







The Oral Health for Brain Health (Mysmile) Study

We want to see whether we can treat gum disease in people who have memory problems (due to Alzheimer's Disease) and if improved gum health could slow memory loss. We are asking for your help. It is up to you if you want to join in. The research is being led by the University of Bristol and funded by the NHS.

Why have you asked me?

You have a diagnosis of memory loss.

Why are you doing this research?

Other research has shown that gum disease may cause memory loss or make it happen faster. We want to see if with help from a dentist and some specialist treatment people with memory loss can improve the health of their gums and slow their memory loss.

Do I have to join in?

No, you do not have to join. Please talk to your family or friends about the research to help you decide. It is OK to say no, you will continue to receive the same healthcare for your memory loss. If you say yes you can change your mind later, you can drop out at any time and continue to receive the same healthcare for your memory loss.

What will it involve?

If you say yes we will start by doing some memory tests:

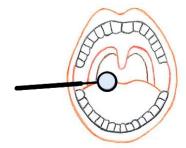


Then we ask you some questions:

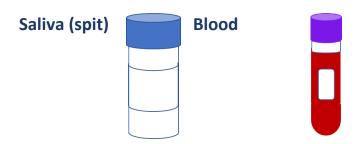
Your current health conditions



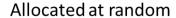
Then a dentist will look in your mouth and assess your gum health:

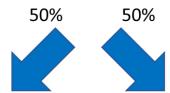


We will check the tests and if it is OK for you to join in we will take some samples:



After this you will be allocated to a study group at random (like tossing a coin):





GROUP 1

Will visit a dental practice 3-4 times:

The dentist will clean your teeth and gums



GROUP 2

No study dental treatment:

You do not have to do anything, but you should continue to visit your own dentist if you have one

Both Groups 1 and 2:

After 6 and 12 months of being in the study both groups will:

- Have memory tests.
- Have dental assessments.
- Give samples of saliva (spit) and blood.

At the 12 month appointment you will also be asked if you can tell us how the study was for you, for example, was it easy to join in? If you do this we will record what you say and a written record will be made from the recording.

After 18 months you will be contacted to see if you are able to do some memory tests by video link, but if you can't that's fine.

What are the good things about being on the study?

The research will help us to work out if treatment to improve the health of a person's mouth and gums could help slow memory loss.

Both groups will be given an electric toothbrush and toothpaste.

Group 1: will be given treatment to make their gums healthy.

Group 2: will be offered the same treatment to make their gums healthy at the end of the study (but they do not have to have it).



What are the bad things about joining in?

You will feel a slight scratch when we take blood, but it should not hurt.

You may find the treatment to treat your gums a bit uncomfortable.

There are quite a few study visits:

- Both groups: 3 visits in 12 months.
- Group 1: an extra 2-3 visits in the first 6 months.

We can give you up to £20 per visit to cover travel costs.

What will happen with the data (information) collected about me?

We will be careful to keep information about you safe and private.

We will replace your personal information with a code number.

We will share what we learn from the study with others, but no one will be able to identify you from this data.

What happens to the samples that I give?

- 1. **Samples are given a code number**, this helps keep information about them private.
- 2. Samples will be sent to laboratory at the University of Bristol.
- 3. **Leftover samples**: We will ask you if your leftover samples can be stored and used in other research. It's fine to say no, we can destroy your left-over samples.

What if something goes wrong or I want to complain?

If you want to complain about the study, you can contact the Patient Support and Complaints Team at the BRI on 0117 342 1050, or by email: PSCT@uhbw.nhs.uk.

What happens now?

If you have any questions, please ask us (see below). If you want to join in, you will be asked to complete a consent form.

Thank you for reading this information sheet

Professor Nicola West, Dr Liz Coulthard.

If you are interested and/or have more questions please:

Contact:

Miss Nikki Hellin (study co-ordinator)

Email: nikki.hellin@bristol.ac.uk.

Tel 07773 579130

OR follow either of these links:

Click here for:

<u>Participant</u> <u>information sheet</u>

