# Participant Information Sheet

# Keeping Active with Texting after Stroke (KATS)

**Study Researcher: Dr Linda Irvine**

**Our research study**

We are doing a **research study** about **keeping active after stroke**.

Some time ago, **you gave us permission to contact you** when your period of rehabilitation was coming to an end. We would now like to invite you to take part.

Before you decide, we want you to **understand why** we are doing the study.

We also want to tell you **what it will involve** if you take part.

Please **read** this information **carefully.**

You can **ask us questions** and **talk to other people** about it.

We will try to answer your questions and give you information you need.

You do not have to decide straight away.

**Why are we doing this study?**

**Keeping active after stroke** is very **important**. Some people have told us that **when rehabilitation ends** they find it **difficult to carry on** with their **exercises.**

We have developed **a new programme** for people who are coming to the **end of rehabilitation**. It involves **keeping in touch by mobile phone**. The programme is designed to **help people** to **keep exercising** and find new ways of being active.

People who have had a stroke, their family members and health professionals have helped us to design this programme. We would now like to **test it** with about **14 people who have had a stroke**.

We would like to **invite you to test the programme** to find out if it is helpful for you. We also want you to **tell us how it can be improved**.

**Do I have to take part?**

No, **it is up to you to choose**. **You do not have to say yes**. If you do choose to take part we will ask you to give consent. You can change your mind at any time and you don't have to give a reason. If you stop you will still get your normal care.

**What will happen to me if I take part?**

If you decide that you would like to take part, we will **get in touch with your therapist** (with your permission), **to ensure that your rehabilitation is coming to an end and you are ready to take part** in the study. We will also ask your therapist to provide brief information about the exercises and activities you have been doing since discharge from hospital.

If you agree to take part, you will be **in the study for 12 weeks**.

The study **researcher, Linda Irvine**, will call you to **answer any questions you have** and to get your consent. The consent form, which accompanies this document, will be completed during the phone call. The researcher will ask for **your permission to audio-record your responses** to the questions on the form. She will complete a copy of the form and will record the date and time when consent is given. A copy of the consent form signed and dated by the research assistant will subsequently be sent to you by email, WhatsApp or by post.

The researcher will then ask you to **complete an interview by telephone** (which will also be audio-recorded, with your permission). During this interview she will **ask questions about yourself** and how the stroke affects you. She will also ask about your rehabilitation, the type of exercises you do now and would like to do in the future.

You will **receive at least one text message every day** over the 12 weeks. Some texts will give **information on keeping active**. The messages will **ask you about goals** you have set with your physiotherapist and will **encourage you to set new goals**. Some messages will include quotes from other people who have had a stroke. These are people who have taken part in our studies before. Some **messages will ask questions**. You do not have to reply to messages, but we'd like to hear from you. You can ask for the messages to be stopped at any time, if you no longer wish to receive them.

We will send you a study handbook that gives more information about the study and will provide information about online resources that offer exercises for people who have had a stroke. We will also send a calendar where you can keep a record of different activities you do. This calendar is for your own use only. We will not ask you to use it to collect information for us and we will not ask you to return it at the end of the study.

The researcher will **keep in touch by telephone**. She will call you 6 weeks into the programme and at the end of the 12 weeks. These calls will also be recorded (with your permission). The

researcher will **ask questions about using the programme and how to improve it**. We will use your suggestions to change the programme to make it suitable for other people who have had a stroke.

You will receive a gift voucher to the value of £20 at the end of the study as recompense for using your mobile phone during the study.

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

We **cannot guarantee any benefits** but being active helps recovery after stroke. **Keeping active may help you to feel better.**

**What are the possible disadvantages and risks of taking part?**

**Exercising after a stroke can be hard**, particularly if you have concerns about your balance or the risk of falling. However, you will **not be expected to take part** in the programme until your own **physiotherapist feels you are ready**.

You can take measures to **reduce risks**. For example, **do your exercises and activities** at times when you have **most energy**. Be sure to hold onto a stable surface like the kitchen worktop to support your balance if you need to. If balance when walking is a problem, **use your stick or walking aid**. If you are going out on your own, **consider taking your phone** with you.

If you have a **community alarm**, make sure it is **close by**. If you ever have a fall, remember to use the instructions that your physiotherapist gave you.

**How will we use information about you?**

We will need to use information from for this research project.

This information will include your:

- Name
- Contact details (address, telephone numbers, email address).
- GP name and address
- Therapist name and email address.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Your information will be held in an encrypted file on a password protected server at the University of Dundee.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team (Dr Linda Irvine, who can put you in touch with our Data Protection Officer) by sending an email to m.a.j.irvine@dundee.ac.uk
- by ringing us on 07565 014511 (Monday – Friday 9am to 5pm)

**Who is organising and funding this research?**

This study is sponsored by the University of Dundee. It is being funded by the Scottish Government. The **study is led by Dr Jacqui Morris**, from the **University of Dundee**.

**Who has reviewed the study?**

This study has been reviewed and approved by the North of Scotland Research Ethics Committee 2 who are responsible for reviewing research which is conducted in humans. The Research Ethics Committee does not have any objections to this study going ahead.

**What if something goes wrong?**

If you are concerned about taking part in the study you can discuss this with a researcher involved in carrying out the study.

If you have a complaint you should talk to a researcher in the study first. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside:

Complaints and Feedback Team
NHS Tayside
Ninewells Hospital
Dundee
DD1 9SY

Telephone: 0800 027 5507
TAY.feedback@nhs.scot

If you think you have come to harm due to taking part in the study, there are not any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice, but you might have to pay for your legal costs.

**Insurance**

The University of Dundee is sponsoring the study. The University of Dundee has a policy of public liability insurance which provides legal liability to cover damages, costs and expenses of claims.

As the study involves University of Dundee staff carrying out clinical research on NHS Tayside patients, these staff hold honorary contracts with Tayside Health Board. This means they will be covered under Tayside's membership of the CNORIS scheme.

**Contact details for further information**

If you are interested in taking part in this research, or if you would like more information, please contact the study researcher, Dr Linda Irvine, by one of the following methods:

Telephone: 07565 014511 (Monday – Friday 9am to 5pm)

Email: m.a.j.irvine@dundee.ac.uk

You can also contact the Chief Investigator, Dr Jacqui Morris

Email: j.y.morris@dundee.ac.uk

Thank you for reading this information and for thinking about taking part in the study.