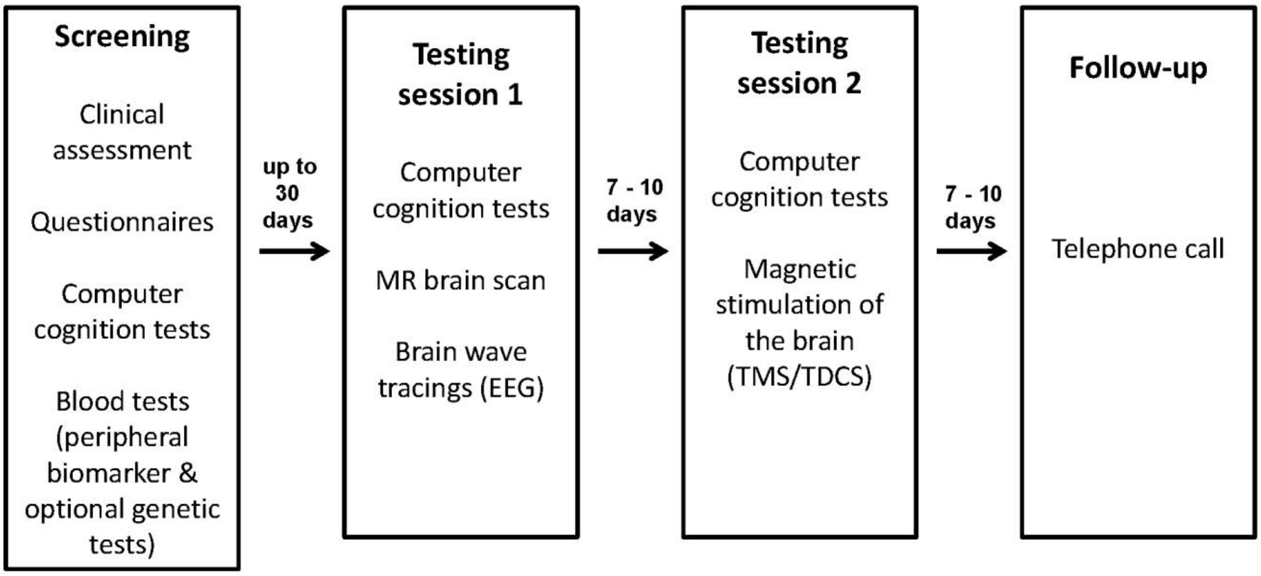
THE CAMBRIDGE BIORESOURCE VOLUNTEER INFORMATION FORM

BDNF gene neuroplasticity study (EMI115831)

WHAT IS THE PURPOSE OF THE STUDY?

Various brain conditions can alter the strength of connections between nerves (synaptic plasticity). There are different forms of the brain-derived neurotrophic factor (BDNF) gene that can alter synaptic plasticity in healthy people. We want to study healthy people with different forms of the BDNF gene using cognitive tests, brain wave testing, brain imaging and magnetic stimulation of the brain. Cognitive tests assess skills such as learning and memory. This form gives you a brief summary of the study and its tests.

WHAT WILL HAPPEN TO ME IF I DO TAKE PART?



There will be 1 screening visit and 2 testing sessions each lasting up to 6 hours at the GlaxoSmithKline Clinical Unit at Addenbrooke's Hospital in Cambridge. Each volunteer is in the study for up to 7 weeks and the testing sessions are spaced about one week apart.

At the screening visit we will tell you about the study & give you an opportunity to ask questions before deciding if you want to take part. If you want to be involved then we will check your suitability by asking you questions about your medical history followed by a physical examination, blood and urine tests and a pregnancy test for women. If you are suitable for the study then you will be invited to the first testing session within the next 30 days.

During this first testing session you will have some computerised cognition tests, a magnetic resonance brain scan and brain wave tracings. Cognition tests are routinely done in hospitals and have no harmful effects. Magnetic resonance imaging of the brain is a standard hospital scanning technique that takes high definition pictures of the brain using a strong magnetic field. We will look at the blood flow to various parts of your brain during some simple cognitive tests and you will not feel anything. The scan can be noisy, is enclosed and it lasts 60 to 90 minutes. The brain wave tracings measure normal brain activity at rest and when you are listening to sound. Cognition tests are routinely done in hospitals and have no harmful effects.

During the second testing session the surface of your brain will be stimulated using a magnetic coil placed on the left side of your head which causes your right hand to twitch. This process is repeated a number of times over a period of approximately an hour. A weak electrical current is then passed through two sponges placed on your scalp to induce an electrical current in your head for 9 minutes to induce a temporary change in brain activity under the sponges. The magnetic stimulation is then repeated. This technique has been used safely for over twenty years with no lasting effects although there is a theoretical risk of inducing a seizure, but this is extremely rare and it is not even certain that it can have this effect on patients with epilepsy.

Finally there is a follow-up telephone call to check on you after the testing sessions have been completed.

WHO SHOULD I CONTACT IF I AM INTERESTED IN TAKING PART?

If you require any more information then please speak to Sarah Nutland, the BioResource co-ordinator on 01223 763223 or Sarah Walsh, recruitment co-ordinator at the GSK Unit on 01223 296009. If you want to be considered for the study then complete and sign the reply slip and return it to Sarah Nutland at the Cambridge BioResource in the freepost envelope provided.

REPLY-SLIP (complete & return to the Cambridge BioResource in the envelope provided if you wish to be considered)

Study number : EMI115831 BDNF gene neuroplasticity study
Researcher: **Professor John A Todd** Cambridge BioResource, Box 299, Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Hospital, Hills Road, Cambridge CB2 0QQ Tel: 01223 763223 or 769215 www.cambridgebioresource.org.uk

Patient Name:	
Patient Address:	
Telephone:	

		Please initial each box
1	I agree to undergo initial screening for the above study.	
2	I understand that sections of any of my medical records may be looked at by authorised, responsible individuals from or delegated by GlaxoSmithKline, or from regulatory authorities where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records and also agree that any relevant personal information can be sent to the GlaxoSmithKline Clinical Unit by secure electronic systems (such as email, secure internet portals or fax). This personal information will allow us to assess your suitability for the study and to arrange screening.	
3	I agree that the GlaxoSmithKline study physicians may contact my General Practitioner to make known my possible participation in this study and I authorise my General Practitioner to disclose details of any relevant medical or drug history in confidence.	
4	I agree that GlaxoSmithKline may contact me to discuss my possible participation in this research study.	
5	I understand that my personal information will be held securely on a database and treated as confidential. Access to that information will be limited to authorised staff within GSK.	
6	I understand I may request access to view or to obtain a copy of my personal information stored by GSK	
7	I understand that my participation in the research study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
8	I understand that signing this pre screening consent form does not oblige me to take part in the study	

Name of volunteer		Signature		Date (DD/MMM/YYYY) Time (hh:mm)