

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

<b>Submission date</b> 11/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/08/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**Contact name**  
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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 behaviour, 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](mailto: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.  $\geq 2$  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](mailto:ulla.wide@gu.se)

### IPD sharing plan summary

Available on request