

# Evaluation of a psychological intervention for better oral health

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| <b>Submission date</b><br>06/03/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>14/03/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>19/05/2023       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Oral health in adolescents and young adults is generally good, but there are subgroups with poor oral health, and there seems to be a strong link between socioeconomic status (SES) and oral health in adolescents and young adults. There is a need to develop more effective methods to change oral health behaviors, as conventional counseling methods are not always effective. This study aims to investigate if a brief psychological intervention based on the acceptance and commitment therapy (ACT) is a possible way of promoting oral health, oral health behaviour and general psychological health in young adults, taking into account the individual socioeconomic status.

### Who can participate?

Adults aged 18 – 25 years with two or more dental caries

### 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 nurse using a brochure on oral health behaviour and caries.

Those in the intervention group also receive cognitive behavioural therapy based on acceptance and commitment therapy (ACT). This emphasises the participants own motivation to change by contacting their values and promoting committed action in line with those values. They receive two individual sessions (45 minutes each) with a licensed psychologist, delivered at their general dental clinic.

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

The participants may benefit from improved oral and general health. Whilst the intervention is assessed for adverse effects, no specific risks for the participants were expected.

### Where is the study run from?

1. Dental Public Service Angered (Sweden)
2. Dental Public Service Vänersborg (Sweden)

### When is the study starting and how long is it expected to run for?

February 2013 to May 2016

Who is funding the study?  
Dental Public Service Region Västra Götaland (Sweden)

Who is the main contact?  
Dr Ulla Wilde (Scientific)  
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## Contact information

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

n.a.

## **Study information**

### **Scientific Title**

Can a brief psychological intervention improve oral health behaviour?  
A randomised controlled trial.

### **Study objectives**

1. A brief psychological intervention (ACT) improves oral health behaviours (such as tooth-brushing and flossing) more than standard information alone
2. A brief psychological intervention (ACT) decreases distress and improves the ability to handle life stressors more than standard information alone.

### **Ethics approval required**

Old ethics approval format

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

Regional Ethical Review Board in Gothenburg Sweden, 03/12/2012, ref: 840-12

### **Study design**

Randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

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

GP practice

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

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Poor oral health ( $\geq$  two manifested proximal 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 nurse using a

brochure on oral health behaviour and caries.

Those in the intervention group also receive cognitive behavioural therapy based on acceptance and commitment therapy (ACT). This emphasises the participants own motivation to change by contacting their values and promoting committed action in line with those values. It also focuses on developing their willingness to experience different negative emotions, that have previously hindered this action to occur. They receive two individual sessions (45 minutes each) with a licensed psychologist specialising in ACT, delivered at their general dental clinic.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Oral health behaviour (tooth-brushing, flossing, tooth picks, additional fluoride) was measured by a self-report questionnaire using single-questions at baseline, 3 weeks, 9 weeks, 18 weeks and 1 year.
2. Oral health (caries, gingivitis) were measured by
  - 2.1. radiographs for manifest caries at baseline and 1 year
  - 2.2. clinical examination for gingivitis using bleeding on probing yes/no at baseline, 9 weeks, 18 weeks and 1 year.
3. Sugar consumption was measured using a self-report questionnaire of several items for consumption of soft drinks and candy/sweets at baseline, 9 weeks, 18 weeks and 1 year.

## **Secondary outcome measures**

1. Psychological distress and general health behaviour was assessed by a
  - 1.1. self-report questionnaire (Hospital Anxiety and Depression Scale HADS) at baseline, 3 weeks, 9 weeks, 18 weeks and 1 year
  - 1.2. self-report single questions (smoking, exercise) at baseline, 9 weeks, 18 weeks and 1 year.

## **Overall study start date**

27/02/2013

## **Completion date**

31/05/2016

# **Eligibility**

## **Key inclusion criteria**

1. 18-25 years of age
2.  $\geq$  two manifested proximal dental caries lesions
3. Good understanding of Swedish

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

**Upper age limit**

25 Years

**Sex**

Both

**Target number of participants**

130

**Total final enrolment**

135

**Key exclusion criteria**

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

**Date of first enrolment**

04/10/2013

**Date of final enrolment**

19/01/2015

**Locations****Countries of recruitment**

Sweden

**Study participating centre****Dental Public Service Angered**

Triörgatan 2

Angered

Sweden

424 65

**Study participating centre****Dental Public Service Vänersborg**

Kronogatan 14

Vänersborg

Sweden

462 30

**Sponsor information**

## Organisation

Dental Public Service Region Västra Götaland

## Sponsor details

Region Västra Götaland

Skövde

Sweden

541 80

+46 10 4417000

info.folktandvarden@vgregion.se

## Sponsor type

Government

## Website

<https://folktandvarden.vgregion.se>

## Funder(s)

### Funder type

Government

### Funder Name

The Health Care Subcommittee, Region Västra Götaland, Sweden.

## Results and Publications

### Publication and dissemination plan

Several publications in scientific peer-reviewed journals are planned within the coming year till 31/03/2019

### Intention to publish date

31/03/2019

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Associate professor Ulla Wide at [ulla.wide@gu.se](mailto:ulla.wide@gu.se)

### IPD sharing plan summary

Available on request

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 03/10/2018   | 12/09/2019 | Yes            | No              |

|   |                        |            |            |     |    |
|---|------------------------|------------|------------|-----|----|
| <a href="#">Results article</a>         | results                | 26/08/2020 | 02/09/2020 | Yes | No |
| <a href="#">Results article</a>         |                        | 18/11/2021 | 19/11/2021 | Yes | No |
| <a href="#">Interim results article</a> | Baseline data analysis | 31/07/2021 | 19/05/2023 | Yes | No |