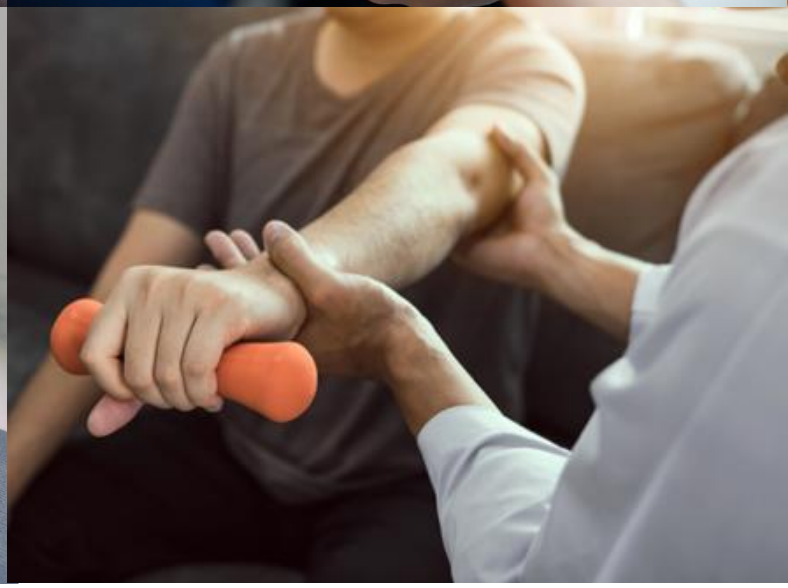
ReSTORe

Remote STrOke Rehabilitation



PARTICIPANT INFORMATION SHEET

WARWICK
CLINICAL TRIALS UNIT

FUNDED BY
NIHR | National Institute for Health and Care Research

NHS
University Hospitals Coventry and Warwickshire
NHS Trust

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WELCOME TO ReSTORe

You are **invited** to **take part** in the **ReSTORe research** study (clinical trial). Before you **decide** whether to take part, this **information booklet** will help you **understand** why this **study** is **being done** and what **you** will **have to do**.

Please take **some time** to **read** this **booklet** and **talk** to others **about** the **study**.

If anything is **not clear**, or if you want **more information**, please **contact** the ReSTORe team based at the Warwick Clinical Trials Unit on **02476 575767.**

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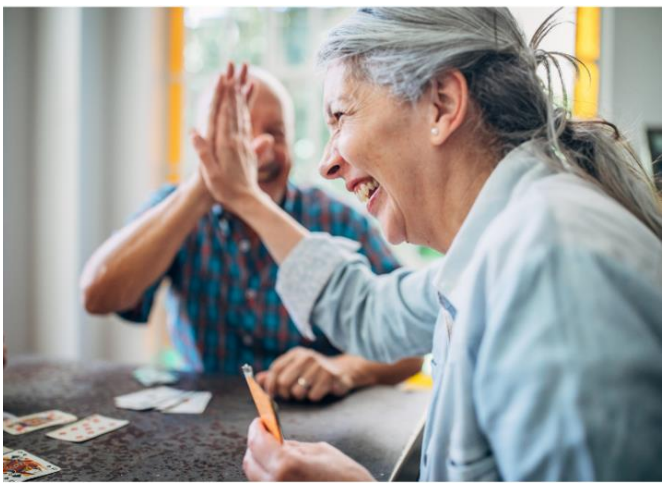
INTRODUCTION TO THE STUDY

After a **stroke**, some people have long-term **health problems** that can greatly **affect** their **quality of life**.

Some people can lead a relatively normal life after a stroke. Others **struggle** with **daily activities** and cannot enjoy life as much as they once could. **Stroke survivors** have **told** us that when their hospital or follow-up care finishes after about six months, **the lack of treatment** for their **ongoing** physical and mental health **problems** is **very challenging and frustrating**.

People who have had a **stroke** and their families have told us that **problems** with feeling tired **(fatigue), feeling worried, poor fitness,** and **low confidence** are common.

Our **aim** is to run a research study in the UK to **test** if an **online programme**, can **improve quality of life** for people with long-term mild to moderate physical and/or mental health disability after stroke. **We want to find out if this rehabilitation programme is better than usual care.**



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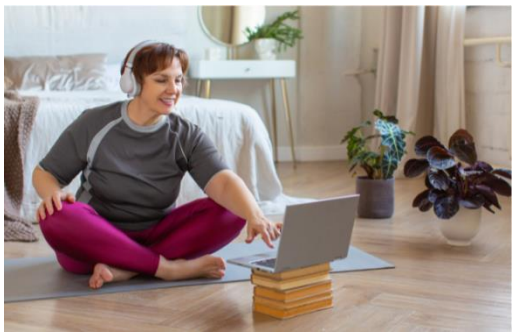
WHAT TREATMENTS ARE WE TESTING?

We will **test** an **online** exercise and support **rehabilitation programme** to find out if it can help people **recover after a stroke.** You will **join one of two groups**, decided by chance. This means you or the research team **cannot choose** which **group** you join. This is so the **study** treatments can be **compared fairly**.

The **groups** involve contact with one or more **trained** healthcare staff **(ReSTORe specialists).** The online sessions will take place via Microsoft Teams.

Group 1



One online **session** of **advice and support** with a trained **professional** for 30 minutes.

Group 2

The ReSTORe **online rehabilitation** programme which you can do at **home** over **10 weeks**. This will include weekly **group exercise** and **recovery support** sessions which last up to an hour. For the **exercise sessions** we advise that you have a **family member/friend nearby** to **support** you.

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❖ How will we know if these treatments can help?

People told us that getting back to work, returning to normal activities, and having a **better quality of life** are **key** goals. We want to **find out** if the ReSTORe **rehabilitation programme** can **help** people **recover**.

We will ask you to complete a **questionnaire 4 times** over **1 year**. These will ask about your quality of life, fatigue, confidence and activity levels.

This will help us **find out** if our online **rehabilitation programme can help** people with long-term problems after a stroke. It will also tell us if the programme is **good value** for the NHS.

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WHO IS ORGANISING THE STUDY?

The study will be managed by a team at **Warwick Clinical Trials Unit (at the University of Warwick).** This team includes **patient partners** and **experts** in stroke, exercise, clinical trials, statistics, and health economics.

The **ReSTORe specialists** who will **talk to you** by phone or video call to check **eligibility**, complete **questionnaires** and deliver the online group sessions will be based at Unveristy Hospitals Coventry and Warwickshire **(UHCW)** NHS Trust.

ReSTORe is funded by the UK Department of Health; the National Insitute for health and Care Research (NIHR HTA 157510).

PARTICIPANT INFORMATION

This part of the booklet will explain more about **taking part in the study.** If there is something you are unsure of, please get in touch.

❖ Why have I been asked to take part?

We are **inviting people** to take part in this study that have had a **stroke** in the **last 3 years**. You may **have ongoing** physical and/or mental health **difficulties related to** your **stroke.**

❖ Do I have to take part?

You can **decide** if you **want to take part**. If you **agree**, you will need to **complete** a consent **form.** If you decide **not** to **take part**, the standard of **care** you receive will **not** be **affected.** If you decide to **stop taking part**, please **let us know**. We will **keep** the **information** about you that we have already **collected**. If you do not want this to happen, please **tell us.** You can **stop** taking part at **any time** without giving a reason.

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WHAT WILL IT INVOLVE?

If you want to take part, follow the website link **www.warwick.ac.uk/restorestudy** to fill in a form online to check if you can join the study.

After that, you need to **complete** a consent **form** to say that you **agree** to **take part** in the study. You can do this **online** with **help** from a **carer, friend/family** member. A **ReSTORe specialist** might get in touch with you on the **phone** to help. We **will email** you a copy of your completed **consent form.**

Once you have **completed** the **questionnaire**, you will be **allocated** by chance to one of two **groups,** and you will **start** your **rehabilitation programme**.

We will get in touch with you at **3, 6 and 12 months** to ask you to complete the **questionnaire again.**

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❖ What equipment or devices do I need to take part?

You will need:

• Laptop • Computer OR • Tablet with a camera	
Mobile phone with a valid phone number	
Internet Access	
Email Address	

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❖ How long will I need to be involved in the study?

Your **involvement** in the study will last for **1 year.** If you are in **Group 2**, the exercise and support **programme** will run during the **first 3 months**.

❖ What are the benefits of taking part?

We **cannot promise** that the **study** will **help you**, but the **information** we get from the study will be **invaluable** in **helping people** in the **future**. This rehabilitation **programme** could **help** people **after** a **stroke**.

❖ What are the risks of taking part?

We do **not expect** any **serious risk** to you. If you take part in the ReSTORe **rehabilitation programme (Group 2)** there is a **very small chance** that **exercise** could cause **tiredness**, **breathlessness**, and **sore** muscles, but this should **get easier** each time you exercise.

You will be **advised** and **monitored** by **specialist staff.**

Although **unlikely,** if you feel **unwell during** any exercise **sessions**, a ReSTORe **specialist** will **contact** you online or by

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telephone to **see** if medical **help** is **needed**. Although there is only a **small risk** of becoming unwell during exercise, we **recommend** that you have **another person nearby** at home when you are doing your first few sessions.

Sometimes, people can **find** the questionnaires or support sessions **upsetting**. Our specialist **staff** are fully **trained** and will **provide** appropriate **support** as needed.

There may be times when the study **team** need to **act** upon **confidential information** for **safeguarding** reasons e.g. if our conversations with you highlight specific health problems. If so, we may **refer** you to your **GP** or other **healthcare staff**.

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❖ What do the study questionnaires look like?

There will be **4 questionnaires** to complete after you join the study. The questionnaires will be available **online** and shouldn't take too long to complete. If you have any **questions** or concerns regarding access, **please call us**.

Your first questionnaire
So we can find more about you and your stroke history.

3 month questionnaire
How you feel, including fatigue, mental health, sleep, pain and social interaction.

6 month questionnaire
How you feel, including fatigue, mental health, sleep, pain and social interaction, physical activity, general health, and any further healthcare you have had.

12 month questionnaire
The 12 month questionnaire is your **final** questionnaire. It will be very similar to the 6 month questionnaire.

PARTICIPANT DATA HANDLING

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This part of the information sheet will **explain** what **happens** to **your information** during the study. If you would like to **talk** to us about how we **handle** your data, please call us.

❖ How will we use information about you?

UHCW NHS Trust is the **sponsor** for the study. The study will be **managed** by Warwick Clinical Trials Unit at the University of Warwick (UoW). **With** your **consent**, UoW and UHCW NHS Trust will use **information you provide**, information **from** your **GP records** and other **NHS data** sources to **carry out** this **study** and will act as **joint data controllers**. This means that together, they are **responsible** for **looking after** your **information** and **using** it **properly**.

Individuals from UoW, UHCW NHS Trust and regulatory organisations **may look** at your **medical** and **research records** to **check** the **accuracy** of the **data** collected during the study. **Your data** will have a **study number**. We will keep all **information** about you **safe** and **secure.**

We will **write** our **reports** in a way that **no-one** can **work out** that **you took part** in the **study**.

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The **people** at the UoW and UHCW NHS Trust who will have **access** to **information** that **identifies you**, will be:

- **Exercise specialists** leading the online groups
- ReSTORe team from UoW who **follow up** on your **progress** or check **questionnaires** are **completed**
- ReSTORe team from UoW who **host** the **database** where your information will be stored, or people who will **audit** the **data collection process**.

The **team that analyse study information** at the UoW will **not** be **able** to **identify you** and will not have access to your name or contact details.

UoW will keep identifiable information **(e.g. name and address)** about you until the final paper has been published, and **non-identifiable information** about you for **5 years.** UHCW NHS Trust will keep identifiable information for **10 years.**

With your **consent**, some of your **contact information** will be **shared** with **third parties** only for the purpose of the **study**. If you agree to take part, your name, telephone number and email address will be shared **so** that we can **contact you** about the study. **Personal identifiable data shared** with or stored by **third parties** will be securely **deleted when** it is **no longer** needed.

If you **agree** to **take part**, we **may use** the **information** collected for **future research** and it may be **shared anonymously** with other researchers. Any future research will **only** proceed **if approved** by a **Research Ethics Committee** where necessary.

This information will not identify you.

❖ 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.

❖ How will we keep your data safe?

To safeguard your rights, we will use the **minimum** personally **identifiable information** possible. **Information** we collect about you during the study will be kept strictly **confidential** and will only be **accessible** to **authorised people**. The **only** reason we would **break confidentiality** would be **in** an **emergency.**

If your **own health**, or **somebody else's** health was in

danger, we may **contact** you, the **emergency services** or other **healthcare** staff.

If you are assigned to the **10-week** online exercise and support **programme, ReSTORe specialists** at UHCW will keep **paper records** of your **contact details** and **medical health** information as per their **safety protocol**. These paper records will be **stored securely** in locked filing cabinets **only accessible** to **study staff**. These records will **not** be **passed onto UoW**.

You can **read** the **privacy** statements on the University of Warwick and University Hospitals Coventry & Warwickshire websites:
https://warwick.ac.uk/services/legalandcomplianceservices/dataprotection/otherprivacynotices/research/

https://www.uhcw.nhs.uk/privacy

You can also find out **more** about how we **use your information** here:
http://www.hra.nhs.uk/patientdataandresearch

❖ Next of kin information

If you agree to take part, we will ask you to **provide** some **contact details** for your **next of kin** in case there is an **emergency,** or we **cannot get in touch** with **you**. Please **show them** this **information sheet** so they **know** about the **study** and **un**derstand **how** we will **use** their **information**. Next of kin information will be **kept confidential**, **secure** and only **accessible** to **authorised people** as per the information and privacy statements above. Please **check with** your **next of kin** if they are **happy** for **us** to **have** their **details** and **get in touch** with them if needed.

❖ Involvement of your General Practitioner (GP)

If you agree to take part and with your permission, your **GP** will be **notified** that **you** are taking part **in** this **study**.

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OTHER HELPFUL INFORMATION

❖ What will happen to the results of the study?

At the **end** of the **study**, we will **publish** the **findings** in medical journals and at medical conferences. **You** will **not** be **identified** in any reports or publications. Once all the patients have been followed up and the results have been analysed, we will make a copy of the study **results available** on the website:

https://warwick.ac.uk/restorestudy

❖ Who has reviewed the study?

Research that involves the **NHS** and **patients** is reviewed by an independent group of people called a **Research Ethics Committee**. This study has been reviewed by Derby Research Ethics Committee. People who have had a **stroke** have also been **involved** in **designing** and setting up this **study.**

❖ What if something goes wrong?

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If you have any **concerns** about any aspect of this study during your **involvement**, you should **speak** with the researchers who will do their best to answer your **questions**. If you remain unhappy and wish to **complain** you can do this through the **NHS Complaints Procedure,** you can find a **guide** here: **https://www.nhs.uk/contact-us/how-to-complain-to-the-nhs/.**

Please contact:

Complaints Manager

University Hospitals of Coventry & Warwickshire NHS Trust

Clifford Bridge Road

CV2 2DX

Email address: complaints@uhcw.nhs.uk

Telephone no: 02476 965 198

As sponsor, **UHCW NHS Trust** provides **indemnity** for this **study**. In the **unlikely event** that you are **harmed** by **taking part** in this study, **compensation may** be **available**. If you suspect that the harm is the result of someone's negligence, then you may have grounds for legal action. You may have to bear the **costs** of any legal action, and you should **seek legal advice** about this.

For **independent advice** on research, you can **contact** PALS (Patient Advice and Liaison Service) on free phone 0800 028 4203, Email: feedback@uhcw.nhs.uk

In the **unlikely** event of you losing your capacity to consent during the study, you would be withdrawn. **Identifiable data** already **collected** with consent would be **retained** and used in the study. No further data would be collected, or any other research procedures carried out on or in **relation** to the participant.

Thank you for taking the time to read our information sheet.

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CONTACT US

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restore@warwick.ac.uk

02476 575767

www.warwick.ac.uk/restorestudy

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