TBI Sertraline study- summary

Depression is very common following a traumatic brain injury, also called a head injury. Around 50% of people with a head injury will have some form of depression over the next 10 years. This is almost 10 times more common than the general public. There are two main symptoms of depression, a constant low mood and a loss of enjoyment in everyday life. Depression can affect relationships, jobs, education, financial hardship and unhealthy lifestyles like smoking and poor diets. People with depression following a traumatic brain injury tend to die earlier than the rest of the population and they are more likely to commit suicide.

Our patient and public involvement group (PPI) recognised the symptoms of depression and also mentioned others such as irritability, confusion, being very sensitive to noises and light. They agree that trying to prevent depression occurring in the first place is very important. The idea that antidepressants given early could stop depression in the first place after a traumatic brain injury was appealing. They said they would want to be given everything for the best chance of recovery. In this study, we want to find out if a commonly used antidepressant called sertraline, is better at preventing depression than a placebo (also called a dummy or ‘fake’ pill). We will also want to study if sertraline improves quality of life, improve other symptoms like headaches, irritability, memory loss, and reduces stress for carers.

Participants will be recruited from 9 Major Trauma Centres across England and from all walks of life. Patients attending A&E with a traumatic brain injury will be given information about this study. We will wait for any immediate effects of the head injury, such as memory loss, to settle. Those patients who are suitable will be invited to consent to join the study. They will be randomised, that is, they will have an equal chance of receiving sertraline or a placebo. We will start the sertraline at the lowest dose which is 50mg and after 2 weeks increase to 100mg. In the older patient, we will increase the dose more slowly. We will then see participants again at 6 weeks and 3,6, 9 and 12 months. At 12 months the sertraline will be slowly reduced and stopped. We will meet the participants once more at 18 months. We will also seek their consent to link the research data with their GP and hospital records to see how they are getting over the next 10 years. We asked some patients attending a typical outpatient clinic for head injury at St George’s Hospital if they would consider participating in this study if it was funded. The vast majority said they were interested in participating in research to prevent depression.

We have brought together a unique team of senior doctors and researchers for this study. At each hospital a psychiatrist will lead the research supported by either a neurologist or neurosurgeon, so that patients are safely managed in terms of mental health and physical health. We also have patient groups working with us, such as the charity, Headway. They have already given feedback on the study which helped us to improve our methods. After the study finishes, we will share our results in medical journals, in social media and to leaders of the NHS so that the prevention of depression can be included for this group of patients.