

# Oral rehabilitation coupled with dietary intervention for older patients

<b>Submission date</b> 22/04/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A poor diet has been shown to be important in patients developing a range of diseases including cancer, heart disease and diabetes. Different factors influence patients' food choices, including income levels, education and living circumstances. However, dental health can also be important, such as the number of remaining natural teeth. As patients get older and lose their teeth they tend to move towards a softer diet composed of foods they find easier to chew. Unfortunately this often means that many patients avoid important things such as fruit, vegetables and meat, which can lead to low levels of vitamins, minerals and fibre in their diets. Unfortunately, simply giving patients new teeth or dentures is not enough for them to break these habits and change their diet. This study aims to test if providing tailored diet advice focused on creating healthy eating habits, in combination with replacing missing teeth, can have a positive impact on the diets of older patients.

### Who can participate?

Patients over the age of 65 with at least six natural teeth in at least one jaw, with missing natural teeth replaced with removable partial dentures or fixed prosthodontics.

### What does the study involve?

All participants receive dental treatment to replace their missing natural teeth. Half of the participants are then randomly allocated to receive the healthy habits diet advice to help them improve their diet, whilst the remainder receive an information leaflet on healthy diets. All participants are asked to fill in surveys asking them about their eating habits, knowledge of nutrition, their satisfaction with food, their physical activity, their quality of life and their oral health, and they repeat these four times: at the start of the study, after 2 months, 4 months and after 8 months. They are also asked to record their food choices during the study using food diaries. In addition, blood samples are taken during the study to measure levels of a variety of vitamins and nutrients. The information from the two groups is compared to test if the healthy habits dietary advice and counselling has resulted in any improvements for that patient group compared to those who did not receive the healthy habits intervention.

### What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?  
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?  
October 2016 to March 2017

Who is funding the study?  
1. Health Services Executive  
2. Public Health Agency Northern Ireland

Who is the main contact?  
Dr Gerald McKenna

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Gerald McKenna

**Contact details**  
Centre for Public Health  
Queen's University Belfast  
Belfast  
United Kingdom  
BT12 6BA

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HAPAI/2015/GM

## Study information

**Scientific Title**  
The impact of a tailored dietary intervention coupled with oral rehabilitation on the nutritional status of older patients

**Acronym**  
DEN-HAB

**Study objectives**

To develop and pilot-test a habit-based tailored dietary intervention, in conjunction with oral rehabilitation, and to examine its impact on positive dietary habit-formation amongst partially dentate older adults.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Office for Research Ethics Committees Northern Ireland (ORECNI), 08/11/2016, ref. 16/NI/0224

### **Study design**

Single-centre randomised controlled clinical trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Nutrition

### **Interventions**

Patients will be randomly allocated to:

1. Intervention: a habit-based dietary intervention suitable for partially dentate older patients
2. Control: no intervention

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Self-reported automaticity for healthy food choices (habit-formation indicator) measured using 4-item Self-Report Habit Index (SRHI) on a scale of 1-7

### **Secondary outcome measures**

1. Consumption of fruit and vegetables, wholegrains and proteins using validated food diaries
2. Food-related well-being using the validated self-report satisfaction with food-related life scale
3. Knowledge of diet-disease relationships and food preparation abilities (from validated General nutrition knowledge questionnaire [Parmenter & Wardle, 1999]; cooking and food abilities [McGowan et al. in press])
4. Oral health-related Quality of Life using the validated short -form Oral Health Impact profile

5. Markers of nutritional status including haematological analysis of carotenoids, vitamin C, alkylresorcinols and iron, vitamin B12 and folate and the Mini Nutritional Assessment (MNA)

**Overall study start date**

20/04/2016

**Completion date**

23/07/2019

## **Eligibility**

**Key inclusion criteria**

Current inclusion criteria as of 18/03/2020::

1. A minimum of six natural teeth in at least one jaw with missing natural teeth replaced with removable partial dentures or fixed prosthodontics
2. Patients over the age of 65 years
3. No medical complications which contraindicate routine dental treatment (e.g., unstable angina; INR level > 4; high risk of infective endocarditis)
4. No evidence of dementia
5. Able to communicate in English
6. Sufficient level of literacy to read study materials and keep a food diary
7. No evidence of diabetes mellitus (Type 1, or Type 2)
8. No history of alcoholism
9. Free-living participant
10. No active treatment for psychiatric disorders
11. Did not follow a strict diet regime recommended by a physician in the prevention or treatment of disease

Previous inclusion criteria:

1. A minimum of six natural teeth in at least one jaw with missing natural teeth replaced with removable partial dentures or fixed prosthodontics
2. Patients over the age of 65 years
3. No medical complications which contraindicate routine dental treatment (e.g., unstable Angina; INR level > 4; high risk of Infective Endocarditis)
4. No evidence of Dementia
5. Able to communicate in English
6. Sufficient level of literacy to read study materials and keep a food diary

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

## **Total final enrolment**

54

## **Key exclusion criteria**

Current exclusion criteria as of 18/03/2020::

1. Less than six natural teeth in at least one jaw
2. Patients under the age of 65 years
3. Medical complications which contraindicate routine dental treatment (e.g., unstable Angina; INR level > 4; high risk of infective endocarditis)
4. Evidence of dementia
5. Inability to communicate in English
6. Insufficient level of literacy to read study materials and keep a food diary
7. Evidence of diabetes mellitus (Type 1, or Type 2)
8. History of alcoholism
9. Not a free-living participant
10. Active treatment for psychiatric disorders
11. Followed a strict diet regime recommended by a physician in the prevention or treatment of disease

Previous exclusion criteria:

1. Less than six natural teeth in at least one jaw
2. Patients under the age of 65 years
3. Medical complications which contraindicate routine dental treatment (e.g., unstable Angina; INR level > 4; high risk of Infective Endocarditis)
4. Evidence of Dementia
5. Inability to communicate in English
6. Insufficient level of literacy to read study materials and keep a food diary

## **Date of first enrolment**

01/10/2016

## **Date of final enrolment**

30/03/2017

## **Locations**

### **Countries of recruitment**

Northern Ireland

United Kingdom

### **Study participating centre**

**Queen's University Belfast**

Centre for Public Health

United Kingdom

BT12 6BA

# Sponsor information

## Organisation

Queen's University Belfast (UK)

## Sponsor details

University Road  
Belfast  
Northern Ireland  
United Kingdom  
BT7 1NN

## Sponsor type

University/education

## Website

<http://www.qub.ac.uk/home/Research/>

## ROR

<https://ror.org/00hswnk62>

# Funder(s)

## Funder type

Government

## Funder Name

Health Services Executive

## Funder Name

Public Health Agency Northern Ireland

# Results and Publications

## Publication and dissemination plan

Current publication and dissemination plan as of 18/03/2020:

In 2020 we plan to publish the following publications in a high-impact peer-reviewed journal:

1. Development and feasibility of A Tailored Habit-based Dietary Intervention Coupled With Oral Rehabilitation On The Nutritional Status Of Older Patients
2. The impact of a tailored habit-based dietary intervention coupled with oral rehabilitation on

the nutritional status of older patients

3. The impact of a tailored habit-based dietary intervention coupled with oral rehabilitation on the nutritional status of older patients: a process evaluation

Previous publication and dissemination plan as of 28/08/2018:

In 2018 we plan to publish the following publications in a high-impact peer-reviewed journal:

1. The impact of dental status on perceived ability to eat certain foods, nutrient intake and nutritional status in older adults: UK National Diet and Nutrition Survey 2008-2014 (01/03/2019)
2. Barriers and facilitators to healthy eating in community-dwelling older adults: A qualitative study (01/03/2019)
3. The impact of a tailored habit-based dietary intervention coupled with oral rehabilitation on the nutritional status of older patients: A pilot study (01/05/2019)
4. The impact of oral rehabilitation coupled with healthy dietary advice on the nutritional status of adults: a systematic review (01/04/2019)

Previous publication and dissemination plan:

In 2018 we plan to publish the following publications in a high-impact peer-reviewed journal:

1. The impact of dental status on perceived ability to eat certain foods, nutrient intake and nutritional status in older adults: UK National Diet and Nutrition Survey 2008-2014 (30/08/2018)
2. Barriers and facilitators to healthy eating in community-dwelling older adults: A qualitative study (01/03/2019)
3. The impact of a tailored habit-based dietary intervention coupled with oral rehabilitation on the nutritional status of older patients: A pilot study (30/10/2018)
4. The impact of oral rehabilitation coupled with healthy dietary advice on the nutritional status of adults: a systematic review (15/09/2018)

### Intention to publish date

30/12/2020

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	feasibility paper	24/08/2020	02/09/2020	Yes	No
<a href="#">Results article</a>		01/02/2023	19/05/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No