Oral rehabilitation coupled with dietary intervention for older patients

Submission date 22/04/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 25/04/2016	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 19/05/2023	**Condition category** Nutritional, Metabolic, Endocrine	[_] 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
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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)

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 cngina; 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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:
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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
United Kingdom

Northern Ireland

Study participating centre
Queen's University Belfast
Centre for Public Health
United Kingdom
BT12 6BA

Sponsor information

Organisation
Queen's University Belfast (UK)

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

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?
Results article		01/02/2023	19/05/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	feasibility paper	24/08/2020	02/09/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes