



# Research Bulletin from the Diabetes Trials Unit Translational Research Group

Issue 13 – January 2014

Welcome to 2014 and the 13<sup>th</sup> issue of the TRG bulletin. The first quarter of this year is set to be full of activity as we look forward to starting recruitment for three new studies with more in the pipeline.

Please read on to find out what our group has been up to...

## MHRA GCP inspection - Good feedback received

The group had a busy end to 2013 when the Aspirin Dosing study was selected as one of two trials to be reviewed as part of a routine “Good Clinical Practice” (GCP) inspection by the Medicines and Healthcare Regulatory Agency (The MHRA). This body is the UK Government’s agency responsible for standards of safety, quality and performance of clinical trials.

We are delighted to report that our trials and procedures received excellent feedback from the Inspector and there were no critical or major findings!

## Looking to recruit in the next few weeks ...

### Lixisenatide in Type 1 Diabetes

*We need 30 people with type 1 diabetes!*

*Contact us now if you are a patient with type 1 diabetes and willing to find out more about this novel research.*

Lixisenatide is used currently to treat people with type 2 diabetes. We are looking to see whether it can also improve blood glucose control in people with type 1 diabetes when given in addition to their usual insulin therapy.

This proof of concept study could pave the way for a major clinical trial and the potential for a new treatment for patients with type 1 diabetes.

## Feeling stressed with diabetes? There’s an ‘App’ for it .....

### A spotlight on **The Remote Mood Monitoring Study** presented by Dr Jyothis George, Study Principal Investigator.

Diabetes is not an easy condition to manage. Like other long-term conditions, it doesn’t ‘go away’ – adding a layer of stress to all the other pressures of everyday life. It is therefore not surprising that psychological conditions like depression are much more common in people with diabetes than non-diabetic peers.

There are over three million people with diabetes in the UK, placing considerable pressure on NHS resources. Expertise available for provision of psychological support for people with diabetes is limited. Therefore, it is important to identify patients who are in most need for such help.

Currently, psychological monitoring involves the doctor or nurse asking patients whether they have had ‘little interest or pleasure in doing things’ or whether they have been ‘feeling down, depressed or hopeless’ in the fortnight before the consultation. Whilst this tool is useful for people who are markedly depressed at the time of consultation, it does not capture episodes of mood fluctuations over the long-term – nor does it capture mood changes or stress associated with depression.

The TRG Remote Mood Monitoring study aims to develop a tool that will provide more comprehensive monitoring of psychological well-being over a longer period of time. Such a system would also be for research, as a tool to monitor the impact of medications, or other interventions on mood or stress.

# True Colours

We are using the True Colours system. True Colours was developed in Oxford and used in patients who have mood problems -enabling them to self-monitor their sense of well-being on a weekly basis, and to text or email questionnaire responses directly to their healthcare team. The team can then use this information to advise on whether any adjustments to treatment are required. We are now testing this system in people with diabetes who are about to start taking injections of insulin or other injectable diabetes medications.

For many people with diabetes, having to take injections every day for the rest of their lives comes as quite a shock. This can often lead to a change in mood or stress levels. Our plan is to test the effectiveness of this system in picking up these changes in mood. If this pilot study is successful, we will move to a larger and longer-term study.

**To find out more about this study E-mail [trg@dtu.ox.ac.uk](mailto:trg@dtu.ox.ac.uk) or call 01865 857287.**

## Study results and new developments recently in the headlines...

### **PREDIMED study – Older patients at high risk of developing diabetes benefit from a Mediterranean diet**

Adhering to a Mediterranean diet high in extra-virgin olive oil intake reduced the risk for diabetes by 40% in older patients at high risk due to pre-existing cardiovascular conditions, according to study findings, just published in the *Annals of Internal Medicine*.

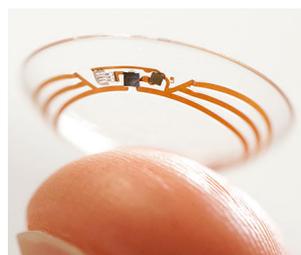
In the PREDIMED study, patients aged 55 to 80 years were randomly assigned to one of three diets: Mediterranean diet supplemented with extra-virgin olive oil, Mediterranean diet supplemented with nuts, or a control diet. Energy restrictions and physical activity increases were not implemented or advised.

Researchers found that over an average of 4 years, both Mediterranean diet groups had increased adherence scores, as measured by a questionnaire. When both Mediterranean diet groups were merged, a 30% relative risk reduction for development of diabetes was noted, whereas the extra-virgin olive oil supplemented group showed a 40% risk reduction.

In addition to possible patient benefit, there are also positive public health implications for primary prevention of diabetes.

### **The smart contact lens – on-track for commercial production within 5 years...**

This month the company ‘Google’ unveiled a prototype contact lens that measures glucose levels in tears. If successful, it will allow people with diabetes to monitor glucose levels without the need to carry out traditional finger-pricking.



The device shown left, consists of a contact lens containing a tiny wireless chip and miniaturised glucose sensor

The smart contact lens is one of several medical devices being designed by companies to monitor glucose. The aim is that the device will be more convenient, less invasive and therefore encourage people with diabetes to check their glucose levels more often.

For more information please go to the following link:

<http://tinyurl.com/smart-contact>

### **FIND OUT MORE ABOUT TRG**

For further information about our group and what we do please: Visit our website,

[www.dtu.ox.ac.uk/trg](http://www.dtu.ox.ac.uk/trg)

or E-mail us at [trg@dtu.ox.ac.uk](mailto:trg@dtu.ox.ac.uk)