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# New study to meet major public-health challenge

**A £2.2 million pound study called the Norfolk Diabetes Prevention Study (Norfolk DPS) from the Norfolk and Norwich University Hospital and the University of East Anglia is setting out to address one of the country's greatest public-health challenges by screening 10,000 people identified at risk of developing type 2 diabetes.**

Diabetes is one of the biggest public-health challenges facing the country and in England it is estimated 2.4 million people have the condition. About 80% of those with diabetes in England have type 2 diabetes. In Norfolk there are about 30,000 people with diabetes and around 2,500 are newly diagnosed each year.

Type 2 diabetes is most commonly diagnosed in adults over the age of 40, although increasingly it is appearing in young people and young adults.

The research study, funded by the National Institute for Health Research (NIHR), will screen 10,000 people in Norfolk who are at risk of developing type 2 diabetes.

Norfolk DPS participants will undergo a simple blood test to check their blood glucose level. Higher than normal glucose (known as Impaired Fasting Glucose or IFG) could mean they are in a "pre-diabetes" phase and more likely to develop type 2 diabetes. Those identified at risk will be invited to enter a dedicated lifestyle education on diet and exercise

that could prevent hundreds of people from developing the condition. They will then be given help to improve their diet and exercise levels to see if positive changes to their lifestyle can help reduce the risk.

Study chief investigator Professor Mike Sampson said: "This study holds a lot of promise for one of the major public-health challenges of our time.

### Human cost

"The cost of diabetes care to the NHS is rising rapidly and if we can demonstrate that an intervention programme can prevent people from developing the condition, the savings in terms of the human cost, and the financial cost to the NHS will be substantial.

"We think that mass screening and intervention programmes to prevent type 2 diabetes could benefit from having people with existing type 2 diabetes provide some of the training and support to those participants.

"This will allow participants in the study to access the help of trained health care professionals and relate to lay members of the public who have already been diagnosed with type 2 diabetes."

- The following people have worked with Professor Sampson on the project during the set-up phase: Nikki Murray, Sara Abadi, Tamsin Marks, Noreen Neal and Aliceon Blair.

**The Norfolk DPS officially starts on 28 February 2011. Turn to p4 to find out how the Norfolk DPS will work in practice.**



## Researchers: We need your FACTS!

**Research teams who took part in the FACTS 2 study have been asked to send in their final data to the lead team based in Ipswich as soon as possible.**

In total 305 young people and their families took part in the study across ten sites in eastern and southern England, as part of the follow-up to the original FACTS study which closed in 2009.

This examined whether structured education with family communication training improves blood glucose control in adolescents with type 1 diabetes.

Chief Investigator Dr Helen Murphy (*photo, top right*) said:



complete by the end of March this year.

"This would mean we could have all the data in by the end of April.

### Results

"We are now asking researchers to send in their six-month and twelve-month data as soon as possible, so we can start to analyse the results.

"Eight of the ten sites which took part in FACTS 2 have now come to the end of the study, with the remaining two due to

### 'Thank you'

"All of us in the research team would like to give a very big thank you to everyone for their hard work over the last year.

"But please do continue to chase questionnaires, as study success relies on this data. It's the only way of finding out for sure if all our hard work was worth it!"

***If your site took part in FACTS 2 please send the final biomedical data to Project Manager Caroline Calver as soon as possible.***

***If you have any issues relating to the data collection please let Caroline know as the team may be able to help.***



## Message from Clinical Lead Professor Nick Wareham

**Patients are at the centre of everything we do.** This is a central theme of the NHS' research strategy and in the Eastern Region Diabetes Network we are committed to enhancing the role of patients with diabetes and those at risk of it in the whole research process. This ranges from the formulation of research priorities, participation in studies, through to the interpretation of the implications of our results. Without the participation of willing patients in clinical trials, there would be no research—and without research we would not have the evidence we need to improve patient care.

Last year saw a big rise in research participation across England. The number of NHS patients taking part in approved studies was more than 67% higher in 2010 than in 2009. Figures from the National Institute of Health Research Clinical Research Network (of which Eastern DRN is a part) show that more than half a million people participated in Network studies during 2010, compared with 300,000 in the previous year.

This increase is partly down to support for research posts and costs in a wide range of NHS Trusts—but raised levels of patient awareness about clinical studies are also helping. People are starting to ask their doctor or nurse about taking part in a research study as part of their care—a trend which I hope will continue over the coming years.

What about in this region? I am pleased to say that in 2010 more than 6,000 people in Eastern England took part in diabetes clinical trials—while the number of studies taking place increased from 46 in 2009 to 54 last year. That is good news for research, but we cannot rest on our laurels.

In this issue we have a feature on Jill, who provides a research participant's experience of the HypoCOMPASS study—just one of the trials for diabetes patients running in this region. Jill ends by saying she wants to give something back. I hope a lot of readers will share this sentiment and also be encouraged to ask about taking part in research. So please ask your doctor or nurse—and let's continue that upward trend in participation.

## Taking part in research: a participant's perspective

***"I want to give something back, and this is my way of helping the medical staff who have helped me."***

That's the conclusion reached by one participant in a research study for people with type 1 diabetes taking place in Cambridge.

The HypoCOMPASS study, which is being run out of five centres across England including Addenbrooke's hospital in Cambridge, is a randomised controlled trial in which 50% of participants have an insulin pump and 50% have multiple daily insulin injection treatment. In addition, half of all participants receive real-time continuous glucose monitoring.

The aim: to improve the management of type 1 diabetes by preventing severe hypoglycaemia (low blood sugar) and restoring hypoglycaemia awareness using modern technologies.

Dr Mark Evans and Dr Lalantha Leelarathna (see photos, below and right) are leading the study in Cambridge. Dr Evans said: "Severe hypoglycaemia affects up to 30% of people with established type 1 diabetes. When your glucose level is too low – called a 'hypo' – your body does not have enough energy to carry out its activities.

"We want to see if modern insulins, insulin pumps and continuous blood glucose meters can help restore falling glucose levels and so prevent future episodes of severe hypoglycaemia, which can be life-threatening."



*Dr Mark Evans*

For participant Jill, it was the educational aspect of the study which attracted her when she was invited to join during a routine visit to the diabetes clinic at Addenbrooke's: "Although pumps have been around for some time, it was the intensive support and education to help me manage my diabetes which really appealed.

"I was originally quite sceptical about the value of pumps and before I started I even went around with a pedometer, just to check I'd be happy to have a pump attached to me 24/7!"

Two months into the trial, Jill is a convert. "I've learnt an awful lot from the study, and it's definitely reduced the number of hypos I have.

"I've gone from a minimum of five injections a day to simply inserting one 'set' [the plastic tube which takes insulin from the pump to the body] every two or three days.

"My weight is more stable, because I'm not constantly eating to stave off a hypo. I still carry an insulin pen round with me, in case something goes wrong but I haven't had to use it.

"In many ways you've given your life away to a computer, but it's more reliable.

"The more hypos you have, the more you get used to operating at low levels and you tend to over correct (eat too much). But with the pump you can tell it your blood meter readings and what you've eaten, and it works out your insulin levels for you

"But it's not an easy option. The pump doesn't do all the work for you – you've got to be prepared to monitor your blood glucose levels at least four times a day, and record the time, signs and symptoms of every hypo. The pay-off is that you no longer have to do injections.

"It sounds terribly worthy, but I want to give something back, and taking part in research is my way of helping the medical staff who have helped me."

***It's not too late to join the HypoCOMPASS study. If you are an adult with type 1 diabetes and would like to find out more, please contact Dr Lalantha Leelarathna at email [lh124@medschl.cam.ac.uk](mailto:lh124@medschl.cam.ac.uk).***



*Dr Lalantha Leelarathna*

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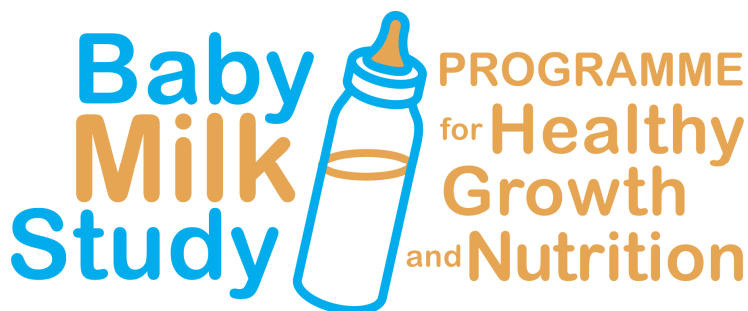
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## New study to look at link between weight gain and nutrition in babies

**RESEARCHERS at the Centre for Diet and Activity Research (CEDAR) and MRC Epidemiology Unit in Cambridge have been working with mothers and healthcare professionals to develop a feeding programme which aims to reduce excess weight gain in formula-milk fed babies.**



The latest national surveys show that more than one in five children are already overweight (13%) or obese (10%) when they start school. The rising prevalence of obesity is leading to an increase in prevalence of type 2 diabetes. Chief Investigator Dr Lakshman said: "Evidence suggests that nutrition and growth during infancy has long-term 'programming effects' by altering the risk of developing obesity and type 2 diabetes in later life. Since infancy is a period of rapid growth, obesity prevention during this period may be effective.

"Our research with parents in the Cambridge Baby Growth Study and others shows that parents who give their babies formula milk as part of their everyday diet need more information and support.

"The programme which we have developed aims to help parents feed the correct amounts of formula milk so that their baby has a healthy pattern of growth—not too fast, which makes babies more likely to become overweight, and not too slow.

"The quantities of formula milk are based on new international guidelines which suggest that the previous 1985 guidelines overestimated energy requirements by 15-20%. This could lead to formula-milk-fed babies being overfed.

"The results of the study will help us understand the links between feeding practices, and babies' behaviour, appetite and growth. This information will help policymakers to decide whether to adopt the new guidelines for formula-milk feeding in the UK."

The programme will be tested in a randomised controlled trial starting in February 2011. One group will be given general advice about formula-milk feeding and weaning. The other group will be given help and support to follow the new guidelines for formula-milk feeding. The growth of babies in the two groups will then be compared.

***Researchers are recruiting parents of babies up to eight weeks old, who are receiving some formula-milk feeds. If you would like any more information about the study, please contact Study Co-ordinator Annie Schiff on freephone 0800 7560878 or email the research team at [babymilkstudy@mrc-epid.cam.ac.uk](mailto:babymilkstudy@mrc-epid.cam.ac.uk).***

***CEDAR is a collaboration between Medical Research Council (MRC) units in Cambridge and the Universities of Cambridge and East Anglia, and is one of five new centres of excellence in public health research funded by the UK Clinical Research Collaboration (UKCRC).***

### How the Norfolk Diabetes Prevention study will work

*Continued from p1*

People living in Norfolk or who are registered with a Norfolk GP and who are identified as most at risk of developing the condition will be invited by their GP to volunteer for the screening programme. Most participants are expected to have normal blood glucose levels and will not be eligible to enter the study. Study participants will then be randomly allocated to one of three groups: a control group; an intervention group; or an intervention group with mentor support. The aim will be for participants to achieve 7% weight loss in the first 6 months of the programme through improved diet and exercise. These participants will receive intervention "lifestyle" sessions from a multi-disciplinary team of physiotherapists, nurses, psychologists and nutritionists. The participants in both intervention groups will have blood samples taken at the start of the study and then at 6, 12, 24 and 40 months.

The study will also recruit up to 50 people who already have type 2 diabetes to act as Diabetes Prevention Mentors (DPMs). Study participants assigned to this group will receive motivational telephone calls from the DPMs to help them meet their study targets. We will also test to see if the act of mentoring itself is beneficial to the DPMs in respect of their lifestyle behaviours.

## Addenbrooke's hosts open day for diabetes patients

**EXERCISE doesn't have to be high-impact – in fact even doing simple movements in your chair can help to burn off sugar.**

That was the message from physiotherapist and specialist diabetes dietician Helen Davies at a free open day for diabetes patients, their families and their carers – and to prove the point Helen then asked the 60-strong audience to do some exercises in the comfort of their chairs!

But exercising wasn't the only thing patients got up to at last year's 'One-Stop Shop' open day at Addenbrooke's hospital in Cambridge – they also had the opportunity to meet clinical staff for workshops, talks and presentations.



*Eastern DRN Lead Research Nurse Kim Cox (far left) talks to visitors to last year's "One-Stop Shop" open day.*



### Link between diabetes and research

Professor Stephen O'Rahilly (*photo, left*) opened the day with a keynote speech stressing the link between diabetes and research. The immediate benefit in taking part in research, Professor O'Rahilly said, was improving patient care in the next five years, but the "real dream" was to prevent diabetes—which means we need a better understanding of the biology: how and why does diabetes happen?

Only continued research can find this out. As well as picking up practical tips and tools for managing their diabetes and preventing complications, patients found out more about the latest in clinical care and about some of the research into the condition being carried out at Addenbrooke's and elsewhere.

Kim Cox, who is Lead Research Nurse for the Eastern DRN, was one of the presenters on the day. Kim said: "I talked about some of the research currently running at Addenbrooke's, and was delighted when three people approached me afterwards to find out more.

"As a result two people have now joined the HypoCOMPASS\* study and one is going onto the artificial pancreas study. Our stand on the day also attracted a lot of interest, with 18 individuals providing their names and addresses to go on our mailing list.

"If you see events like this going on at your local diabetes clinic please do go along – it's a great way to find out the latest diabetes news and you may even find out about a research study you could take part in!"

**\*See also page 3 for more on HypoCOMPASS.**



### **R**andomised controlled trial of **P**eer Support **I**n **T**ype 2 **D**iabetes across the **C**ambridgeshire **C**ommunity

People with diabetes have to face a lot of challenges in their lives. Risks of long-term complications can be reduced with changes in lifestyle, monitoring and usually different medications.

But these changes often require significant personal effort and dedication and can impact on quality of life.

As part of a global collaboration, funded by Peers for Progress, a team at Addenbrooke's Hospital is undertaking a randomised controlled trial of the possible benefits of people with Type 2 diabetes supporting one another with the changes that may improve their condition on a day-to-day basis.

In the coming year the RAPSID Team will launch an education programme, support groups and 1:1 meetings across Cambridgeshire as part of this research project.

**For more information please telephone the RAPSID Research Team on:  
freephone 0800 084 2362**

## DRN studies in the Eastern region

Below is a list of DRN studies which are actively recruiting to Eastern sites. Some studies have been co-adopted with other networks; where this is the case the lead network is shown in the final column. **There are studies elsewhere in the UK that are looking for Principal Investigators, new sites and participants. If you would like to receive a regular e-bulletin with this information, please contact us at [drn@mrc-epid.cam.ac.uk](mailto:drn@mrc-epid.cam.ac.uk).** Paediatric studies open to children and adolescents are highlighted in blue. We have also listed on page 7 those studies which are in *set-up*: see opposite for definitions.

### Studies actively recruiting to Eastern sites

Study Title	Chief Investigator	DRN Code / Lead Network
<a href="#">AddIT - Adolescent Type 1 Diabetes Intervention Trial - Adolescent Type 1 Diabetes Cardio-Renal Protection Study</a> <b>OPEN TO NEW SITES</b>	Prof David Dunger	DRN068
<a href="#">ADDRESS Study</a> <b>OPEN TO NEW SITES</b>	Prof Des Johnston	DRN094
<a href="#">Anti-thyroid drug treatment in paediatric Graves' disease</a>	Dr Tim Cheetham	DRN494
<a href="#">ASCEND - 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</a> <b>OPEN TO NEW SITES</b>	Dr Jane Armitage	DRN023
<a href="#">Cardiovascular risk factors in parents of children with type 1 diabetes - Familial aggregation of cardiovascular disease risk factors in parents of adolescents with type 1 diabetes and incipient nephropathy</a>	Prof David Dunger	DRN539
<a href="#">CLIP-02 - Closed Loop in Pregnancy Normal Daily Activities</a>	Dr Helen Murphy	DRN474
<a href="#">DAFNE 5 x 1 day - Improving Management of Type 1 Diabetes in the UK: The DAFNE (Dose Adjustment For Normal Eating) Programme as a Research Test-Bed - 5 x 1 day randomised control trial</a>	Prof Simon Heller	DRN429
<a href="#">DAFNE Research Database. Improving management of Type 1 Diabetes in the UK - the DAFNE programme as a Research Test Bed</a>	Dr Peter Mansell	DRN240
<a href="#">DAN02—Closing the Loop for 36 hours in Adolescents</a>	Dr Roman Hovorka	DRN473
<a href="#">DARE - Diabetes Alliance for Research in England</a>	Prof Andrew Hattersley	DRN082
<a href="#">DECIDE - Delivering Early Care in Diabetes Evaluation - An RCT to assess hospital versus home management at diagnosis in childhood diabetes</a>	Prof John Gregory	UKCRN 4171 MCRN
<a href="#">Detemir Glargine - A comparison of the effects of insulin Detemir with insulin Glargine on weight gain in female adolescents and young adults with Type 1 Diabetes on a basal bolus regime</a> <b>OPEN TO NEW SITES</b>	Prof David Dunger	UKCRN 4903 MCRN
<a href="#">DGAP - Type 1 Diabetes and Autoimmune disease: Genes, Biomarkers and Immune phenotypes</a>	Prof David Dunger	DRN231
<a href="#">DGAP - Unaffected Siblings: Phase II</a>	Prof David Dunger	DRN450
<a href="#">Diabetes and complications associated with obesity—Metabolic and endocrine characterisation of subjects with severe obesity</a>	Prof Ismaa Sadaf Farooqi	DRN492
<a href="#">DIPSat (DTSQ) - Assessing and improving inpatient diabetes treatment satisfaction in different ethnic groups in the UK</a>	Prof Mike Sampson	DRN072
<a href="#">Eating behaviour and obesity—Relationships between energy intake, energy expenditure, autonomic nervous system activation and body fat distribution in severe obesity</a>	Prof Ismaa Sadaf Farooqi	DRN493
<a href="#">Emotional Stress and Wound Healing in Diabetes Version 1</a>	Prof Andrew Boulton	DRN294
<a href="#">EPIC - Norfolk Third Health Check - Diet, lifestyle and biological determinants of health and chronic disease: A Prospective Population Study</a>	Prof Kay-Tee Khaw	UKCRN 2219 PCRN
<a href="#">Evaluation of The Health Foundation's Co-Creating Health Initiative v1</a>	Prof Louise Wallace	UKCRN 4641 CRN

**DRN studies in the Eastern region** (continued from page 6)**Studies actively recruiting to Eastern sites**

Study Title	Chief Investigator	DRN Code / Lead Network
FENLAND - A population based cohort study of the interaction between environment and genetic factors in determining obesity, insulin sensitivity and hyperglycaemia	Prof Nick Wareham	DRN055
Genetics of Obesity - The genetic basis of severe childhood obesity	Prof Sadaf Farooqi	DRN490
HypoCOMPASS v1.0 - Prevention of Recurrent Severe Hypoglycaemia - a Definitive RCT Comparing Optimised MDI and CSII with or without Adjunctive Real-time Continuous Glucose Monitoring <b>SEE ALSO PAGE 3</b>	Prof James Shaw	DRN430
<b>Nephropathy Family Study (NFS) - Genetic analysis of risk factors for the development of diabetic complications OPEN TO NEW SITES</b>	Prof David Dunger	DRN085
PATHWAY1 - Comparison of single and monotherapy diuretics in therapy in low-renin hypertension <b>OPEN TO NEW SITES</b>	Prof Morris J Brown	UKCRN 4499 CRN
PATHWAY2 - Optimal treatment of drug resistant hypertension <b>OPEN TO NEW SITES</b>	Prof Morris J Brown	UKCRN 4500 CRN
PATHWAY3 - Comparison of single and combination diuretics in therapy in low-renin hypertension <b>OPEN TO NEW SITES</b>	Prof Morris J Brown	UKCRN 4501 CRN
Phenotypes and obesity: Phenotypic characterisation of subjects with genetic defects associated with severe childhood obesity	Prof Sadaf Farooqi	DRN491
RAPSID: Can peer support, delivered as a group or individual intervention, enable people with diabetes and improve their health? <b>SEE ALSO PAGE 5</b>	Dr David Simmons	DRN261
SIRS: Study of the genetics of Severe Insulin Resistance	Dr Robert Semple	DRN079
TrialNet Natural History Study of the Development of Type 1 Diabetes. Phase 1, 2 and 3 <b>OPEN TO NEW SITES</b>	Prof Polly Bingley	DRN100
Vitamin D Supplementation in People at Risk of Type 2 Diabetes <b>OPEN TO NEW SITES</b>	Prof Graham Hitman	DRN415

**IN SET-UP: New studies and proposed Eastern sites of existing studies**

Study Title	Chief Investigator	DRN Code / Lead Network
Comparison of two algorithms for closed-loop control in T1 - An open-label, randomised, three period crossover study to evaluate the efficacy and safety of automated closed-loop insulin delivery in comparison with conventional insulin pump treatment in adults with type 1 diabetes	Dr Roman Hovorka	DRN508
DALI: Group Interviews - Developing a programme for optimal adherence to lifestyle & dietary interventions for prevention of gestational diabetes mellitus	Dr David Simmons	DRN503
Fibreglass casts for heel ulcers: Evaluation of lightweight fibreglass heel casts in management of ulcers of the heel in diabetes <b>OPEN TO NEW SITES</b>	Prof William Jeffcoate	DRN528
JUMP - Joining together to Understand diabetes mellitus type 2 Progression in children: Building a platform for interventions to prevent the progression to cardiovascular disease <b>OPEN TO NEW SITES</b>	Prof Tim Barrett	UKCRN 7574 MCRN
Norfolk Diabetes Prevention Study (NDPS) - Delivering a realistic diabetes prevention programme in a UK community <b>SEE ALSO PAGES 1&amp;4</b>	Prof Mike Sampson	DRN544 and 545
Pre-POINT - A dose-finding safety and immune efficacy study for primary mucosal insulin therapy in islet autoantibody negative children at high genetic risk for Type 1 Diabetes	Prof Polly Bingley	DRN506
TrialNet Oral Insulin Study	Prof Polly Bingley	DRN438

**OPEN:** a study that is open is recruiting participants, looking for new NHS sites to help with recruitment of participants or following up with a group of participants who have been involved in the study previously.

**IN SET-UP:** a study that is in the stages of preparation and planning before opening to recruit participants.

## Role of the nurse in paediatric research explored in student course



**Students in their final year of a paediatric nursing diploma at University Campus Suffolk have found out more about the role of the nurse in paediatric nursing, in a half-day session run by Eastern DRN's lead paediatric research nurse, Jon Hassler-Hurst (pictured, above).**

Ten students attended the session in Ipswich last November. Jon said: "I was keen to make this interactive and involve the students as much as possible, with discussions, questions and role-play.

"I told the students from the outset that I wanted to bring research alive for them and hoped that they would see this as a career option. As well as the nurse's role we looked at volunteer consent/

assent by way of role play. I gave unfinished scenarios for them to complete and then act out.

"This was the second time I had supported this particular course, and was grateful for the opportunity to deliver this session and raise the profile of the role of the nurse in research.

"I wanted the students to be confident in discussing the importance of the nurse's role in paediatric research and the importance of consent/assent. I felt that I achieved all of the aims with the interaction I had at the time and the feedback I've received since delivering it."

Course leader Sarah Todd thanked Jon for the training: **"All the students found your session very informative, well-presented, fun and they felt that they had learnt a lot."**

## Date for your diary: Diabetes UK Annual Professional Conference

The Annual Professional Conference from Diabetes UK is taking place this year from 30 March to 1 April at the International Convention Centre (ICC), London ExCeL. It is the only event of its kind in the UK run exclusively for healthcare professionals and scientists working in the field of diabetes. It is one of the largest healthcare conferences in the UK and provides delegates with an opportunity to:



- explore a variety of different aspects of diabetes
- hear from a wide range of speakers
- find out about the latest research
- share best practice and network with colleagues
- ideal event to add towards continuing professional development (CPD) portfolios

***This year's conference is called One Step Ahead: Meeting Future Challenges in Diabetes. To find out more visit the Diabetes UK website at: [www.diabetes.org.uk](http://www.diabetes.org.uk).***

## NIHR CRN Training Courses: IMPORTANT INFORMATION

The training provided by the Clinical Research Network Coordinating Centre (CRN CC) is going through transition. CRN CC is working closely with the Department of Health and other areas of the NIHR to produce a coherent strategy that will guide future activities. During this transition all eligible participants can continue to access the core training provision, including the online and taught Good Clinical Practice (GCP) and Valid Informed Consent training. Visit [www.crncc.nihr.ac.uk/training/courses](http://www.crncc.nihr.ac.uk/training/courses) for more information.

### Eastern Region DRN Newsletter Issue 4: Spring 2011

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[drn@mrc-epid.cam.ac.uk](mailto:drn@mrc-epid.cam.ac.uk).

The Diabetes Research Network is part of the National Institute of Health Research (NIHR).