

OHIP study in edentulous population.

<https://www.isrctn.com/ISRCTN99907946>

Research protocol part 1

PROJECT SUMMARY

This study was designed to enable the application of the OHIP-EDENT questionnaire to the quality of life (QOL). On the basis of OHIP-EDENT the changes of the quality of life and changes of the oral health of edentulous patients can be established. Considering the linguistic, cultural and ethnic specificities of the region where the research is to be conducted, the original version of the OHIP-EDENT questionnaire was translated to OHIP-EDENT B&H, modified and extended with additional tests related not only to subjective parameters, but also to the condition of persisting (if any) acrylic complete dentures of edentulous patients, and needs for interventions in that domain, also.

For these reasons the protocol of the present study is focused to:

- Assessment of the quality of life of edentulous patients with acrylic removable complete dentures and demographic characteristics of selected patients who participated in this study
- Establishing the need for interventions on removable complete dentures of edentulous patients of this study

Population of this study is consisted of a number of edentulous examinees – not only women but men too, with different occupations and different levels of education who collaborated in answering the specific questions and filling in the OHIP-EDENT modified B and H questionnaire. Examinees of this study should have been aged 50 yrs. or more. The frame is covered by overall trial end date in September of 2019.

GENERAL INFORMATION

Protocol title, protocol identifying number (if any) and date

OHIP STUDY IN EDENTULOUS POPULATION.

ISRCTN99907946

Name and address of the sponsor/funder. NOT APPLICABLE

Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number of the research site(s) including responsibilities of each.

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or

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RATIONALE AND BACGROUND INFORMATION

Pathologic conditions in the area of the oral cavity follow a person throughout his lifetime. These diseases are not only a biological phenomenon, but also a psychological and social phenomenon. It is evident that the loss of teeth, partial edentulism or total toothlessness, due to illness or injuries, is a traumatic experience. There is a disturbance in the jaw relations and the changes take place over a long period of time. This is reflected to the temporomandibular joint, as well as on the jaw musculature causing changes in them as well.¹The task of specialist of dental prosthetic is to restore and

¹ Social dentistry is defined by the American Board of Dental Public Health as: "... the science and art of preventing and controlling dental disease and promoting oral health through organized community efforts. It is that form of dental practice that has the community as its patient, not the individual. It is engaged in public education in the field of oral health, applied dental research, management of dental care programs, as well as prevention and control of dental disease in the community..."

maintain oral functions by compensating for loss of the oral tissues - teeth and their supporting structures. The role of dental prosthetics in oral rehabilitation procedures is particularly important from a socio-medical point of view, because the rehabilitation of the stomatognathic system solves not only medical, but also social, emotional, psychological, professional and socio-economic problems of such patients. Their quality of life, that is, the reintegration of these patients into the normal life should have been achieved.

With the increase in average of life expectancy, an increase in the number of patients with complete dentures is expected, so it is necessary to focus attention to the ways of solving their problems, and therefore to their quality of life. Quality of life (QOL) questionnaires that measure the frequency of events in which oral health conditions affect a patient's daily activities are effective tools for comparing the outcomes of prosthetic interventions and actions.

The original version of OHIP-EDENT instrument contains 19 questions. OHIP-EDENT is designed to custom the frequency of responses to specific questions exposing changes in oral health - related quality of life of edentulous patients. The use of such instruments, which were originally created in different language areas, requires their adaptation to the frame of reference of the respondents, especially from the aspect of the language they use. For these reasons, it is necessary to examine the reliability and validity of the translated questionnaire.

When designing this research, the researcher was of the opinion that it would be expedient to expand domestic version of the OHIP-EDENT questionnaire with data related to the condition of the respondents' removable dentures, the need for interventions in that domain, as well as the results of those interventions-actions.

This way, on the basis of the particular methodologic approach, not only that it is possible to assess the quality of life of edentulous patients, but it is also possible to assess the impact of specific interventions on prosthetic restorations (i.e. dentures) to the quality of life of these patients, which can be a contribution to doctrinal attitudes in this area.

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STUDY GOALS AND OBJECTIVES

The first goal of this study is to assess the reliability and validity of domestic B&H version of the OHIP-EDENT questionnaire by interviewing 117 edentulous patients who are complete denture wearers (or not), and in order to establish the internal consistency, reliability and stability of the questionnaire make confirmation of its importance to be used as an instrument for assessing the quality of life of the selected group of patients or more.

The research hypotheses are:

- H1. The research confirmed the expediency of applying the domestic-translated version of OHIP-EDENT B and H modified version of the original OHIP-EDENT questionnaire, as an instrument for assessing the oral health quality of life of edentulous patients with complete dentures;
- H2. After interventions on acrylic complete dentures of edentulous patients, their oral health quality of life improves significantly;

STUDY DESIGN

This research was conceived as an RCT study, that is, a quantitative, comparative, controlled experiment in which researchers' study where two or more interventions on a series of people who appear in random order. It should be noted that this is one of the simplest and most powerful tools in clinical research.²

METHODOLOGY

The basic research instrument was the domestic B&H version of the OHIP-EDENT questionnaire, which, in addition to the standard questions, also included questions related to the state of dental compensation, the interventions that need to be undertaken on acrylic surfaces of complete dentures or artificial dental arches, comprehensively outcoming of the implemented interventions.

During the first visit, the patients were examined by a doctor specialist of dental prosthetics, and their condition and treatment needs were established, with accompanied records in the medical-dental documentation. At the same time, the doctor interviewed the patient about his quality of life, and entered the answers, as well as information about the condition of the prosthesis and the interventions that need to be undertaken, into the B & H version of the OHIP-EDENT questionnaire, with the ID number of the respondent and the ID of the examination, which in this case is 1 (the first trial). Every patient was examined by a specialist of dental prosthetics one month after the intervention on the dentures. During that control examination, the dentist noted and assessed the changed condition of the prostheses, and again interviewed the patient about the quality of life. The obtained data were entered into the medical documentation and a new questionnaire of the domestic B&H version of the OHIP-EDENT questionnaire, with the same ID number of the respondent and the ID of the examination, which in this case is 2 (the second stay).

The researchers assume that processing the data obtained in this way will confirm the set hypotheses.

^{2 2} RCT Randomized controlled trial

² <https://www.medicinenet.com/script/main/art.asp?articlekey=39532#>

❖ ※ Test ID, with answer marks

1= first trial

2 = second trial

❖ ※ Respondent ID, which is the serial number of respondents assigned in the order of registration at the Dental Clinic of FZF of University of Travnik

❖ ※ Data obtained by interviewing respondents using the OHIP-EDENT Questionnaire, which, for the purposes of this research, was translated by a professional translator for the English language, with 19 questions, with answer marks:

1 = never;

2 = sometimes;

3 = almost always.

❖ ※ Questions of the OHIP-EDENT questionnaire on the oral health quality of life of respondents (OHIP-EDENT COMPONENTS)

❖ OHIP-EDENT1. Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?

❖ OHIP-EDENT2. Have you had food catching in your teeth or dentures?

❖ OHIP-EDENT3. Have felt that your dentures have not been fitting properly?

❖ OHIP-EDENT4. Have you had painful aching in your mouth?

❖ OHIP-EDENT5. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?

❖ OHIP-EDENT6. Have you had sore spots in your mouth?

❖ OHIP-EDENT7. Have you had uncomfortable dentures?

❖ OHIP-EDENT8. Have you been worried by dental problems?

❖ OHIP-EDENT9. Have you been self-conscious because of your teeth, mouth or dentures?

- ❖ OHIP-EDENT10. Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?
- ❖ OHIP-EDENT11. Have you been unable to eat with your dentures because of problems with them?
- ❖ OHIP-EDENT12. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?
- ❖ OHIP-EDENT13. Have you been upset because of problems with your teeth, mouth or dentures?
- ❖ OHIP-EDENT14. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?
- ❖ OHIP-EDENT15. Have you avoided going out because of problems with your teeth, mouth or dentures?
- ❖ OHIP-EDENT16. Have you been less tolerant of your partner or family because of problems with your teeth, mouth or dentures?
- ❖ OHIP-EDENT17. Have you been irritable with other people because of problems with your teeth, mouth or dentures?
- ❖ OHIP-EDENT18. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures?
- ❖ OHIP-EDENT19. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?
- ❖ ※ The questionnaire OHIP-EDENT B&H also included questions related to the condition of the complete dentures

- Condition of the teeth in the acrylic prosthesis, with answer marks

- o 1 = intervention required

- o 2 = no intervention required;

- Base adaptation, with answer marks

- o 1 = adapted

- o 2 = not adapted;

- Condition of acrylic denture base, with answer marks

- o 1 = adapted

o 2 = not adapted;

- Occlusion, with answer marks

o 1 = satisfactory

o 2 = unsatisfactory;

- Functional equilibrium with answer marks

o 1 = satisfactory

o 2 = unsatisfactory;

- Retention, with answer marks

o 1 = excellent,

o 2 = good

o 3 = bad;

- Stability of prosthetic restorations, with response markers

o 1 = excellent

o 2 = good

o 3 = bad.

The research methodology enabled the formation of a derived parameter, the general state of the respondents, with answer marks

o 1 = unchanged

o 2 = improved

SUBJECTS

More than 500 complete denture wearers were initially asked to participate in this study. However, a total of 117 edentulous patients, aged 50 yrs. or more were selected for this study.

Participant inclusion criteria were

1. Edentulous maxilla and edentulous mandible
2. Healthy mucosa (no signs of inflammation, traumatic lesions, candidiasis, hyperplasia or cancer)

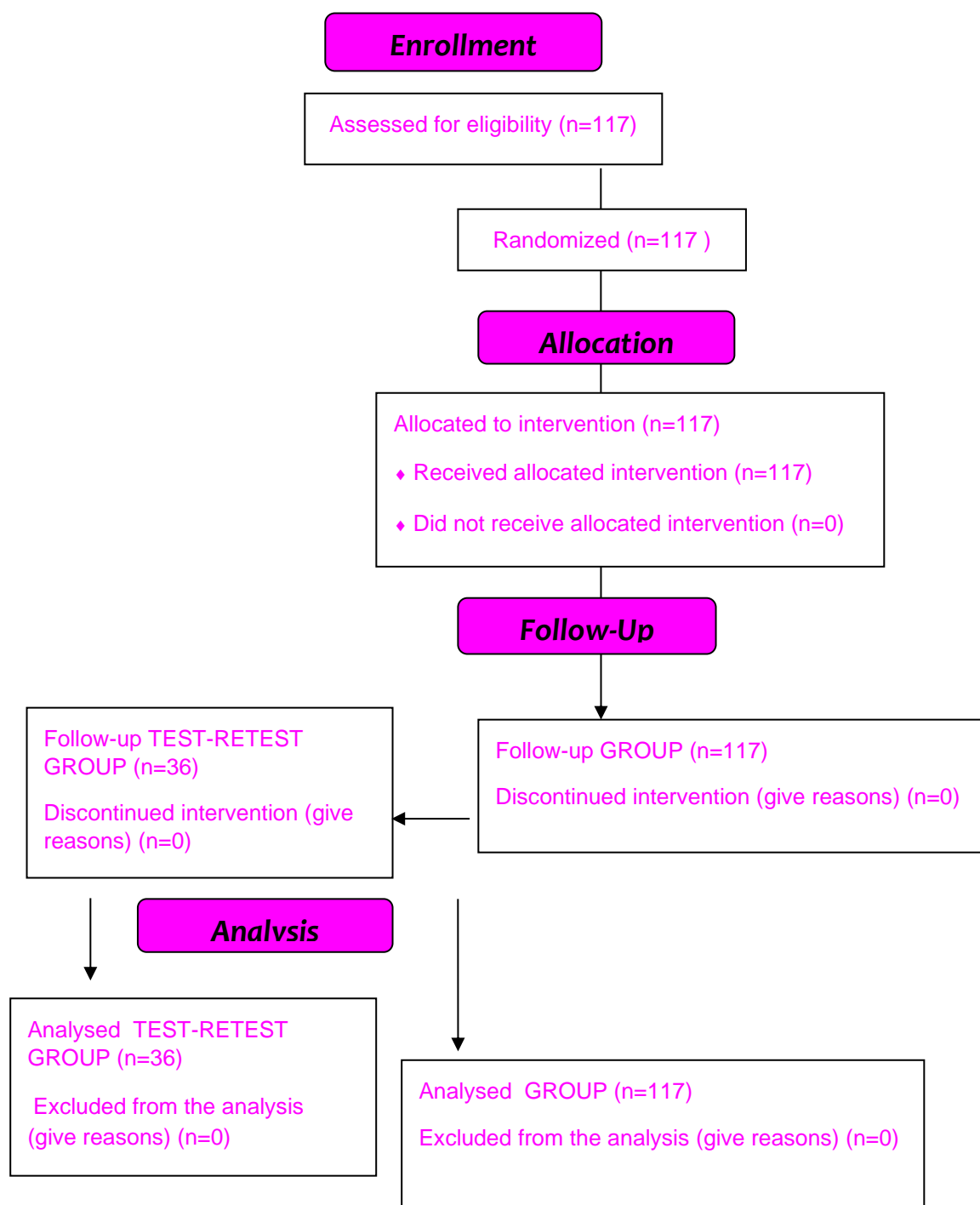
Participant exclusion criteria were:

1. Residual ridge and residual vertical bone height less than 10 millimeters

2. No attached mucosa in any region of mandible (type E)
3. Neurological diseases
4. Lack of motor coordination
5. Difficulty of understanding instructions and the conditions of the study
6. Patients with residual roots, cysts or bone spicules
7. Patients with allergies
8. Knife-edge mandibular ridges

FLOW DIAGRAM

Flow Diagram



SAFETY CONSIDERATIONS

It is useful to remember that even administering a research questionnaire can have adverse effects to individuals.

FOLLOW-UP

An one follow-up will be provided.

DATA MANAGEMENT AND STATISTICAL ANALYSIS

The research methodology enabled the formation of a derived parameter, the general state of the respondents, with answer marks

o 1 = unchanged

o 2 = improved

The database was created in the SPSS v 17.0 tool, SPSS Inc.,

⌘ Seven dimensions of oral-health quality of life were formed in the database, the values of which are created by adding up the values of individual answers to questions from the questionnaire:

❖ 1.FUNCTIONAL LIMITATION, formed by the sum of the answers to the questions in the questionnaire:

- Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?
- Have you had food catching in your teeth or dentures?
- Have felt that your dentures have not been fitting properly?

❖ 2. PHYSICAL PAIN, , formed by the sum of the answers to the questions in the questionnaire:

- Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?
- Have you had sore spots in your mouth?
- Have you had uncomfortable dentures?

❖ 3. PSYCHOLOGICAL DISCOMFORT , formed by the sum of the answers to the questions in the questionnaire:

- Have you been worried by dental problems?
- Have you been self-conscious because of your teeth, mouth or dentures?

❖ 4. PHYSICAL DISABILITY, formed by the sum of the answers to the questions in the questionnaire:

- Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?
- Have you been unable to eat with your dentures because of problems with them?
- Have you had to interrupt meals because of problems with your teeth, mouth or dentures?

❖ 5. PSYCHOLOGICAL DISABILITY , formed by the sum of the answers to the questions in the questionnaire:

- Have you been upset because of problems with your teeth, mouth or dentures?
- Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?

❖ 6. SOCIAL DISABILITY, formed by the sum of the answers to the questions in the questionnaire:

- Have you avoided going out because of problems with your teeth, mouth or dentures?
- Have you been less tolerant of your partner or family because of problems with your teeth, mouth or dentures?

- Have you been irritable with other people because of problems with your teeth, mouth or dentures?

❖ 7. HANDICAP formed by the sum of the answers to the questions in the questionnaire:

- Have you been unable to enjoy other people's company as much because of
- Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?

In the database, the specific parameter was created and derived to measure the impact of the implemented prosthetic interventions on the quality of life of the respondents. Namely, after the second examination, by comparing the data on the condition of the prosthetic restorations established in the first examination and the data on the condition of the same in the second examination, the general condition of the examinee is established. The general condition of the subject was considered unchanged (1) if, after the answer in the second examination, the same combination of answers was recorded as during the first examination., . In other cases, the subject's condition is considered as an improved one (2) ...

STATISTICAL ANALYSIS AND INFORMATIC TOOLS

Up to dated statistical methods were chosen for this study to enable:

- • Accurate description of the observed phenomenon;
- • A specialized way of presenting primary results in the most convenient form for further inference;
- • Observing existing characteristics and legality;
- • Analysis of the causes and factors resulting from the current state of the studied phenomenon;
- • Making general conclusions;
- • Design of a monitoring model of the basic characteristics of the observed phenomenon.

The implemented methods of statistical analysis, which were applied to all data obtained through research, both original and derived, are:

- Methods of descriptive statistical analysis (measures of central tendency and variation);
- Correlation analysis methods (Pearson's and Spearman's correlation coefficients and Spearman's rank correlation);
- Determination of internal consistency of data by Cronbach's Alpha coefficient ($C\alpha$);
- Discriminative analysis of the answers to individual questions of the subjects of the pilot study, before and after the treatment;
- Hypothesis testing
 - o Hi 2 – test;
 - o Student's t test;
 - o Testing the significance of the linear correlation coefficient;
 - o Mann–Whitney test for dependent samples;
 - o Wilcoxon's test for paired samples;
 - o Analysis of variance (ANOVA);
- Graphical analysis methods.

The IT tools that were used to create the database, statistical analysis and graphical display are:

- MS Office 2003
- SPSS v 17.0, SPSS Inc.,
- EpiInfo 2002, US Department of Health, CDC.

EXPECTED OUTCOMES OF THE STUDY

This study should have been provided insight to condition of oral health of edentulous populations of selected cantons in the Federation of B&H. Moreover, this study should be guide for application of similar studies in the regions and other territories of Balkan region.

DURATION OF THE PROJECT

Overall trial start date 01/09/2016

Overall trial end date 01/09/2019

PROBLEMS ANTICIPATED

Not applicable.

PROJECT MANAGEMENT

Not applicable.

ETHICS

The Ethics Committee of the FZF Faculty of the University of Travnik gave consent number 36/18 to conduct this research. This research was designed as, and the clinical research was designed as an evaluative and social-medical, prospective epidemiological study.

Research protocol part 2

BUDGET

Not applicable.

OTHER SUPPORT FOR THE PROJECT

N/A.

Collaboration with other scientists or research institutions

FZF Zdravstveno-farmaceutski fakultet u Travniku, Federation of B and H

Links to other projects

N/A

Curriculum Vitae of investigators

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Education high

Thesis PhD and MSc

Research Experience

Jan 1999 – Mar 2022 **Associate Professor**

University School of Dental Medicine in Belgrade, Serbia, Dental Prosthetic
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Statistics

RG Score 19.5

Publications 185
Reads 36,195
Citations 199

Awards & Grants

Oct 1991 October Prize of the town of Beograd

Oct 2015 Award: Nikola Tesla Golden Medal

Aug 1999 Award: IADR/CED Travel Award

Skills & Activities

Skills Osteoporosis, Bone, Bone Research, Complete Denture, Occlusion, Stomatognathic System, Prosthodontics, Oral Hygiene, Dentistry, Artificial Tooth, Dental Materials, Veneers, Amygdala, Calcium Phosphates, Removable Prosthodontics, Bone Regeneration, Implant Dentistry, Prosthetics, SEM Analysis, Clinical Dentistry, Dental Prosthesis, Geriatric Dentistry, Fixed Prosthodontics, Bone Resorption

Languages English, Russian

Scientific IADR/CED

Memberships European Prosthodontics Association
BaSS-Balkan Association of Dental Practitioners and Researches

Interests Swimming, Tracking, Dancing

Books

Srdjan Postic, Mithat Asotic: *Radioloske metode u dijagnostikovanju osteoporoze vilica*. 1st 11/2014;
Farmaceutsko-zdravstveni fakultet u Travniku., ISBN: 978-9958-640-45-2

Srdjan Postic: *PRAKTIKUM-Totalna proteza-pretklinika*. 1st 12/2013; Univerzitet u Travniku,
Farmaceutsko-zdravstveni fakultet., ISBN: 978-9958-640-34-6

Srdjan Postic: *Terapija i protetsko zbrinjavanje bezubih grebenova osteoporoznih vilica*. the 1st 10/2010;
Zadužbina Andrejević., ISBN: 978-86-7244-870-2

Srdjan Postic: *Osteopenicne i osteoporoticne promene u segmentima mandibula*. the 1st 01/2000;
Zaduzbina Andrejevic., ISBN: 86-7244-168-0

Book

Chapters

Journal

Publications

More than

150

Other research activities of the investigators

N/A.

Financing and insurance

N/A.