ASSESSMENT OF QUALITY OF LIFE OF ACRYLIC REMOVABLE DENTURE WEARERS

ISRCTN11586190

Research protocol: part 1

Project summary

This protocol is designed to help assessing of quality of life and oral health of edentulous patients who are acrylic complete denture wearers. This protocol is focused to points of main importance for assessment of possible problems and places for occupation not only on oral tissues of a living human, but on dental prostheses and prosthetic constructions too. The main intention was to design the protocol for overall assessment of oral condition and therapeutic success in therapies of edentulous patients who are conventional acrylic complete denture wearers, but this protocol could be used in wider population of edentulous patients-for example to implant supported dentures in edentulous subjects. Population of this study is consisted of men and women who are edentulous patients and who are planned to be in therapy by conventional acrylic complete denture. Time frame is not strict and covers a period of several years-up to decade.

General information

Protocol title, protocol identifying number (if any), and date. ***ASSESSMENT OF QUALITY OF LIFE OF ACRYLIC REMOVABLE DENTURE WEARERS*** ***ISRCTN11586190***

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- 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(s) of the research site(s), including responsibilities of each. SRDJAN D. POSTIC, MSc, PhD
- FZF Travnik -The Faculty of Pharmacy and Health in Travnik in Federation of B and H.,

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and local ambulances in governmental services of Central Bosnian canatons

Rationale & background information

Progress in the field of public health and biomedical research in the late twentieth century has significantly transformed the lives of people by finding cures for many diseases and disorders. In the new era of genetic medicine and bioengineering, people's expectations are much higher: they want to live longer and well, without damage, disabilityorhandicap, and they want an optimum quality of life. These reasons indicate that there is a need for the formulation of concepts and methods for determining the quality of life related to health, but especially oral health, which is a relatively new field of science. Because of new social norms and cultural values, people expect that their teeth should be maintained throughout life and that pain and dysfunction should be eliminated. The parameters of the quality of life, bearing in mind the outcomes of oral health, should be used for achieving these objectives [1].

In industrialisedsocieties, more than 50% of the elderly population aretoothless[2]. To determine the prognosis and decide on the treatment options, various systemic and local factors, as well as previous experience of people with dentures, need to be considered [2]. The complexity of the rehabilitation of edentulous patients requires developing strategies that meet the expectations of patients from all aspects: functional, aesthetic, psychological and social [3].

Numerous population studies in the field of dentistry note the emphasis on the need to introduce the concept of qualityoflife outcomes research. To achieve this objective, longitudinal and interventional studies use questionnaires to examine and change the quality of life of patients in the delivery of dental care.

However, it should be noted that there are rarely any reference values or norms that indicate the levels at which certain results of dental procedures can be referred to as 'decisive' or as having an 'impact on the patient's quality of life'. The results of such studies are more important to describe the trends of dental care and the treatments, but it is essential to research the direct impact of oral health on quality of life of the population [4].

The Oral Health Impact Profile (OHIP) is designed to measure people's perception of the frequency of problems associated with the oral health (mouth, teeth, or dentures) on their well-being [5].OHIP-49 consists of 49 questions covering functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability and

handicap - in the sense of a physical or mental disability making participation in certain of the usual activities of daily living more difficult. Each question is rated on a 5-point Likert scale regarding the severity of oral distress which the patient has felt during the past twelve months. The un-weighted sum of all questions is recommended to compute the total score (Total score ranges from 0 to 196 with higher scores indicating poor oral-health-related quality of life). OHIP-14, a shortened version of the OHIP-49, consists of two questions in each of the seven above-mentioned dimensions. Studies showed the degree of reliability and validity of the OHIP-14, as a measure of oral-health-related quality of life in community-living older adults, iscomparable to that of the OHIP-49.

The Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT) is a shortened version of the OHIP, consistingof 19 items targeting edentulous patients [6]. OHIP-EDENT can detect oral-health-related changes in quality of life in edentulous patients with new or different prosthetics [7, 8]. This questionnaire has been validated in several languages: Brazilian, Nepalese, Arabic, Japanese, Chineseand others [9-12].

The rationale for condicting the current study is increased number of acrylic complete denure wearers in many populations. Moreover, specific actions are expected to be provided for complete denture wearers such as check of occlusion, articulation, fit of the denture, rebasing, relining and other actions.

This study affects cantons in Central Bosnian part of the Federation of B and H, and all of ethnic grouphs settled in these regions. The gender should not be important factor in this study since it was expected that not only men but women too would have been observed in this study. The frequence depends on condition on the local area of examination. At leas 3 recalls are included in the plan of observation.

References (of literature cited in preceding sections)

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Study goals and objectives

The aim of this study is to assess the reliability and validity of the Bosnian version of the questionnaire OHIP-EDENT-B&H.The hypothesis was that the implementation of the Bosnian version of OHIP-EDENT-B&Hwill be required to show good internal consistency, interdependent correlation, content validity, as well as simultaneous validity.

The goals of this study are focused to the most relevant actions that should have been provided-occlusal checks, rebasing, relining etc. with the intention that the quality of oral health status and oral health quality of life would had improved in specific situations.

Study design

Generally and initially this study was designed as the cross-sectional study on widely accepted voluntaries-edentulous patients who are and who will be in therapy by conventional acrylic complete dentures for upper and for the lower jaw. However due to several recalls this study accepted elements of observational study too.

14 October 2020

Methodology

For the purpose of this study, the questionnaire OHIP-EDENT was used, considering the advantages mentioned in the conclusion of the study, 'The Modified Short Version of OHIP for the Assessment of the Impact of Oral Health on Quality of Life of Edentulous Patients'. The conclusion indicated that the OHIP-EDENT questionnaire has measuring properties comparable to the full version with 49 entries . In addition, the results of numerous studies indicate that this modified, shortened version may be much more suitable for use in research conducted on edentulous patients .

OHIP-EDENT contains 19 questions that are designed so that their frequency response can detect changes in the quality of life related to the oral health of edentulous patients (Table 1a).

The usage of the instrument OHIP-EDENT-B&H, which was initially created in English, requires a conversion to, and adjustment of, the reference frames of local subjects (patients) following the accepted techniques of cultural adaptation and the forward-backward method (Table 1b) . Further, it is necessary to examine the reliability and validity of the translated questionnaire and to establish its internal consistency, reliability and stability and confirm the appropriateness of its use .

This study was designed as an evaluation and a socio-medical prospective epidemiological study conducted on a group of subjects of both sexes aged over 40 years, of various professions and status, before and after dental-prosthetic treatment.

The study was designed as a randomised controlled trial study, and it involved a quantitative, comparative, and controlled experiment in which researchers studied two or more interventions on a range of people who presented in random order. The study was conducted before and after the dental-prosthetic interventions on a group of 117 edentulous patients, who randomly presented over a period of eight months during 2016 and who asked for professional dental help at the dental department of the Faculty of Pharmacy and Health in Travnik, because of the problems they were experiencing with removable acrylic complete dentures. Two specialists of prosthodontics in specialised dental services conducted the study.

The selected unit contained every edentulous patient with removable dentures who was complaining of dental problems caused while wearing dentures, in order of occurrence and of visits to the doctor and check-ups. Each patient received the ID number of their own, which was important for the statistical calculations of the respondents' data.

OHIP-EDENT-B&H contains seven dimensions, as shown in Table 2: Functional restriction (three components), Physical pain (four components), Psychological discomfort (two components), Physical disability (three components), Psychological disability (two components), Social disability (three components), and Handicap (two components). Respondents, in assessing the frequency with which dental health problems affected their daily activities over the past month, answered as follows: 4 = very often; 3 = fairly often; 2 = occasionally; 1 = hardly ever; and 0 = never/do not know. OHIP-EDENT-B&H has values between 0 and 57, and a greater value points to a lower level of oral health quality of life.

Subjects

Initially more than 300 edentulous patients were observed. A total of 117 edentulous patients—53–91 years, 36 men, mean age 72.83 ± 9.1, and 81 women, mean age 73.05 ± 6.7—who visited the hospital's dental department over an 8-month period in 2016, and who were seeking intervention for the upper and lower complete dentures, agreed to participate in this study. The actual needs for the interventions on the complete dentures were related to the condition and preservation of acrylic artificial teeth in complete dentures, the adaptation of a base, the persistent condition of the state of the acrylic base of the denture, the occlusion, the functional equilibrium and the retention and stability of the prosthetic restorations.

In this way, the two groups of patients were formed:

- In group A were all the patients who had problems with dentures.
- Group B consisted of the same patients after the dental-prosthetic interventions had been conducted.

For the purposes of the test–retest analysis, during the first four weeks of research, 36 randomly selected patients (test–retest group) who did not participate in the first survey were interviewed again by another physician-specialist in dental prosthetics.

Reliability

Cronbach's alpha (α) was used to measure the internal consistency of the summary scores for OHIP-EDENT-B&H and various subscales in Groups A and B.

To evaluate reliability, the test–retest reliability method is one of the simplest methods. The test–retest method was conducted in a way that, during the initial fourweeks after prosthodontic treatment and corrections, 36 of the patients agreed to be interviewed. These 36 patients were randomly selected by a dental prosthetics specialist, and these patients did not participate in the first part of this study because they did not have appointments at the dental institution during the first part of this study. The interclass correlation coefficient (ICC) and 95% confidence interval (CI) of the summary scores for the OHIP-EDENT-B&H and various subscales were calculated.

Validity

Content validity. To detect any difference in oral-health-related qualityoflife between the group of patients requiring treatment and the same group after the dental-prosthetic treatment had beenconducted, a t-test of the equality of means was calculated.

Concurrent validity. Assuming that patients with a self-reported high degree of satisfaction with interventions have a low OHIP score, the Spearman's correlation coefficient between the summary scores for OHIP-EDENT-B&H was calculated for the test–retest group, too.

Responsiveness

The responsiveness of interventions was analysed using repeated measures ANOVA, when the change of OHIP-EDENT-B&H values and the effect size were established before and after the interventions and corrections.

Table 1a. Original oral health of edentulous patients (OHIP-EDENT) questionnaire

Functional limitation
1. Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?
2. Have you had food catching in your teeth or dentures?

3. Haveyoufelt that your dentures have not been fitting properly?

Physical pain

4. Have you had painful aching in your mouth?

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

6. Have you had sore spots in your mouth?

7. Have you had uncomfortable dentures?

Psychological discomfort

8. Have you been worried by dental problems?

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

Physical disability

10. Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?

11. Have you been unable to eat with your dentures because of problems with them?

12 Have you had to interrupt meals because of problems with your teeth, mouth or dentures?

Psychological disability

13. Have you been upset because of problems with your teeth, mouth or dentures?

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

Social disability

15. Have you avoided going out because of problems with your teeth, mouth or dentures?

16. Have you been less tolerant of your partner or family because of problems with your teeth, mouth or dentures?

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

Handicap

18. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures?

19. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?

Response categories for all questions:

4 = very often; 3 = fairly often; 2 = occasionally; 1 = hardly ever; 0 = never/do not know.

Funkcionalno ograničenje

1. Da li imate teškoće tokom žvakanja bilo kakve hrane zbog problema sa Vašim zubima, ustima ili protezama?

2. Da li ste osjećali da se hrana zadržava naVašim zubima ili protezama?

3. Da li ste imali utisak da vase proteze ne odgovaraju ili na odgovarajući način naležu na potporna tkiva u Vašim ustima?

Fizičkibol

4. Da li ste osjećali bolne senzacije u Vašim ustima?

5. Da li ste osjećali nelagode za vreme konzumiranja bilo koje hrane zato što je niste mogli sažvakati Vašim zubima, protezama ili usled teškoća u Vašim ustima?

6. Jeste li imali upaljena mjesta u ustima?

7. Da li ste osjećali da Vam je u ustima ,,nelagodno,,zbog postojanja proteza?

Psihološka nelagodnost

8. Da li stebilizabrinutizbogVašihdentalnihproblema?

9. Da li ste sebe preispitivali zbogVaših zuba, usta ili proteza?

Fizička invalidnost

10. Da li ste morali da izbjegavate jesti neku hranu zbog problema sa zubima, ustima ili zubnim protezama?

11. Da li zbogteškoćaiproblemasaprotezamanistemoglijesti?

12.Da li ste morali prekidati obroke zbog problema sa zubima, ustima ili zubnim protezama?

Psihološka invalidnost

13. Jeste li se uznemirili zbog problema sa zubima, ustima ili zubnim protezama?

14. Da li Vam je bilo malo neugodno zbog problema sa zubima, ustima ili zubnim protezama?

Socijalna invalidnost

15. Da li steizbjegavaliizlazakzbogproblemasazubima, ustimailizubnimprotezama?

16. Da li stebilimanjetolerantnipremapartneruiliporodicizbogproblemasazubima, problema u Vašimustimailiprotezama?

17. Jeste li bilirazdražljivipremadrugimljudimazbogteškoćasazubima, problema u Vašimustimailiprotezama?

Hendikep

18. Da li niste mogli toliko uživati u društvu drugih ljudi zbog problema sa zubima, ustima ili Vašim protezama?

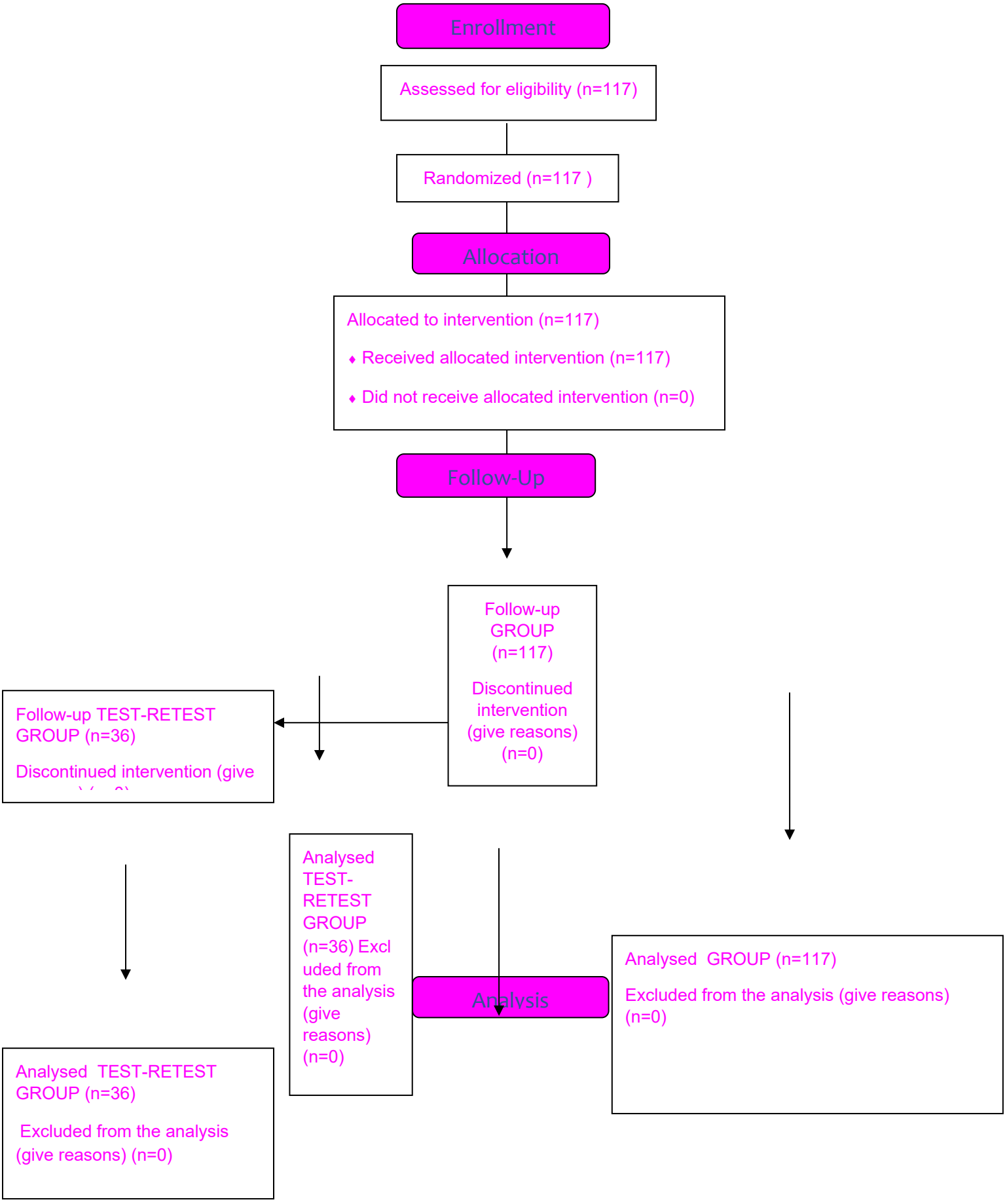
19. Jeste li osjećali da Vam život općenito nije zadovoljavajući zbog problema sa zubima, ustima ili Vašim protezama?

Subjects answered questions regarding frequency of influence of oral aspects ofeveryday activities, usingof the scale: 4 = very often; 3 = fairly often; 2 = occasionally; 1 = hardly ever; 0 = never/do not know.

Ispitanici su odgovarali na pitanja koja se tiču učestalosti uticaja oralnih aspekata zdravlja na dnevne aktivnosti, korišćenjem skale: 0- nikada, 1- gotovo nikada, 2- ponekad, 3 –prilično često, 4- vrlo učestalo.

- **Participant Flow: A flow diagram showing participants involved at each stage of the study (namely enrolment, intervention allocation, follow-up, and data analysis).**

Flow Diagram


Enrollment
Assessed for eligibility (n=117)
Randomized (n=117)
Allocation
Allocated to intervention (n=117)
♦ Received allocated intervention (n=117)
♦ Did not receive allocated intervention (n=0)
Follow-Up
Follow-up GROUP (n=117)
Discontinued intervention (give reasons) (n=0)
Follow-up TEST-RETEST GROUP (n=36)
Discontinued intervention (give
Analysed TEST-RETEST GROUP (n=36) Excl uded from the analysis (give reasons) (n=0)
Analysis
Analysed GROUP (n=117)
Excluded from the analysis (give reasons) (n=0)
Analysed TEST-RETEST GROUP (n=36)
Excluded from the analysis (give reasons) (n=0)

Analysed GROUP (n=117)

Excluded from the analysis (give reasons) (n=0)

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- **Baseline Characteristics: A tabular summary showing demographic data and any clinical characteristics for participants at the baseline, as well as any measures assessed at the baseline that were used in the analysis of a primary outcome measure.**

Safety considerations

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

Follow-up

At least 3 follow ups will be provided for each participant. The interval between follow ups is 6 months.

Data management and statistical analysis

The data were processed using IBM SPSS 19.0 software. The normal distribution of the variables was calculated using the Kolmogorov-Smirnov test. The internal consistency of the OHIP-EDENT-B&H scale was measured with Cronbach's alpha. Differences in frequencies were computed by means of the Chi-square test, and differences in scores with paired samples t-test (test *vs*. retest and Group A *vs*. Group B). Spearman's correlation coefficient between the degree of satisfaction with denture intervention and the summary scores for OHIP-EDENT-B&H was calculated.

Quality assurance

Expected outcomes of the study

This study will contribute to advancement of knowledge not only in local area but internationally too.

Dissemination of results and publication policy

The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.

Duration of the project

The time is not possible to strictly envelope and bound. This study was open for all of volunteers who accepted participation in this study on the basis of criteria for the selection of the patients..

Problems anticipated

Not applicable.

Project management

Not applicable

Ethics

The investigator obtained oral agreement and participation of every each edentulous patients who participated in the 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 Belgrade, Serbia

Statistics

RG Score 18.5

Publications	185
Reads	16,195
Citations	189

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 Memberships	IADR/CED European Prosthodontics Association BaSS-Balcan 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.