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Evaluation of a psychological intervention for better oral health

Submission date	Recruitment status	[_] Prospectively registered
06/03/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/03/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2023	Oral Health	

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 behavious 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Poor oral health (≥ 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 behavious 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(s)
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.

Key secondary outcome(s)
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.

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. 18-25 years of age
2. ≥ two manifested 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
25 Years

Sex
All

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

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 Associate 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?
Results article	results	03/10/2018	12/09/2019	Yes	No
Results article	results	26/08/2020	02/09/2020	Yes	No
Results article		18/11/2021	19/11/2021	Yes	No
Interim results article	Baseline data analysis	31/07/2021	19/05/2023	Yes	No