



Study title: Feasibility study of a supported self-management intervention for aphasia (StarStep study)


You are being invited to take part in a research study

What is the research about?


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|  | <p>We are doing some research.</p> <p>It is about improving support for people with aphasia.</p> <p>Research helps us learn.</p> <p>We need to know more about how to help.</p> |
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Who is doing the research?


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|  | <p>The Chief Investigator is Dr Faye Wray.</p> <p>The research is run from the University of Leeds.</p> |
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Why are we doing the research?


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|  | <p>There is a new type of therapy. The therapy is to help build confidence and ways to cope with aphasia. Speech and language therapists give this therapy.</p> <p>We want to study the new therapy. We want to see how feasible it is to give at your local NHS service.</p> <p>You will get the new therapy <u>and</u> your usual therapy.</p> |
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Why me?





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|  | <p>You have aphasia after your stroke.</p> <p>Aphasia can make it hard to:</p> <ul style="list-style-type: none">• Speak• Understand what other people say• Read• Write |
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What will I have to do?





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|  | <p><u>Do an assessment</u></p> <p>The researcher will assess your language (when you join the study). It will take 5-10 minutes.</p> |
|  | <p><u>Complete some questionnaires</u></p> <p>Fill in some questionnaires about your health (when you join the study and 6 months later). It will take 30-60 minutes.</p> <p>Fill in a questionnaire about the therapy after each session. It will take 5 minutes.</p> <p>Tell us if you need help. We will help you.</p> |
|  | <p><u>Take part in observations</u></p> <p>Your speech and language therapist will video record your therapy sessions.</p> <p><u>Or</u></p> <p>A researcher will watch <u>one</u> of your speech and language therapy sessions. This will happen if there are any problems with the video recording.</p> <p>We would like to find out about how the therapy works in practice.</p> |
|  | <p><u>Access to your medical and care records</u></p> <p>We would like to find out about;</p> <ul style="list-style-type: none"> • The type of stroke you had. |

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| | <ul style="list-style-type: none"> • How your health has been affected <p>The information will be anonymised so you cannot be identified.</p> |
|  | <p><u>Take part in an interview</u></p> <p>We may contact you about this. We would like to know your views of the therapy you receive.</p> <p>You can agree or refuse at this time.</p> |




What happens if we can't meet in person due to the COVID-19 pandemic?

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|  | <p>A researcher may visit you at home to:</p> <ul style="list-style-type: none"> • complete the questionnaires • watch a therapy session • do an interview |
|  | <p><u>But</u>, We will not visit if it is not safe.</p> <p>We will not visit if you do not feel comfortable.</p> |
|  | <p>We may use an on-line platform, e.g. Microsoft Teams or Skype (for questionnaires and interviews).</p> |
|  | <p>We will help you to access on-line platforms.</p> <p>We will have regular breaks.</p> |

Do I have to take part?



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|  | <p>You can decide. You don't have to.</p> <p>If you don't take part you will still get your normal help.</p> |
|   | <p>You can stop at any time.</p> <p>You don't have to give a reason.</p> <p>If you stop you will still get your normal help.</p> |
|  | <p>You can decide</p> <ul style="list-style-type: none">a) if you want to take part in the observations.b) if you want to complete the questionnaires.c) If you want to take part in the observations <u>and</u> complete the questionnaires |

Who will see the information about me?

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|  | <p>We will keep the information about you safe.</p> <p>Only the researchers will see the information about you.</p> <p>We will keep your information (at the Academic Unit for Ageing and Stroke Research) for 3 years.</p> |
|  | <p>But if the researcher is worried that you or someone else is at risk of harm we will tell someone in your local healthcare services.</p> <p>We will tell your GP that you are taking part in the study.</p> |
|  | <p>Contact us if you would like your information removed from the study.</p> <p>Contact us within 2 weeks.</p> <p>After 2 weeks your information cannot be removed.</p> |




What might be good about taking part?




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|  A woman with short blonde hair, wearing a purple jacket, smiling. | <p>You will help people in the future.</p> <p>They will get better help.</p> |
|  A man with short dark hair, wearing a purple shirt, resting his chin on his hand in a thoughtful pose. | <p>You may enjoy taking part.</p> <p>You may find it interesting.</p> |




What might be difficult about taking part?

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|  A woman with short blonde hair, wearing a purple jacket, talking on a mobile phone. | <p>You may find the questions in the questionnaires upsetting.</p> <p>You might not like being watched or video recorded when taking part in therapy.</p> |
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Is the research safe?

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|    | <p>A committee decides if research can happen.</p> <p>This is the Essex Research Ethics Committee (Ref: 21/EE/0115).</p> <p>They say that this research can happen.</p> <p>They say that it is safe.</p> <p>They say that it has been planned properly.</p> |
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Will I be harmed by the research?

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|  | <p>This is very unlikely.</p> <p>However, the NHS has set up a committee.</p> <p>This committee will monitor the research.</p> <p>The committee has different people from those who do this research.</p> |
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What will happen after the research?

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|  | <p>The researchers will look at the results.</p> |
|  | <p>They will learn more about supporting people with aphasia after stroke.</p> |


What will happen to the results?

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|  | <p>We will send you a summary of the results.</p> |
|  | <p>We will share the results with other researchers at conferences and meetings in academic journals.</p> |
|  | <p>The results will not use your name.</p> |
|  | <p>The results may include what you said but not who said it.</p> |


What next?

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|  | <p>Do you want to take part?</p> <p>You need to decide.</p> |
|   | <p>If you want to take part we will ask you to sign a consent form. Someone can help you with this.</p> <p>This says that you understand the research and you agree to take part.</p> <p>We may ask you to agree verbally if we meet you by videocall. We will take a sound recording of this.</p> |
|  | <p>If you decide not to take part you do not need to do anything.</p> |
|   | <p>If you want more information</p> <p>Please contact the researcher: Faye Wray</p> <p>Telephone 01274 38 3400 Or</p> <p>Email f.d.wray@leeds.ac.uk</p> |



Claims and insurance

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|  | <p>If you take part in the research and if you think you were harmed you may be able to claim compensation from the University of Leeds.</p> <p>You may have to pay legal costs.</p> |
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What if there is a problem?

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|  | <p>If you want to discuss this study with someone independent contact:</p> <p>Clare Skinner on: 0113 343 4897 or email: governance-ethics@leeds.ac.uk</p> |
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Where could I get further support?

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|   | <p>If you have concerns about the care you have had in the NHS</p> <p>or you need advice about other organisations who can help you can contact:</p> <p>The Patient Advice and Liaison Service (PALS). Phone 111 for details of your nearest PALS or visit https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/</p> <p>Or the Stroke Association on 0303 3033 100</p> |
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Thank you for taking the time to read this information.

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