

EASY-ACCESS PARTICIPANT INFORMATION SHEET

Oral health assessment in acute dysphagic stroke

V1; 28/7/14 REC Ref:



University Teaching Trust

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Manchester Vascular & Stroke Centre

Institute of Cardiovascular Sciences, University of Manchester, CSB, Salford Royal Foundation Trust, Salford in collaboration with Manchester Dental School

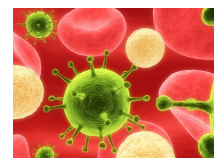
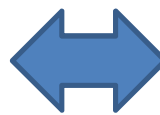
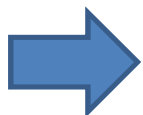
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1. Study title: Oral health and development of stroke-associated pneumonia



2. The invitation. You are invited to take part in a research study

To have
checks of
your mouth



By a **nurse** and a
Dental Hygienist



Before you decide, it is **important** for you to **understand** why the research is being done and **what it will involve**.

Please take the time to read the following information.



Ask if anything is **not clear** or if you would like **more information**.



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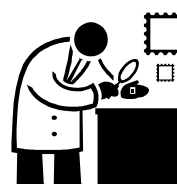
3. What is the **purpose of the study?**

We want to see if an **assessment** of the mouth after stroke is useful,

so we can check for a **link** between the **condition** of the mouth is after stroke and the development of **pneumonia**.

If we can **identify** pneumonia **earlier**, it can be **treated** sooner,

leading to **improved recovery** from stroke and shorter hospital stay.



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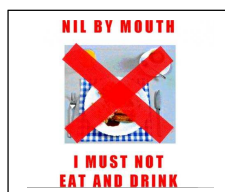
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4. Why have I been chosen?

You have had a **stroke**



You are unable to **swallow**



You will be in **hospital** for at least 3 days



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5. Do I have to take part?

No. It is **up to you** to decide whether or not



to take part.

The **standard of care** you receive will not be affected in any way



6. What will be involved if I agree to take part?

Whilst you are in **hospital**

Salford Royal 
NHS Foundation Trust

We would like to carry out **two examinations** of your mouth. Each will last about half an hour.



X2



These will be done by a **research nurse** and a **dental hygienist** on the **first day** after your stroke.



&



on



The research nurse will record **information** about your **health**, including **medication** you currently take and **details of your stroke**



The dental hygienist will perform a full examination of your mouth; including your **teeth** or **dentures**.



She will also **inspect** the gaps between your teeth. This may be slightly **uncomfortable**.



The hygienist will **pause** as often as necessary.

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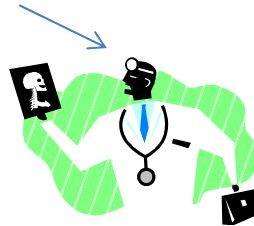
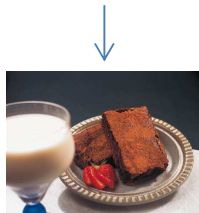
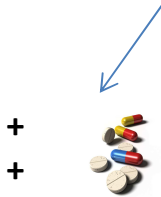
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The research nurse will visit on **alternate days** to see **how you are**.



She will record **changes** to your **medication**, check if you can **eat and drink** and check your **general health**.



This will **continue** to do this even if you **leave Salford Royal** and **return to your local hospital**



Assessments will continue for **up to 10 days** after your stroke. After this time your participation in the study will end.



7. What are the benefits of taking part?

Taking part in the study will **not benefit you** but you will help **increase our understanding of mouth hygiene and stroke-associated pneumonia**



8. What are the risks of taking part?

We do not anticipate there to be any **risks** to participation.



You may pause or stop the assessments at any time.

You are free to withdraw from the study at any time.



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9. Will my taking part in the study be kept confidential?

All your **personal information** (name, address and telephone number) will be kept confidential



and **securely stored** at Salford Royal Hospital



Your name will not be shown

~~John Smith~~

You will be identified by a number

C131

Only **authorised** people will be **allowed** to see your information.



10. What will happen if I do not want to carry on with the study?

You are **free to withdraw** from the **study at any time**



If you withdraw, we will use the information already collected in the final analysis.

If you do not want us to use your information, please tell us and it will be confidentially destroyed.

11. Who is organising and funding the research?

This study is **organised** by the Stroke and Vascular Centre and the Dental School within the **University of Manchester**

The study is **funded** by **The University of Manchester Dental School**

This study has been **approved** by a **NHS Research Ethics Committee**

12. What will happen to the results of the research study?

We will **publish** the **study results** in an academic journal.

The results may be **presented** at **conferences**.



The results will be part of an **educational project** for Kate McKenzie, Dental Care Professional. You will **not be identified**.

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13. What if I need more information or there is a problem?

If you need further **information**



or have any concerns about the study please contact the research team on:

0161 206 2188

If you decide you would like to take part, please read and sign the consent form.



You will be given a copy of this information and signed consent form to keep.

Please take time to decide whether you want to take part.



Thank you for reading about this study.



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Consent Form for Patients

V1; 28/7/14

Please initial the boxes

	<p>1. I confirm that I have read and understood the information sheet dated 28/7/14 (version 1) for the above study. I have had the opportunity to ask questions.</p>	
	<p>2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without medical care or legal rights being affected.</p>	
	<p>3. I understand that my data will be collected for this study and may be used as part as part of an educational project. Data protection regulations will be observed. Confidentiality will be maintained.</p>	
	<p>4. I understand that even if I withdraw from the study, the data already collected from me will contribute to the study unless I specifically withdraw consent for this.</p>	
	<p>5. I agree to my data being stored by the Stroke and Vascular Centre and the Dental School at The University of Manchester. This will be anonymised as soon as possible.</p>	
	<p>6. I understand that authorised individuals may require access to my personal detail in order to monitor study conduct.</p>	
	<p>7. I agree to take part in the above study.</p>	

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Participant:

Name (capitals)

Date

Signature

Witness:

Name (capitals)

Date

Signature

Researcher:

Name (capitals)

Date

Signature

(1 copy for the participant, 1 copy for CRF, 1 copy for notes)