

BRAIN DIABETES: Border Region Area Lifestyle Intervention study for healthy Neurocognitive ageing in Diabetes. Led by Professor Peter Passmore

Why did we conduct this research?

The [FINGER study](#) showed that a multidomain intervention in older people - (diet, exercise, cognitive training, and intensive vascular management) improved cognition. This is a very intensive and complicated regimen to follow. In people with diabetes mellitus there is a greater risk of developing Alzheimer's disease. There are few multidomain interventional studies in diabetes. We wished to study whether a multidomain novel intervention based on the FINGER study would be acceptable to people with diabetes and whether such an intervention could produce improvements in physical and mental health and cognition. We wished to test the feasibility of the multidomain intervention in a representative local population so the CHITIN call gave us the perfect opportunity to conduct a cross border study in Sligo and Enniskillen. This was to be a pilot study over one year.

What did we do?

We recruited people with diabetes living in the two cross-border sites i.e. Sligo University Hospital (catchment Sligo/Leitrim/West Cavan) and South Western Area Hospital, (SWAH-catchment Tyrone/Fermanagh). Participants were randomised to either continue with their usual diabetes care or to receive the multidomain intervention. The intervention group were to receive an intensive programme for the first four months, then receive some reminders over the next two months and then be left to continue without reminders for the next six months. To make sure the study was designed for our local population, we first drew up a study protocol based on FINGER and then consulted with groups of people with diabetes mellitus in Enniskillen and Sligo to get their views on what was proposed. As a result, we were able to modify our design based on what people with diabetes felt could be acceptable and could be done. We planned to recruit 140 people from two sites, one in Sligo (70) and one in Enniskillen (70). Please refer to our qualitative study for more information, available at: [A qualitative study to inform adaptations to a brain health intervention for older adults with type 2 diabetes living in rural regions of Ireland - PubMed \(nih.gov\)](#)

Unfortunately, as the study was due to start, Covid-19 arrived and we had to modify the protocol to ensure that it was acceptable to participants and safe to deliver during the pandemic. As a result of the delays caused by Covid-19 the study had to be shortened and the time available for recruitment also needed to be shortened. Thus, the study lasted for six months rather than 12 months. The total number recruited to the study was 52 over a 7-month period instead of the planned two years.

What answer did we get?

As this was a feasibility study the recruitment rate of 6-7 participants per month exceeded the set monthly target which was very encouraging. Furthermore, most people completed the study with an overall retention rate of 81% at six months and similar to other lifestyle interventions for people with diabetes. The two groups were well matched at baseline. At four months there was an improvement in mental health score and diet score in the intervention group. At six months mental and physical health scores and diet scores were improved. The experience of taking part in the study was highly rated and most participants reported they would recommend the programme to friends and family. Overall, interviews with participants revealed useful feedback about how acceptable the interventions were. Participants generally found making the diet and exercise changes easier than doing the computerised cognitive training programme.

What should be done now?

This was a feasibility study done to see whether a full study is possible. We know recruitment is possible and the most successful routes for recruiting people with diabetes to take part. We have information on what was most acceptable in terms of interventions and can use this information to refine the overall programme and data collection measures. We were able to observe changes in important health outcomes in response to the intervention that will help to inform the outcomes for a larger study. This pilot study provided crucial information to estimate how many people we would need to recruit in a larger study to determine if the multidomain intervention is effective for mental and physical health.