

Prevention, Targets and Therapies for Type 1 diabetes Clinical Studies Group

Annual progress report

April 2017-April 2018

In brief

This Clinical Studies Group (CSG) aims to improve our understanding of how to develop new approaches to prevent and treat Type 1 diabetes. This includes treatments to change the immune system, cell therapies, insulin-producing cell transplantations and insulin delivery systems.

So far the group has held three face to face meetings and three teleconferences.

The group reviewed the priorities for Type 1 diabetes research according to people living with diabetes, carers and healthcare professionals. They also reviewed Type 1 diabetes research recommendations made by the National Institute of Clinical Excellence (NICE) and a series of word maps derived from social media discussions about Type 1 diabetes.

Together, this allowed CSG2 to map research projects currently underway across the UK against research areas of importance. This was used to identify gaps, so the group could begin to develop projects over the next year.

“Potential therapies for Type 1 diabetes includes treatments that may preserve islet function, replace islets in the form of islet transplantation and regenerate islets. How to measure in a standardised way the outcomes from these treatments including patient reported outcomes is a huge challenge but will ultimately lead to us making better informed decisions around therapies for our patients.” **Dr Shareen Forbes, Edinburgh**

Progress so far

To identify research priorities, CSG2 reviewed research happening across the UK, Type 1 diabetes research recommendations made by NICE, and a series of word maps derived from social media discussions. They also used existing Type 1 diabetes research priorities identified by people with diabetes, carers and healthcare professionals in an exercise known as a Priority Setting Partnership. More information about these priorities and the organisation that runs them, the James Lind Alliance, can be found at:

www.diabetes.org.uk/research/our-approach-to-research/have-your-say

A road map

With this information, CSG2 began to create a ‘road map’ outlining factors that matter to people with Type 1 diabetes (like quality of life and risk of complications) and, upstream of this, factors that influence these (like technology, treatments in development, stress or diet).

This road map helped CSG2 to spot priority areas in need of more research and start working on how to achieve this. These areas were presented to the Lay & Healthcare Professional Forum (lay and healthcare professional members of all CSGs together).

So far, CSG2 has outlined 10 research areas:

Effects of Hormones on Type 1 diabetes

Managing Type 1 diabetes can often become more difficult during times of changing hormone levels, such as puberty, the menstrual cycle and menopause. However, there are no clear

guidelines on how to overcome this, and there appears to be little research in this area. To address this, members of CSG2 have joined forces with members of CSG1, CSG4, CSG5 and CSG7 to develop a plan.

C-peptide and glucose variability

When the pancreas produces insulin, a molecule called C-peptide is produced as a side product. In people with Type 1 diabetes, as insulin-producing cells are destroyed, C-peptide levels drop. However, tiny levels of C-peptide can sometimes be detected years after a person is diagnosed with Type 1 diabetes.

Research has linked higher levels of C-peptide to less variable blood glucose levels in people with Type 1 diabetes, and CSG2 want to understand why.

Continuous glucose monitoring and quality of life

Continuous Glucose Monitoring (CGM) devices continuously measure blood glucose levels and have been shown to have a positive impact on the quality of life of people with Type 1 diabetes. This has been measured using Patient Reported Outcome Measures, or PROMs, which track factors that matter to patients and participants in trials. CSG2 want to understand more about the improvements in quality of life seen using CGM devices, and encourage researchers to use PROMs when testing new treatments.

What do technology users want?

CSG2 want to ensure that the needs of people with Type 1 diabetes are considered when new devices to deliver insulin or monitor blood glucose levels are designed. To do this, they hope to bring information on what users want to, and work with, relevant pharmaceutical and technology companies.

Improving mental health in people with Type 1 diabetes

Mental health conditions are thought to be under-diagnosed in people with Type 1 diabetes. Treatment strategies for people coping with long-term health conditions who also develop mental health conditions can be unclear, and there is little research in this area. CSG2 is working with the other CSGs to try and assess the scale of the issue and find ways to improve this for people with Type 1 diabetes. CSG2 would also like to understand what elements of living with diabetes contribute most to the “burden of diabetes” that people with the condition and their carers feel (eg fear of hypoglycaemia, frustration with variable blood sugars). CSG2 hope that understanding this will aid the development of new treatments to target these.

A new way to measure success in beta cell preservation/replacement trials

When testing if new treatments can restore insulin production in people with Type 1 diabetes, HbA1c – to look at long-term blood glucose levels – is often the standard measure used.

Other factors that could have a significance impact on the lives of people with Type 1 diabetes, such as blood glucose variability or beta cell function, often aren't taken into account. CSG2 have been developing a new measure to take this into account, to improve the accuracy and knowledge gained from future trials.

Beta cell regeneration – what should we be trying to achieve

Scientists are looking for ways to restore or regenerate the function of insulin-producing beta cells in people with Type 1 diabetes. CSG2 believes that clear guidance on the levels of meaningful improvements the trials should aim for, alongside improved collaboration between researchers working on these techniques, is an important step for future research in this area.

Engaging the National Institute for Health Research's Clinical Research Network

The National Institute for Health Research's Clinical Research Network (NIHR CRN) supports scientist to design studies, find funding and recruit people into their trials. CSG2 hopes to work with the NIHR CRN for Type 1 diabetes studies and clinical trials, and encourage more research into the condition.

Non-insulin therapies for people with Type 1 diabetes

Drugs used to manage blood glucose levels in people with Type 2 diabetes (such as SGLT2 inhibitors or GLP-1 agonists) may help people with Type 1 diabetes too. CSG2 believes that more research is needed to find out if this strategy could be effective.

Hypo awareness

Some people with Type 1 diabetes lose their ability to sense when their blood glucose levels fall too low, known as losing hypo awareness. CSG2 believes there is a need to better understand why this happens in some people, and find ways to prevent this from happening.

Engaging with communities

CSG2 presented their emerging ideas at the Diabetes UK Professional Conference and at the Lay and Healthcare Professional Forum.

Links and collaborations

CSG2 plans to work with other CSGs, researchers in academia, the pharmaceutical industry and the NIHR CRN to encourage and support research into Type 1 diabetes.

Collaborations with academia, the NIHR's Clinical Research Network, who support the delivery of clinical research, and the pharmaceutical industry are also planned and some preliminary meetings have taken place.

Joint activities with CSGs whose areas overlap with those of CSG2 are also taking place as discussed. An approach towards looking at C-peptide and glucose variability is being developed in collaboration with CSG1. Plans have also been made to involve CSG5 and CSG7 in developing an approach to improving mental health, and CSG5 in user needs in technology.

Next steps

CSG2 plan to better understand each of the priority areas they have identified, with different CSG members leading on each area. These project leaders will look at how to advance research in each area and develop calls for research and project proposals, consult with stakeholders and researchers consultations to better understand the problems and how to address them and report back at the next CSG2 meeting in November.

Find out more

To find out more about the work of the CSG, please contact csgs@diabetes.org.uk to be put in contact with the group.

CSG members

Current CSG membership, including affiliations.

Name	Affiliation	Role on group
Prof Colin Dayan (Chair)	Cardiff	Chair
Assoc. Prof. Ramzi Ajjan	Leeds	Deputy Chair
Mirjam Eiswirth	Edinburgh	Member
David Dupont	Devon	Member
Becki Millar	Belfast	Member
Dr Ivy Cheung	Swansea	Member
Dr Shareen Forbes	Edinburgh	Member
Professor John Gregory	Cardiff	Member
Dr Parth Narendran	Birmingham	Member
Dr James Cantley	Oxford	Member
Dr Vinod Patel	Warwick	Member
Katherine Jones	Wolverhampton	Member
Elaine Hibbert-Jones	Newport	Member