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Assessment of quality of life of acrylic removable denture wearers

Submission date
23/06/2018

Recruitment status
No longer recruiting

Registration date
12/07/2018

Overall study status
Completed

Last Edited
16/11/2022

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim was to investigate the effect of improving the condition and fit of dentures on quality of life in people who have lost all their teeth.

Who can participate?
Adults who are edentulous (have lost all their teeth) and wear acrylic removable dentures who have reported problems from wearing dentures.

What does the study involve?
On the first visit, the participants will be assessed by a specialist in prosthodontics (artificial tooth replacements). The specialist will examine the dentures and score them on the basis on alterations needed to improve the condition and fit. The participants will also fill out questionnaires to assess their quality of life with respect to their oral health and their dentures. The dentures will be altered and then the participants will come back after 1 month and 3 months and will repeat the questionnaires. The prosthodontic specialist will also assess the condition and fit of the dentures at these visits.

What are the possible benefits and risks of participating?
Participants might benefit from their dentures being made more comfortable. There are no potential risks of participating.

Where is the study run from?
Travnik Medical Center, Bosnia & Herzegovina

When is the study starting and how long is it expected to run for?
January 2014 to June 2018

Who is funding the study?
The researchers are funding the study themselves.

Who is the main contact?
Professor Srđan Poštić, srdjan.postic@stomf.bg.ac.rs

Study website
https://sdpprosthodontic.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3

Study information

Scientific Title

Oral health-related quality of life of edentulous acrylic removable denture wearers - comparison of GOHAI and OHIP-EDENT

Acronym
GOHAI/OHIP-EDENT

Study objectives
Hypotheses of this research are:
1. The Serbian versions of the Oral Health Impact Profile for Edentulous (OHIP-EDENT) and the Geriatric Oral Health Assessment Index (GOHAI) are confirmed as valuable instruments for the assessment of oral-health quality of life of edentulous patients treated using acrylic complete dentures, prior to prosthodontic manipulations and after prosthodontic procedures, interventions and corrections
2. One questionnaire is more useful than the other.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Faculty of Pharmacy and Health of the University of Travnik, 03/03 /2014, 03-67-1/14 (for OHIP questionnaire)
2. Ethics Committee of the Faculty of Pharmacy and Health of the University of Travnik, 05/01 /2018, 05-01-03-13/18 (for GOHAI questionnaire)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Edentulism and the state of oral functions of complete denture wearers

Interventions
This study included 117 terminally edentulous or completely edentulous patients with acrylic removable dentures who reported particular problems during wearing of their dentures. During the first visit, the patients were observed by a prosthodontics specialist and their conditions were checked and established with respect to need for prosthodontic treatment, with

appropriate notation in medical-dental documentation (the first check-up). The prosthodontics specialist also interviewed the patients regarding quality of life using the OHIP-EDENT and GOHAI questionnaires. The selected denture wearers of this study (after assumed previous fabrication of new acrylic dentures) were initially examined for the condition of artificial teeth in acrylic dentures. This inspection assumed any wear or abrasion of occlusal surfaces of artificial teeth, appearance of any of premature contacts, any discoloration and change of the quality of polymerized artificial teeth in acrylic dentures as well as formation of broaden and unnecessary extended occlusal contact surface with the changes of the conventional "one point" occlusal scheme to extended widen contacting area. Moreover, occlusal corrections of repaired tooth in acrylic dentures were also provided for a number of the patients of this study. Also, any irregularities concerning denture flanges or denture borders in collision with supporting tissues were corrected. Finally rebasing and relining of the denturing bases were provided when necessary. For the diagnose of premature, non-conventional or additionally formed occlusal contacts, articulating paper was used. Furthermore T-scan analysis and records (if they were made, or if they existed and were available) were also been used as the fundamental level for future corrections. Electromyographic findings (based on electromyographic records of the masseter and temporalis muscle activities) were also accepted. The prosthodontics specialist administered the Serbian version of OHIP-EDENT questionnaire and the Serbian version of GOHAI questionnaire and recorded data on the condition of the denture and potential interventions in the future.

At the second check-up, 1 month after the initial visit, the prosthodontics specialist assessed and classified any change of surface or acrylic teeth of the dentures, using a new specific and separate questionnaire was prepared on the condition of the surfaces in acrylic dentures, and readministered the OHIP-EDENT and GOHAI questionnaires. This questionnaire was applied after the interviews of the patients who responded to questions from the OHIP-EDENT questionnaire, and again after the interviews of the patients who answered the questions from the GOHAI questionnaire.

Based on the sum of the value of the response from the questionnaire, a special parameter was made to measure the impact of the conducted prosthetic interventions on the quality of life of the patients. Incidentally, after the second study, by comparing the data on the state of mobile remedies (acrylate prostheses), which was previously established in the first study, as well as data on the condition of the same in the second study, the patient's general condition was definitely recognized. The general condition was considered unchanged if the dental state of the prosthesis requires an intervention, i.e. the prosthesis base was not adapted, the condition of the base of a denture was not satisfactory or not adapted, the occlusion was not satisfactory, the functional equilibrium was not satisfactory, the retention was poor, and the stabilization was poor.

On the contrary, the condition of the patient was considered to be improved if the dental state of the denture did not require a correction, if it is basically adapted to the adaptation of the base of the prosthesis, if the condition of the denture base is satisfactory, if the occlusion is satisfactory, if the functional equilibrium is satisfactory, if retention is excellent or good and the stabilization was excellent or good.

Questionnaire on denture condition:
1. The condition of artificial teeth of acrylic dentures, with possible answers:
1.1. there is a need for additional intervention (1 point)
1.2. there is no need for the additional intervention (2 points)
2. The adaptation of the base, with possible answers:
2.1. adapted (1 point)

2.2. not adapted (2 points)
3. The condition of the acrylic base of a denture, with possible answers:
3.1. adapted (1 point)
3.2. not adapted (2 points)
4. Occlusion, with possible answers:
4.1. satisfactory (1 point)
4.2. not satisfactory (2 points)
5. Functional equilibrium, with possible answers:
5.1. satisfactory (1 point)
5.2. not satisfactory (2 points)
6. Retention, with possible answers:
6.1. excellent (1 point)
6.2. good (2 points)
6.3. poor (3 points)
7. Stability of the denture, with possible answers:
7.1. excellent (1 point)
7.2 good (2 points)
7.3. poor (3 points)

The results obtained on or after the responses from this questionnaire were formed by the sum of the values of the responses at three timepoints - baseline, after 1 month and subsequently up to 3 months after the start of the trial.

Intervention Type
Other

Primary outcome measure
1. Oral health-related quality of life (OHRQoL) assessed using Serbian version of translated OHIP-EDENT questionnaire in original English text, which were primarily based on the standard original questions but with the addition of specific questions related to the state of dental constructions and dentures, interventions that had to be conducted as well as comprehensive outcome of all of interventions and corrections performed.
2. OHRQoL assessed using Serbian version of translated GOHAI questionnaire in original English text, which were primarily based on the standard original questions but with the addition of specific questions related to the state of dental constructions and dentures, interventions that had to be conducted as well as comprehensive outcome of all of interventions and corrections performed.
The timepoints were baseline, 1 month and 3 months.

Secondary outcome measures
Questionnaire on denture condition and function
The timepoints were baseline, 1 month and 3 months.

Overall study start date
01/01/2014

Completion date
01/08/2018

Eligibility

Key inclusion criteria
Candidate for acrylic dentures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
117

Key exclusion criteria
1. No infectious diseases
2. Willing and able to participate

Date of first enrolment
01/02/2016

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
Bosnia and Herzegovina

Study participating centre
HEALTH CENTER OF THE FACULTY OF PHARMACY AND HEALTH OF TRAVNIK, B&H
Slavka Gavrancica 17c
Travnik
Bosnia and Herzegovina
72270

Study participating centre
Health center Bugojno
Bugojno
Bosnia and Herzegovina
70230

Study participating centre

Health Center Zenica
Zenica
Bosnia and Herzegovina
72102

Sponsor information

Organisation
Medical Centar Travnik

Sponsor details
Slavka Gavrančića 17c
Travnik
Bosnia and Herzegovina
72270

Sponsor type
Hospital/treatment centre

Website
http://www.medical-centar.ba

Funder(s)

Funder type
Not defined

Funder Name
Dr. M. Asotić

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal during 2019

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			08/06/2020	No	No
Results article		14/08/2021	16/08/2022	Yes	No
Protocol file			17/08/2022	No	No