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Is dietary consultation an effective intervention to improve health-related behavior and oral health in adults with severe caries disease?

Submission date
11/08/2023

Recruitment status
No longer recruiting

Registration date
15/08/2023

Overall study status
Completed

Last Edited
14/08/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Dietary factors (mainly sugars) play a crucial role for the development of caries disease. There is a need to develop more effective methods to change oral health behaviors, as conventional counseling methods are not always effective. The aim of the project is, by means of a Randomized Controlled Trial, to evaluate dietary counselling provided by a dietician, in dentistry. Can this preventive health promotive treatment change health behaviors (e.g. decreased sugar consumption) so that the risk for caries will decrease over time?

Who can participate:
Young adults (18-30 years) with caries disease (two or more manifested proximal dental caries lesions) and good understanding of Swedish.

What does the study involve:
Participants are randomly allocated to an intervention or control group. Both groups receive standardised oral health information, provided verbally by a registered dental hygienist using a brochure on oral health behaviour and caries. Those in the intervention group also receive manual-based dietary counselling provided by a licensed dietician, two individual sessions at the dental clinic and one booster session on telephone.

What are the possible benefits and risks of participating:
The participants may benefit from improved oral health. Whilst the intervention is assessed for adverse effects, no specific risks for the participants are expected.

Where is the study run from:
The Institute of odontology, The Sahlgrenska academy, University of Gothenburg, Sweden.

When is the study starting and how long is it expected to run for:
September 2015 to June 2022

Who is funding the study:
The Health Care Subcommittee, Region Västra Götaland, Sweden.

Who is the main contact:
Ulla Wide, licensed psychologist, professor ulla.wide@gu.se

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Is a manual-based dietary intervention more effective to improve health-related behavior and particularly dietary habits, in young adults with severe dental caries disease, compared to standard information? A randomized controlled trial

Study objectives
A manual-based dietary intervention improves health-related behavoir, particularly dietary habits, significantly more than standard information alone

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/04/2016, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 10 475 08 00; registrator@etikprovning.se), ref: 185-16

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Poor oral health, dental caries lesions

Interventions
Participants are randomly allocated to an intervention or control group.

Both groups receive standardised oral health information, provided verbally by a registered dental hygienist using a brochure on oral health behavior and caries.

Those in the intervention group also receive a manual-based dietary intervention (two individual sessions at the clinic, one telephone booster session), provided by a licensed dietician.

Duration of the intervention: two individual sessions (50 min each), one booster session (30 min).

The follow-up for each arm: 6 weeks, 18 weeks, and 1 year for both study arms.

Randomisation process: The randomisation was performed via a block randomisation process, and sealed envelopes.

Intervention Type
Behavioural

Primary outcome(s)
1. Dietary intake and meal patterns measured using the 59-item Food Frequency Questionnaire, at baseline and 6 weeks, 18 weeks and 1 year
2. Sugar consumption measured using a self-report questionnaire (items for consumption of soft drinks and candy/sweets) at baseline and 6 weeks, 18 weeks and 1 year

Key secondary outcome(s))
1. Self-rated oral health measured with a single question, at baseline and 6 weeks, 18 weeks and 1 year
2. Oral health-related quality of life measured with OHIP-5 (Oral health impact profile) at baseline and 6 weeks, 18 weeks and 1 year
3. Health locus of control and self-efficacy, measured with Health locus of control scale and General self-efficacy scale, at baseline and 6 weeks, 18 weeks and 1 year
4. Oral health behavior measured by a self-report questionnaire at baseline and 6 weeks, 18 weeks and 1 year
5. Psychological distress measured by EQ5D5L at baseline, 18 weeks and 1 year

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Aged 18-30 years
2. ≥2 manifest proximal dental caries lesions
3. Good understanding of Swedish

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Total final enrolment
74

Key exclusion criteria
Psychiatric/neuropsychiatric diagnosis, such as depression, psychosis, autism spectrum disorder, mental retardation, substance abuse.

Date of first enrolment
01/04/2019

Date of final enrolment
24/05/2021

Locations

Countries of recruitment
Sweden

Study participating centre

Public dental service clinic Vänersborg, Region Västra Götaland
Kronogatan 14
Vänersborg
Sweden
46230

Sponsor information

Organisation
University of Gothenburg

ROR
https://ror.org/01tm6cn81

Funder(s)

Funder type
Government

Funder Name
The Health Care Subcommittee, Region Västra Götaland, Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Ulla Wide at ulla.wide@gu.se

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes