







## 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?

A person who knows you well and has a diagnosis of memory loss wants to join this study. If they join in they would like you to be their project partner and come to study visits with them. We will need you to come to their first visit to ensure they understand the study and what they are agreeing to do if they join, after that it is up to you and the person you are partnering if you attend too.

#### Why are you doing this research?

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, your partner with memory loss will continue to receive the same healthcare for their memory loss. If you say yes you can change your mind later, your partner with memory loss will continue receiving the same healthcare.

#### What will it involve?

If you say yes we will start by asking your partner to do some memory tests:

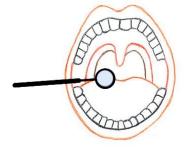


## Then we ask them some questions:

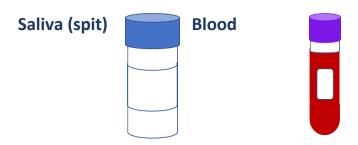
Their current health conditions



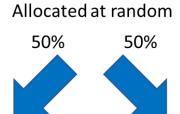
Then a dentist will look in their mouth and assess their gum health:



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



After this they 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 their

teeth and

gums

GROUP 2
No study dental treatment:

They do not have to do anything for the study, but they should continue to visit their own dentist if they 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 the person with memory loss that you are partnering will also be asked if they can tell us how the study was for them. If they do this we will record what they say and a written record made from the recording.

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

#### What are the good things about joining in?

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 with memory loss:

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?

The person with memory loss will feel a slight scratch when we take blood, but it should not hurt.

They may find the treatment to treat their 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 the pair of you up to £20 per visit to cover travel costs.

# What will happen with the data (information) collected about the person with memory loss?

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

We will replace their 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 them from this data.

## What happens to the samples the person with memory loss gives?

- 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 them if their leftover samples can be stored and used in other research. It is fine it they no, we can destroy their leftover 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:

Miss Nikki Hellin (study co-ordinator)

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

Tel 07773 579130

Contact:

OR follow either of these links:

Click On:
<u>Project partner</u>
<u>information sheet</u>

