PARTICIPANT INFORMATION SHEET

Title of study: Development and Psychometric Testing of a Daily Activity Questionnaire for Stroke Survivors and the online StrokeSurvivorsHub.com

Name of Researcher: Nazemin Gilanliogullari

Introduction

We are inviting you to take part in a research study. It is important for you to read and understand why this research is taking place and what it involves before you make a decision. Please take your time to read the following information carefully. You may discuss with others if you wish.

You can find contact details of the researchers at the bottom of this page. Please do not hesitate to contact us if there is anything that is not clear or if you would like further information. After you have read it carefully, take your time to decide if you would like to take part or not.

What is the purpose of the study?

There are 1.2 million Stroke Survivors in the community and two-thirds of them continue to need help with daily activities. Main functions such as movement, sensation, speech, coordination, memory, cognition, balance and vision can be impaired after stroke. This can result in difficulties in common daily activities; such as walking or dressing, which is linked to poor quality of life (QoL).

It is important that all functional assessments are comprehensive to aid planning of rehabilitation goals. Patient Reported Outcome Measures (PROMs) are important to understand the limitations from a patient's perspective and allows the prioritisation of patient's own goals. PROMs are self-completed questionnaires, but patients can also get help from carers/family if needed. There are many different daily activity assessments for Stroke Survivors, but all have limitations and not comprehensive. Most importantly only a few are patient reported. Such PROM, which overcome all

these limitations exists for rheumatic and musculoskeletal conditions; the Evaluation of Daily Activity Questionnaire (EDAQ).

We would like to develop a version of the EDAQ that is adapted for use in Stroke Survivors (EDAQ-SS), and test the validity and reliability. Once it is developed and tested, we are aiming to make this tool freely accessible to all. Therefore, we are also developing an online platform to include the EDAQ-SS as an easy to complete electronic assessment to help both Stroke Survivors and the health professionals working with them to have an improved access to assessment tools.

Why have I been invited to take part?

We will need the involvement of 700 Stroke Survivors in Phase-2, where we make sure that the new developed EDAQ-SS has good validity and reliability. Whether you have any limitations or not, it does not matter. We will need a wide range of people with stroke and we understand that limitations can vary from one person to another. We are kindly asking you to take part if you meet the following criteria:

You are a Stroke Survivor living in the UK;

- 18 years old or over
- can understand, read and write in English
- have access to internet and to a personal email account

Do I have to take part?

No, you do not have to take part. Participation is voluntary, so it is your decision whether or not to take part. Your participation will help us to develop better assessments of daily activity limitations in Stroke Survivors to improve the treatment they receive, which can lead to improve quality of lives. Additionally, your collected anonymised data will be used to complete a secondary analysis. This will help to understand which daily activity limitations are most common amongst Stroke Survivors. If you do agree to take part, you will be asked to sign an online consent form. Once you have consented, you will still be free to withdraw at any time without giving a reason.

What will happen to me if I take part?

If you decide to take part, please visit www.strokesurvivorshub.com/register to register at the website and to complete an online consent form. Once you have registered, you will have access to the questionnaire at the dashboard and will have a week to complete it. This means you can save your responses at any time and come back to your questionnaire to complete it at a later time, to suit your needs. We do not want this to be a burdensome activity for you and really appreciate your contribution. Once you have completed the questionnaires, two to three weeks later we will ask you to complete the same questionnaire again. This is not to test you, but to test the validity and the reliability of the questionnaire. We will also ask some additional questions about your health to help us understand whether any changes to your responses are driven through your health or not. This will also help us to establish how sensitive this assessment is on picking up the changes on your health and functioning.

The questionnaires that we would like you to complete are:

- ✓ UK Evaluation of the Daily Activity Questionnaire for Stroke Survivors (EDAQ-SS) (including About You and Your Health)
- ✓ Stroke Impact Scale (SIS)
- ✓ Rivermead Mobility Index (RMI)
- ✓ SF-12v2 Health Survey
- ✓ Patient Health Questionnare-9 (PHQ-9)
- ✓ General Anxiety Disorder-7 (GAD-7)
- ✓ The Measure of Activity Performance in the Hand (MAPHAND)
- ✓ The Disability Arm Shoulder Hand scale (DASH)

If you struggle to complete the questionnaire due to functional problems, you can get help from your family/carers or friends as long as you are comfortable with this. We are also happy to provide assistance if you feel comfortable with this. If so, we could telephone you and go through the items with you on the telephone. Please let us know if this is something you would consider.

It is really important for us to receive your answers within a week as this can affect the results of the study. If the questions are not completed within a week, all responses

will be reset automatically by the system and you will need to start again. Finally, you will receive a thank you email to inform you that your participation is ended.

What are the possible disadvantages and risks of taking part?

There is no potential risk to you during at any part of the data collection. However, the questionnaires are about your limitations in daily activities and general health. So, completing a lot of questions about these limitations may result in feelings of loss, sadness or frustration. Also, the completion of the online questionnaires may take up a long time. This is why we are asking you to take your time and complete the whole survey within a week. So, you may stop, have a rest, and continue to complete them whenever you wish within a week. Additionally, you may use the contact details provided to you to contact the researcher and discuss your further concerns at any time, before, during or after the completion of the questionnaires.

All data will be anonymised for confidentiality. All person identifiable electronic data (such as age, date of birth) will be stored securely within the University server, and only accessible by the research team. This is necessary for audit purposes so we can prove that the data was not falsely generated.

Publications will only include anonymised and aggregated data, written in a way to disguise the identity of all participants. Data will not be used in a way that you can be identified.

If you have any concerns about any aspect of this study, you should ask to speak to the researcher (Nazemin Gilanliogullari, email: n.gilanliogullari@edu.salford.ac.uk). We will do our best to answer your questions. If you remain unhappy about anything and/ or would like to speak to a registered health professional about your concerns, you can talk to the Chief Investigator, Dr Yeliz Prior on 0161 295 0211 or email her at y.prior@salford.ac.uk [Monday to Friday 09:00 – 17:00]. If the matter is still not resolved, please forward your concerns to Professor Andrew Clark, Chair of the Health Research Ethical Approval Panel, Tel: 0161 2954109, Email: a.clark@salford.ac.uk.

Information collected about you during this study may be used to support other research in the future (e.g. secondary analysis), providing a separate ethical approval is obtained from the University. After receiving the graduate award, person identifiable data will be stored and archived for 6 more years, to allow verification of data from external sources if necessary, before destroyed confidentially.

What are the possible benefits of taking part?

You will not benefit directly from taking part in this research. Although, you may become more aware of your functional limitations and this may help you to be more proactive in your treatment. Additionally, you will contribute to a research project, which can change the assessment process significantly for Stroke Survivors to help them achieve better rehabilitation outcomes.

Also, your online account will always be freely available to you. You may use it as a self-assessment tool in the future as your rehabilitation goals change.

What will happen if I don't carry on with the study?

Your participation is completely voluntary. You are free to withdraw from the study at any time without giving a reason. However, all the data collected from you, up to the point of withdrawal, will be anonymised and used in the research.

What will happen to the results of the research study?

The results of the study will be used as part of a Doctor of Philosophy (PhD). This will help to share the new knowledge acquired, and lead to the improvements in the field of clinical rehabilitation of Stroke Survivors.

Further information and contact details:

If you have any questions, would like more information, or would like to volunteer please do not hesitate to contact:

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Thank you for taking your time to read this information.