

Name of study: The **ACT NoW Study**

**Assessing the effectiveness of Communication Therapy in the North West**

we would like you and your family to think about taking part in research. This information sheet is to explain **why** the research is being done and **what** would happen if you take part. It is long but please read it carefully and discuss it with your family. Ask us if there is anything that is not clear or if you would like more information.

The information in this booklet is available in an audiotape 🎧 or video/DVD 📺. We can provide it in large print. We can also provide a version which includes more pictures and has fewer words.

**Thank you** for reading this.

The next few pages answer some of the questions you and your family may have about taking part in this research project

### **Why Me?**

You are invited to take part because you had a stroke and have difficulty communicating (speech, writing, spelling or understanding). We need 170 people who have had a stroke, from all over the North West.

### **What is the Research?**

This project compares two different ways of giving people help with their communication. One is with a speech and language therapist and the other is with an ACT NoW visitor. We do not know if one is better than the other. If enough people take part we may find out.

### **Who is doing the project?**

The project is organised by people from The University of Manchester, with help from experts who know a lot about stroke and about research.

### **Why is the research happening?**

The government have asked us to do the research. They are paying for the study. The study will cost about £1 million pounds. They want us to try to find out the best way to help people who have had a stroke in the future.

**Will I work with a speech and language therapist or an ACT NoW visitor?**

Nobody knows which would be better for you. If you take part in the study, it will be decided by **chance**. We will use a computer to randomly pick names. It means that each person has an equal, 50:50, chance.

This is called a randomised controlled trial. It is the best type of research for helping the government to plan future care for people who have had a stroke.

**What would the speech and language therapist or the ACT NoW visitor do?**

A speech and language therapist would do speech and language therapy with you. This would try to help your communication. There are likely benefits to receiving this speech and language therapy.

An ACT NoW visitor is like a friend who would offer company and support. There are likely benefits to this regular contact with someone outside of your family and friends.

The speech and language therapist or the ACT NoW visitor would visit you wherever you are, at hospital or at your home.

### **How long will it take?**

You would be involved for about **6 months**. You would see either a speech and language therapist or an ACT NoW visitor up to 3 times per week for up to an hour at a time for 4 months. This would then stop. Another 2 months after that an interviewer from the University would visit you to assess your communication. They would video you and also talk with your family.

The interviewer would ask you and your family's opinions about your communication. Your opinions will be treated in confidence. After these interviews you would then finish the project.

### **Do I have to take part?**

No. Research is voluntary. If you take part you will be given this information sheet to keep and be asked to sign a consent form. If you later change your mind, you may withdraw without giving a reason. If you do not want to take part, this will not affect the care you receive from the NHS. It is important that nobody feels pressured into taking part.

### **Who will see my video?**

The video and all other information you provide us with will be treated in confidence. Only people involved in the research project will see your video and they will not know your details. We need to see how you are getting on with communication after the 6 months. We also need to compare videos of people who worked with the therapists and those with ACT NoW visitors. We will store the videos and all written records safely for several years after the project.

### **Will my name and address be made public?**

No. We will keep this information in confidence. Your hospital doctor and your GP will be notified that you are taking part in the study.

### **What are the possible benefits of taking part?**

Everybody in the study will receive 4 months of support immediately after their stroke. We hope that this will help you, but this cannot be guaranteed. The information we get from this study may help us to treat future patients who have had a stroke better.

### **Are there any risks or inconveniences if I take part?**

We hope there are no risks but we cannot guarantee this. Stroke can cause tiredness. If so you may find the frequent support too tiring. There is no reason to think the risk is higher with either the speech and language therapist or the ACT NoW visitor. You may find it inconvenient to receive the support or to be visited by the interviewer at the end of the study.

### **Are there any risks if I do not take part?**

If you do not want to take part in the research you will not receive the 4 months of support. Instead you would receive whatever therapy is available on the NHS. This varies from hospital to hospital but is likely to be less than in the study or of a different quality.

### **What if something goes wrong?**

This research is sponsored by the University of Manchester so they would provide compensation for any negligent harm caused by taking part in this study. The University of Manchester also provides cover for non-negligent harm. The NHS has set up an independent committee to monitor the project.



### **What happens when the research stops?**

Your part in the study stops after 6 months. If you would like more support we will help you to contact your local NHS therapy service.

### **What will happen to the results of the research?**

Throughout the study we will send everyone who takes part regular newsletters of our progress. We have also set up a website. When the study ends you and your family will be invited to a conference to hear the results. We will also send you a summary of the final report. We will publish scientific reports so that the NHS can use the results to improve future stroke care. We will never publish people's names, addresses or video without their written permission.

### **What now?**

An interviewer from the University will visit you again soon and answer any questions you have. Your family may also want to meet the interviewer. If you agree to take part, you will be asked to sign a consent form. You will be given a copy of this information sheet and the consent form. Copies will also be placed in your *Medical Records*.

## Thank you

for reading this information sheet and for considering our research project

If you have any questions please telephone 📞, write 📧, or e-mail 💻 the research manager, Emma Patchick:

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