**PARTICIPANT INFORMATION SHEET**

**(TRIAL RESIDENTS – INTERVENTION GROUP)**

**Study title:** uSing rolE-substitutioN In care-homes to improve oRal health (SENIOR)

We would like to invite you to take part in a research study exploring whether different members of the dental team could provide care for residents in care homes. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. You are free to choose whether you would like to take part. If you decide not to take part, it will not affect any dental care you may be receiving.

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

Poor oral health is a very common problem for older people residing in care-homes and this issue is becoming increasingly important. Oral conditions impact on resident’s quality of life, self-esteem, general health and diet. Despite this high level of need, dental service provision in residential care can be limited, with little emphasis on prevention.

Earlier studies have suggested that different members of the dental team, like dental therapists and dental nurses, could offer an alternative to using dentists to provide care. Given their training, they may also improve the level of prevention offered to residents.

Researchers from Bangor University, along with Queen’s University, University College London, the University of Sheffield and Cardiff University, are all undertaking a study (called SENIOR) to understand whether using these different members of the dental team could improve the oral health of residents.

**Why have I been chosen?**

You have been chosen because your care-home is taking part in this study and you are a full-time resident aged 65 years or over with some or all of your natural teeth.

A total of 40 care-homes will be taking part in the study across Northern Ireland, England and Wales (involving 280 residents).

**Do I have to take part?**

No. It is up to you to decide if you want to take part in this research. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. If you do decide to take part, you are still free to withdraw at any time without giving a reason. This will not affect your care and legal rights.

As part of the study, you will also have a Six Item Cognitive Impairment Test as it is important for the study team to understand any impact this may have. The results of this test will be passed onto your care-home manager under the duty of care obligations.

**What will happen to me if I take part?**

Your care-home is taking part in the study and has been randomised by a computer programme into one of two groups: the intervention group or the control group (50% chance of being allocated to the intervention group).

Your care-home is in the intervention group:

1. Dental therapists will visit your care-homes every six-months and will undertake any treatment that you need (e.g. fillings);
2. Dental nurses will visit your care-home every month (for the first three months), then three-monthly afterwards. They will provide you with some advice about how to improve your oral health (e.g. how to clean your teeth) and apply fluoride to your teeth, to make them stronger and more resistant to dental decay; and
3. You may also be recommended to use a fluoride toothpaste and receive advice from dental nurses on the Eatwell guide, which outlines how to eat a healthy balanced diet.

The length of the trial is for twelve months, after which, care will continue as before.

**What do I have to do?**

If you decide to take part, your care-home will organize these visits to fit into your usual routine.

Any active treatment will take no longer than a quarter of an hour (unless a filling is required). Any treatment that can’t be undertaken by the dental therapist will be signposted to a dentist. On the basis of earlier research, the vast majority of dental treatment can be provided by a dental therapist.

You will also be examined by a trained dentist to count how many teeth you have and record how clean your mouth is. This is so we can understand whether using different members of the dental team can improve the health of your mouth.

We do not anticipate that there are any problems associated with taking part, but you are free to withdraw from the study at any stage if you do not wish to participate further. There are no special compensations relating to harms associated with the trial, however, in the unlikely event of clinical negligence, you may have grounds for a legal action directly with the professional responsible.

**What are the benefits of taking part?**

The study will help us understand whether using different members of the dental team can improve your oral health. If the results are positive, this will help us to plan future services.

**What are the possible disadvantages and risks of taking part?**

Other than the time commitment taking part in the study, we do not anticipate there being any risks.

**Withdrawal**

You can withdraw from the study at any time without affecting your medical care or legal rights, but data collected up to your point of withdrawal may be used.

**If I take part, will it be confidential?**

Bangor University is the Sponsor for this study. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Bangor University will keep identifiable information about you in a secured location for five years after the study (e.g. your consent forms).

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. This is standard practice i.e. what we would do normally. These organisations may be Universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research.

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR) and the Data Protection Act 2018. All information collected about you will be kept strictly confidential.

The Chief Investigator Professor Paul Brocklehurst will take responsibility for data destruction and all collected data will be destroyed on or before end December 2028

Bangor University is the Data Controller for the information you provide. You have the following right to access information held about you. Your right of access can be

exercised in accordance with the General Data Protection Regulation and the Data Protection Act 2018. You also have other rights including rights of correction, erasure, objection, and data portability. For more details, including the right to lodge a complaint with the Information Commissioner’s Office, please visit [www.ico.org.uk](http://www.ico.org.uk). Questions, comments and requests about your personal data can also be sent to the University Data Protection Officer: Gwenan.hine@bangor.ac.uk.

It is important for you to know that researchers have an ethical obligation to report observed instances of serious abuse and/or health-endangering or dignity-demeaning treatment, to the relevant regulator and/or the police as appropriate.

This obligation does not in any way require researchers to seek out instances of neglect/ill-treatment, or to engage in proactive examinations of care home inhabitants. However, if researchers become aware of any serious abuse and/or health-endangering or dignity-demeaning treatment, they will follow the study protocol to respond to such instances, which may involve the loss of anonymity for safeguarding purposes.

**What if there is a problem?**

If you have a concern about any aspect of the study, you should ask to speak to the Chief Investigator Professor Paul Brocklehurst, who will answer your questions (using the contact details that are provided above). If you remain unhappy and wish to make a formal complaint, you can do this by contacting Dr Lynne Williams, Head of the School of Healthcare Sciences at Bangor University (01248) 383170 lynne.williams@bangor.ac.uk.

Help is also available from the Patient Advice and Liaison Service (PALS). This can be found on the NHS Choices website (<http://www.nhs.uk/pages/home.aspx>).

**What will happen to the results of the research study?**

The results will be published in scientific journals and presented at conferences.

The reports and presentations we write will not include personal details of the people who take part.

**Who is organising and funding the study?**

The study is organised by Professor Paul Brocklehurst at Bangor University in North Wales. Bangor University is the Sponsor of the study. The research has been funded by the National Institute for Health Research’s Health Services and Delivery Research Programme.

**Who has reviewed this study?**

The National Institute for Health Research reviewed the study before they funded it. Like all research in the NHS, it has been looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the [Enter REC details]

**Who can I contact for further information or if I have concerns?**

Chief Investigator: Professor Paul Brocklehurst, NWORTH, Bangor University, Y Wern (Normal Site), Holyhead Road, Bangor, LL57 2PZ. Tel: 01248 383216

Email: p.brocklehurst@bangor.ac.uk.

Thank you for your interest in the study and for taking the time to read through the information sheet. You will be provided with a copy of this information sheet along with a copy of the consent form which you have signed, if you decide to participate.