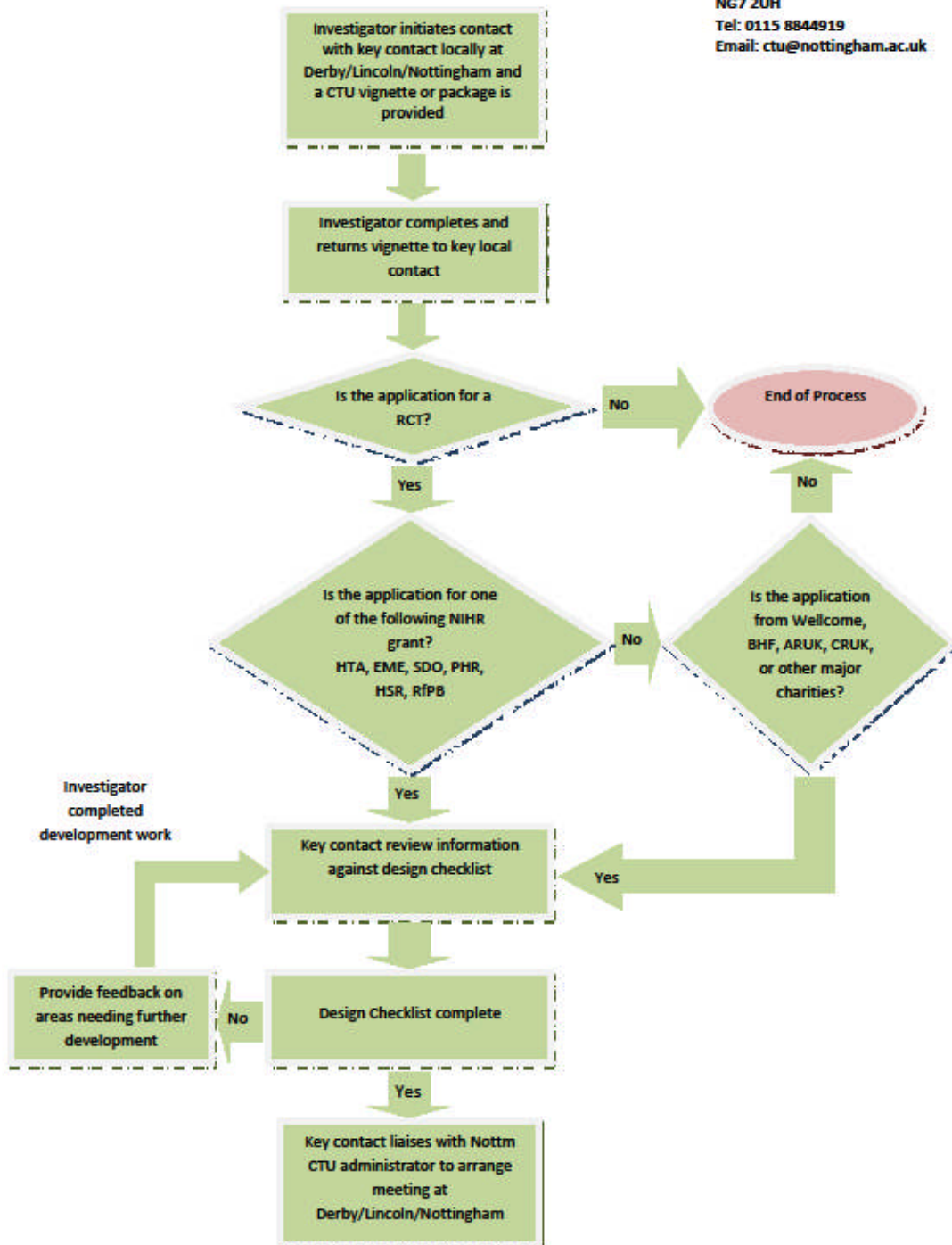
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CLINICAL TRIALS UNIT



CTU collaboration Process Map

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CLINICAL TRIALS UNIT

Seminar Speakers 2010

SEMINARS 2010

Thursday 20th May 2010

Min Yang

Professor of Medical Statistics in School of Community Health Sciences

“Applying multilevel models in evaluation of bioequivalence in drug trials”

Professor Yang is currently working for both the NIHR NDL CLAHRC (a partnership between University of Nottingham and the NHS Trent Trusts) and the CTU of the university. Her research interest is multilevel models in analysing large and complex data. She has extensive experience in developing, applying and training to use multilevel models in the fields of social sciences, education, medical and public health study. Her publication covers multilevel multivariate models for both continuous and binary outcomes, multilevel multinomial models for ordinal and nominal data, multilevel survival models in health inequalities and multilevel models in meta-analysis.

Thursday 17th June 2010

Rowan Harwood

Consultant Geriatrician and special Professor in Geriatric medicine

“Tribulations of trials:evaluating complex interventions”

RCTs aim to give unbiased estimates of treatment effects, primarily when testing drugs. The pragmatics of performing trials can be difficult where the intervention is ‘complex’, such as services with multiple elements or contributors. The intervention can be difficult to describe or standardise, and the conditions for successful delivery or replication need to be elucidated. The measurable benefits of the intervention can be uncertain in advance of the research. Operational constraints in the health service can make conventional trial design difficult or impossible. This talk explored solutions to these issues using examples from trials (mainly done in Nottingham), and their application to the design of a trial on a medical and mental health unit for older people

Thursday 7th October 2010

Casey Quinn

Health economist and econometrician

“Value of information analysis and pilot trials”

Dr Quinn is a health economist and econometrician working in the Division of Primary Care at the University of Nottingham. His research specialises in cost-effectiveness analysis alongside clinical trials, programme evaluation and the estimation of treatment effects. He also works on the microeconometrics of health and lifestyles using routine, administrative and survey databases. He is currently involved with several projects funded by the NIHR, MRC, Health Foundation and EPSRC.

CLINICAL TRIALS UNIT

Meetings and Training 2010

Trial Manager's Forums

Thursday 3rd June 2010

Post Graduate Education Centre, QMC Campus

Thursday 4th November 2010

Post Graduate Education Centre, QMC Campus

Nottingham CTU Away Day

20th August 2010

Nottingham Activity Centre

CTU Training Day

24th May 2010

Clinical Trials 'The Basics'

The key principles involved in the design, interpretation & clinical application of randomised controlled trials.

The Systematic Evaluation of Aspirin and Fish Oil Polyp Prevention Trial (seAFood) **EME**

A randomised controlled trial of eicosapentaenoic acid (EPA) and/or aspirin for colorectal adenoma (or polyp) prevention during colonoscopic surveillance in the NHS Bowel Cancer Screening Programme: The seafood (Systematic Evaluation of Aspirin and Fish Oil) Polyp Prevention Trial.

Mesalazine for the treatment of IBS-D (MIBS) **EME**

This is a multi-centre randomised, double-blind, placebo-controlled trial using a parallel group design to assess the effect of mesalazine on stool frequency.

Work Rehabilitation in Inflammatory Arthritis (WORK IA) **ARUK**

Effectiveness and cost effectiveness of an occupational therapy (OT) job retention intervention: a pilot randomised controlled trial.

Fibreglass casts for heel ulcers in diabetes (HEELS) **HTA**

To evaluate the use of fibreglass heel casts in the management of ulcers of the heel in diabetes.

Visual cues for gait training post-stroke **RfPB**

2-arm parallel group, multicentre randomised controlled pilot trial comparing Visual Cue Training (VCT) to same amount of conventional over-ground walking training.

Bullous pemphigoid steroids & tetracyclines study (BLISTER) NIHR HTA

A randomised controlled trial to determine whether doxycycline (a member of the tetracycline family of antibiotics) would be a good alternative to prednisolone (a corticosteroid) for treating bullous pemphigoid.

A clinical trial to investigate the best treatment for pyoderma gangrenosum (STOP GAP) NIHR via Skin Disease Programme Grant

A randomised controlled trial to determine whether ciclosporin (an immunosuppressant) is better at treating Pyoderma Gangrenosum (PG) than prednisolone.

Psychological treatments for depression in aphasic stroke patients (CALM) Stroke Association

A randomised controlled trial to evaluate behaviour therapy to treat low mood in people with aphasia after a stroke.

Getting out of the house (TOMAS) NIHR HTA

Comparing the effectiveness of treating people who have had a stroke with a new outdoor mobility rehabilitation intervention or standard care

Pre-treatment interview reduce dropouts for patients with personality disorders (PCI) NIHR RfPB

A pilot study to test the feasibility of delivering a motivational intervention in a community personality disorder treatment service.

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Projects—Ongoing

Pilot study for Obstetric Cholestasis Trial (PITCH) NIHR RfPB

A pilot trial to test the feasibility of a factorial trial to evaluate two interventions, ursodeoxycholic acid and timed early delivery, for the treatment of obstetric cholestasis.

Psychoeducation & problem solving - effects on social functioning (PEPS) NIHR HTA

A randomised controlled trial to evaluate the effectiveness of PEPS therapy (Psycho-education with problem solving) compared with standardised treatment as usual in improving social functioning in community adults with personality disorder.

Smoking, Nicotine and pregnancy (SNAP) NIHR HTA

A randomised controlled trial to investigate whether nicotine replacement therapy (NRT) is effective and safe when used for smoking cessation in pregnant women.

Prophylactic Antibiotics for the treatment of cellulitis at home (PATCH) Action Research

A double-blind, parallel group, randomised controlled trial comparing 12 months of penicillin with placebo, in patients with at least 2 previous episodes of cellulitis of the leg.

Efficacy of Nitric Oxide in Strokes (ENOS). MRC

A collaborative, international, multicentre, parallel-group, single-blind randomised controlled trial designed to test the safety and efficacy of: transdermal glyceryl trinitrate (a nitric oxide donor) or control; and continuing or temporarily stopping prior anti-hypertensive medication.

Autologous Stem Cell Transplantation for Crohn's Disease (ASTIC)

European Bone Transplant Group. The Broad Foundation

An open label, randomised, international multicentre study comparing early transplantation procedure with transplantation carried out to the same protocol but delayed by one year. Evaluating the potential clinical benefit of hematopoietic stem cell mobilisation followed by high dose immuno-ablation and autologous stem cell transplantation versus hematopoietic stem cell mobilisation in patients with Crohn's disease.

Bacterial QSSMs, Innate and Adaptive Immunity in Healthy Subjects

A randomised controlled trial to determine the effects of antibiotics, probiotics and prebiotics on quorum sensing signal molecules (QSSMs).

Reducing Falls in elderly patients (REFINE)

NIHR RfPB

Pragmatic parallel arm randomised controlled trial to evaluate the effect of pressure sensors upon in-patient falls in hospitalised older people.

A randomised, parallel group design, placebo-controlled trial of Necator americanus-mediated immunomodulation for relapsing multiple sclerosis (WIRMS)

MS Society

A randomised controlled trial of hookworm versus placebo in multiple sclerosis patients.

The effect of n-3 PUFA supplementation in patients with steatosis due to non-alcoholic fatty liver disease

The purpose is an objective assessment to determine any true effects on the hepatic steatosis content and biochemistry of n-3 PUFA supplementation in Non-Alcoholic Fatty Liver Disease patients.

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Projects—Ongoing

Ondansetron for the treatment of IBS with diarrhoea (IBS-D): Identifying the “responder”

NIHR RfPB

A crossover randomised trial comparing Ondansetron dose titration up or down according to response, with matching Placebo.

Physical activity as an aid to smoking cessation during pregnancy (LEAP)

NIHR HTA

A trial to test the hypothesis that among pregnant smokers, an exercise programme increases smoking abstinence rates.
Randomisation and database support

PPAR-gamma: a novel therapeutic target for asthma (PANTS)

NIHR EME

A double blind, parallel group, randomised placebo controlled trial to determine whether the effects of peroxisome proliferator-activated receptor seen in the laboratory can be a potential drug target in asthma

Effect of Topical Imiquimod on Lentigo Maligna (LIMIT 1)

NIHR RfPB

A pilot study to determine whether imiquimod is a sufficiently effective treatment for lentigo maligna to progress to a randomised controlled trial (RCT) which would compare imiquimod with the current standard treatment (surgery).

Doxycycline in lymphangiomyomatosis (LAM)

British Lung Foundation Grant

A randomised, double blind, placebo controlled trial of doxycycline to determine if doxycycline will prevent tissue destruction in lymphangiomyomatosis (LAM) thus preserving lung function, exercise capacity and quality of life.

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Projects—Complete

Pilot trial; Diet & Endometrial Cancer Risk in Polycystic Ovary Syndrome (PCOS) **Cancer Research UK**

A pilot study to test the feasibility of a trial to test the hypothesis that dietary interventions in PCOS can reduce risk markers for later cancer development.

Potential of the family history in risk assessment and primary prevention of coronary heart disease (ADDFAM) **DoH**

A trial to estimate the extra proportion of patients at higher risk of CHD, who would benefit from intensive lifestyle advice and medications, when systematically collected with family history risk assessment, in comparison with current practice.

Water Softeners for the treatment of atopic eczema in children (SWET) **NIHR HTA**

A randomised controlled trial of ion-exchange water softeners for the treatment of eczema in children.

Comparing two fixed daily doses of FSH for ovarian stimulation during in-vitro fertilisation **NUH Trust**

A prospective, randomised study among women without 3 D ultrasound evidence of polycystic ovaries (PCO) who are undergoing IVF/ICSI treatment. To examine the hypothesis that increasing the dose of gonadotrophins from 225 IU to 300 IU during IVF does not change the number of mature oocytes retrieved or the pregnancy rates in women with predicted low or intermediate ovarian reserve based on antral follicle count.

Helicobacter Eradication v Aspirin Toxicity Trial (HEAT) Pilot study **MRC**

Double blind randomized multi-centre study of early versus delayed Helicobacter Pylori eradication in infected patients taking aspirin \leq 150mg daily, recruited from primary care.

Proactive Or Reactive Telephone Smoking Cessation Support (PORTSSS) **DoH**

A parallel group, factorial design RCT, conducted through the English national NHS Smoking Helpline, comparing proactive versus reactive support and the offer of NRT versus no offer.

Hookworm infestation as therapy in Crohn's disease **Broad Foundation**

A randomised controlled trial to compare a single dose of hookworm larvae and placebo in reducing disease activity in Crohn's disease

Water Softeners for the treatment of atopic eczema in children (SWET) **NIHR HTA**

A randomised controlled trial of ion-exchange water softeners for the treatment of eczema in children.

Efficacy of Nitric Oxide in Strokes (ENOS).

MRC

A collaborative, international, multicentre, parallel-group, single-blind randomised controlled trial designed to test the safety and efficacy of: transdermal glyceryl trinitrate (a nitric oxide donor) or control; and continuing or temporarily stopping prior anti-hypertensive medication.

UK Dermatology Clinical Trials Network's PATCH Study Group and Thomas KS. Title. Studying a disease with no home—lessons in trial recruitment from the PATCH 11 study. *Trials* (in press).

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UK Dermatology Clinical Trials Network's PATCH Study Group
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CLINICAL TRIALS UNIT

Visitors 2010

Adams, Clive	University of Nottingham
Ahmed, Tanweer	United Lincolnshire Hospitals NHS Trust
Guru, Aithal	University of Nottingham
Albrighton, Mark	Nottingham University Hospitals NHS Trust
Armstrong, Sarah	University of Nottingham
Arundell, Melanie	Derby Hospitals NHS Foundation Trust
Atiomo, William	University of Nottingham
Bailey-Flitter, Natalie	Primary Care Research Network
Bath Hextall, Fiona	University of Nottingham
Batty, Martin	University of Nottingham
Bewick, Thomas	Nottingham University Hospitals NHS Trust
Bird, Lydia	University of Nottingham
Bolton, Charlotte	University of Nottingham
Chalmers, Jo	University of Nottingham
Coomarasamy, Arri	University of Birmingham
Connell, Louise	University of Nottingham
Cox, Karen	University of Nottingham
Currie, Graeme	University of Nottingham
Davis, Tim	Nottingham University Hospitals NHS Trust
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Drummond, Avril	University of Nottingham
Duley, Leila	University of Leeds
Evans, Julie	CLAHRC
Fakis, Apostolos	Derby Hospitals NHS Foundation Trust
Fox, Mark	University of Nottingham
Game, Fran	Nottingham University Hospitals NHS Trust
Glazebrook, Cris	University of Nottingham
Grieve, Teresa	Derby Hospitals NHS Foundation Trust
Guha, Neil	University of Nottingham
Hammond, Alison	Salford University
Harrison, Tim	University of Nottingham

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Visitors 2010

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Hedges, Lucy	University of Nottingham
Heras-Palou, Carlos	Derby Hospitals NHS Foundation Trust
Hull, Mark	University of Leeds
Irving, Will	University of Nottingham
Jansen, Victoria	Derby Hospitals NHS Foundation Trust
Jawhari, Aida	University of Nottingham
Jeffcoate, William	Nottingham University Hospitals NHS Trust
Jones, Matthew	University of Nottingham
Keeley, Vaughan	Derby Hospitals NHS Foundation Trust
Klonizakis, Markos	University of Lincoln
King, Anthony	Nottingham University Hospitals NHS Trust
Koufali, Maria	Nottingham University Hospitals NHS Trust
Lanyon, Peter	Nottingham University Hospitals NHS Trust
Llewellyn, Jo	University of Nottingham
Lobban, Fiona	University of Lancaster
Logan, Pip	University of Nottingham
Lees, Angela	University of Nottingham
Lim, Wei Shen	Nottingham University Hospitals NHS Trust
MacDonald, Ian	University of Nottingham
Maddocks, Matthew	University of Nottingham
McMaster, Nicola	Nottingham University Hospitals NHS Trust
Mahajan, Ravi	University of Nottingham
Marsden, Jerry	University Hospitals of Birmingham NHS FoundationTrust
Masud, Tash	Nottingham University Hospitals NHS Trust
Moffatt, Christine	Derby Hospitals NHS Foundation Trust
Morrell, Jane	University of Nottingham
Morriss, Richard	University of Nottingham
Mortimer, Kevin	University of Nottingham
O'Brien, Mary	Nottingham University Hospitals NHS Trust
Odudu, Aghogho	Derby City General Hospital

CLINICAL TRIALS UNIT

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Radford, Kate	University of Nottingham
Raginath, Krish	University of Nottingham
Ryder, Steve	Nottingham University Hospitals NHS Trust
Sahota, Opinder	University of Nottingham
Saini, Gauri	Respiratory BRU
Savage, Viv	Nottingham University Hospitals NHS Trust
Scott, Tony	Nottingham University Hospitals NHS Trust
Sempic, Joe	Loughborough University
Simpson, Alistair	Nottingham University Hospitals NHS Trust
Siriwardena, Niro	University of Lincoln
Spencer, Robert	Nottingham University Hospitals NHS Trust
Spiller, Robin	University of Nottingham
Walker, Kate	Nottingham University Hospitals NHS Trust
Wallace, Ian	Nottingham University Hospitals NHS Trust
Nicola Wells	University of Nottingham
Whitehouse, William	University of Nottingham
Williams, Hywel	University of Nottingham
Andrew Wilcock	University of Nottingham
Yang, Min	University of Nottingham

