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Psychometric Properties of the 14 Items Oral Health Impact Profile Questionnaire Translated into the Macedonian language

Psihometrijska svojstva upitnika Oral Health Impact Profile od 14 stavki prevedenoga na makedonski jezik

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Abstract
Objective: Due to the consideration that oral/dental health is an important part of general health, well-being, and an individual's quality of life, the need for appropriate instruments assessing oral health-related quality of life is emphasized. This study aimed to evaluate the psychometric properties of the Oral health-related quality of life questionnaire consisting of 14 questions among the Macedonian language-speaking adults (OHIP-MAC 14). **Material and methods:** A total of 270 adults participated in the study. The reliability of the questionnaire was examined by testing the internal consistency and reproducibility (test-retest). The responsiveness of the instrument was tested by computing the pre-intervention and post-intervention OHIP-14 scores using the paired t-test followed by the determination of the effect-size. The two aspects of the construct validity were evaluated: concurrent validity and discriminative validity. **Results:** A concurrent validity analysis confirmed that the instrument performed well. Discriminative validity also confirmed good psychometric properties (P<0.01). The ICC statistics and the Cronbach alpha coefficients indicated the appropriate reliability of the instrument for the included groups of participants. The responsiveness of the questionnaire was also acceptable (P<0.01) demonstrating the large effect-size of 1.43. **Conclusion:** The OHIP 14 MAC showed acceptable psychometric properties and can be recommended as a valuable instrument in assessments of the Oral health-related quality of life in the Republic of North Macedonia.

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Introduction

The original version of the Oral Health Impact Profile (OHIP) instrument consists of 49 items divided into 7 subscales related to (a) functional limitation, (b) physical pain, (c) psychological discomfort, (d) physical disability, (e) psychological disability, (f) social disability, and (g) handicap (1). In that model, the status of oral health was hierarchically ordered from biological and physical levels to behavioral and social levels. The exploratory study carried out on international general population subjects and prosthodontic patients (2) revealed four inter-correlated factors named Oral Function, Orofacial Pain, Orofacial Appearance, and Psychosocial Impact, which were corroborated by confirmatory factor analyses in a subsequent study (3).

The applicability, along with the construct and metric equivalence of measures originally generated in one culture needs to be empirically tested in cultures they are intended to be used. This process of cross-cultural adaptation establishes whether the instruments are valid and reliable when used

Uvod

Izvorna verzija upitnika Oral Health Impact Profile (OHIP) sastoji se od 49 stavki podijeljenih u sedam podstavki koje se odnose na (a) funkcijska ograničenja, (b) tjelesnu bol, (c) psihičku nelagodu, (d) tjelesni invaliditet, (e) psihički invaliditet, (f) socijalni invaliditet i (g) hendikep (1). U tom je modelu stanje oralnoga zdravlja hijerarhijski poredano od biološke i tjelesne razine do bihevioralne i društvene. Eksplorativno istraživanje provedeno na međunarodnoj općoj populaciji i pacijentima s protetikom (2) otkrilo je četiri uzajamno povezana čimbenika pod nazivom oralna funkcija, orofacijalna bol, orofacijalni izgled i psihosocijalni utjecaj koji su potkrijepljeni potvrdnom faktorskom analizom u naknadnom istraživanju (3).

Primjenjivost, zajedno s konstrukcijom i metričkom ekvivalentnošću mjera izvorno generiranih u jednoj kulturi, potrebno je empirijski ispitati u kulturama u kojima se namjeravaju upotrebljavati. Tim procesom međukulturne prilagodbe utvrđuje se jesu li instrumenti valjani i pouzdani ka-

in cultures different from the original one (where it has been developed).It is considered to be necessary due to many cultural, linguistic, and socio-economic differences that might reflect the measurement of the constructs (4).

The appropriate psychometric properties of the original OHIP-49 version have been proven in many studies carried out in different cultures and in numerous different spoken languages (5), contributing to the high reputation of the instrument among oral health researchers in different cultures. It was also translated from the English to the Macedonian language, with an evaluation of its psychometric properties, which confirmed good psychometric properties. Therefore, the OHIP-MAC 49 was recommended for use among the Macedonian-speaking population in 2012 (6).

The popularity of the OHIP 49, as well as the burden (time consumption) of the instrument, resulted in the development of versions specifically intended to target certain subpopulations. Thus, different OHIP versions were developed, such as the OHIP for patients with temporomandibular disorders (OHIP-TMD) (7), the OHIP for edentulous patients (OHIP-EDENT) (8), and the OHIP version for assessment of the effects of orofacial esthetics on the Oral health-related quality of life (the OHIP-ESTHET) (9).

The OHIP questionnaire has a history of being one of the instruments most frequently used for assessment of the oral health-related quality of life (OHRQoL), thus expressing personal satisfaction and personal experience of symptoms related to oral and dental status and reflection of oral and dental problems on the performance of daily activities (10, 11). However, it was also demonstrated that the OHIP-49 might be too demanding in terms of time consumption and effort in filling in the questionnaire (12), especially for elderly patients or respondents with lower educational levels. Consequently, a large number of researchers and clinicians faced reduced motivation for participation from respondents who omitted answers when the instrument was administered as a questionnaire to be self-filled-in. Therefore, short versions of the instruments were developed.

The advantage of the shortened versions is primarily in the shorter time consumption and less effort among the respondents in completing the instrument that still retained the ability to measure relevant aspects of oral and dental health-related well-being: self-reported functional limitation, discomfort, and disability attributed to oral conditions. The two different 14-item versions of the OHIP instrument (OHIP-14) were developed. One short form was proposed by Slade (13), and the other one was developed by Locker and Allen (12). Both versions have been successfully translated and adapted to many different cultures (14-18). They were also used in young orthodontic patients (14), indigenous populations (19), postpartum women (20, 21) and geriatric patients (22). However, the most recent findings strongly suggest that widening the usage of the instrument to samples without prior psychometric evaluation might easily compromise its validity (23).

da se upotrebljavaju u kulturama različitima od izvorne (gdje su nastali). Smatra se nužnim zbog mnogih kulturnih, jezičnih i društveno-ekonomskih razlika koje bi mogle odražavati mjerenje konstrukata (4).

Odgovarajuća psihometrijska svojstva izvorne verzije OHIP-a 49 dokazana su u mnogim istraživanjima provedenima u različitim kulturama i na mnogim različitim jezicima (5), pridonoseći visokoj reputaciji instrumenta među istraživačima oralnoga zdravlja u različitim kulturama. Također je preveden s engleskoga na makedonski jezik, uz ocjenu njegovih psihometrijskih svojstava, čime su potvrđena dobra psihometrijska svojstva. Zato je 2012. OHIP-MAC 49 preporučen za uporabu među populacijom makedonskoga govornog područja (6).

Popularnost OHIP-a 49, kao i opterećenje (utrošak vremena) instrumenta, rezultiralo je pojavom inačica posebno namijenjenih određenim subpopulacijama. Tako su nastale različite verzije OHIP-a, kao što su OHIP za pacijente s temporomandibularnim poremećajima (OHIP-TMD) (7), OHIP za bezube pacijente (OHIP-EDENT) (8) te verzija za procjenu učinaka orofacijalne estetike na kvalitetu života vezanu uz oralno zdravlje (OHIP-ESTHET) (9).

Upitnik OHIP već je odavno jedan od najčešće korištenih instrumenata za procjenu kvalitete života povezane s oralnim zdravljem (OHRQoL), čime se izražava osobno zadovoljstvo i osobni doživljaj simptoma povezanih s oralnim i dentalnim statusom te odraz oralnih i dentalnih problema na obavljanje svakodnevnih aktivnosti (10, 11). No pokazalo se i da bi OHIP-49 mogao biti prezahtjevan kad je riječ o utrošku vremena i trudu pri ispunjavanju upitnika (12), posebice za starije pacijente ili ispitanike nižeg stupnja obrazovanja. Posljedično, mnogi su se istraživači i kliničari suočili sa smanjenom motivacijom za sudjelovanje ispitanika koji su izostavili odgovore kada je instrument primijenjen kao upitnik koji su sami ispunili. Zato su razvijene kratke verzije instrumenata.

Prednost skraćenih verzija uglavnom je u kraćem vremenu potrebnom za ispunjavanje i manjem trudu, no i dalje je zadržana mogućnost mjerenja relevantnih aspekata dobrobiti povezanih s oralnim i dentalnim zdravljem: samoprijavljeno funkcijsko ograničenje, nelagoda i invaliditet koji se pripisuje oralnim stanjima. Postoje dvije različite verzije OHIP-a (OHIP- 14) od 14 stavki. Jednu kratku formu predložio je Slade (13), a drugu su prilagodili Locker i Allen (12). Obje su uspješno prevedene i prilagođene mnogim različitim kulturama (14 – 18). Također se upotrebljavao za mlade ortodontske pacijente (14), domorodačko stanovništvo (19), za žene poslije poroda (20, 21) i gerijatrijske pacijente (22). No nedavna otkrića snažno upućuju na to da bi proširenje uporabe instrumenta na uzorke bez prethodne psihometrijske procjene moglo lako ugroziti njegovu valjanost (23).

Aim of the study

Since the longer version of the OHIP-MAC 49 instrument already exists, the aim was to evaluate the psychometric properties of the shorter version, namely the OHIP-14 among Macedonian-speaking adults.

Material and method

Participants

The participants for this study were selected from four different populations (Table 1). They took part on a voluntary basis and their responses were anonymous. In developing the sampling strategy, we used the models implemented to evaluate the psychometric characteristics of the longer version of the instrument (OHIP-49) carried out in North Macedonia in 2012 (6). The general population sample was randomly selected among blood donors who arrived to donate blood at the Institute of Transfusion Medicine in Skopje during the period when the data were collected. The sample of 27 students was also recruited from the pool of students of Dentistry at the Medical school at the University of Ss. Cyril and Methodius in Skopje, who were attending the third year of study. The sample of prosthodontic patients was composed of 53 consecutively selected prosthodontic patients who received treatment at the Institute for Dental Health in Skopje, whereas the sample of 48 subjects, who needed treatment due to acute or chronic toothache and attended the same institution or a private dental office in Ohrid, comprised another consecutively selected sample. The response rate in the population of blood donors was 90%, whereas all students and patients responded positively to participate in the study. The description of the samples, the selection of participants, the way the instrument was implemented, and the purpose of the research are presented in Table 1. Three questionnaires were discarded due to missing data, and ten patients reported difficulties in understanding the language as they were not native Macedonian-language-speaking individuals.

Svrha istraživanja

Budući da dugi oblik instrumenta OHIP-MAC 49 već postoji, cilj je bio procijeniti psihometrijska svojstva kraće verzije, točnije OHIP-14 među odraslim osobama koje govore makedonski.

Materijali i metode

Ispitanici

Sudionici za ovo istraživanje odabrani su iz četiriju različitih populacija (tablica 1.). Sudjelovali su dobrovoljno, a odgovori su bili anonimni. U razvoju strategije uzorkovanja koristili smo se modelom implementiranim za procjenu psihometrijskih karakteristika dulje verzije instrumenta (OHIP-49) provedene u Sjevernoj Makedoniji 2012. (6). Uzorak opće populacije nasumično je odabran među darivateljima krvi koji su došli u Zavod za transfuzijsku medicinu u Skoplju u razdoblju prikupljanja podataka. Uzorak od 27 studenata također je odabran iz skupine studenata stomatologije na Medicinskom fakultetu Sveučilišta sv. Ćirila i Metoda u Skoplju koji su pohađali treću godinu. Uzorak protetičkih pacijenata sastavljen je od 53 uzastopno odabrana protetička pacijenata koji su bili na liječenju u Institutu za stomatološko zdravlje u Skoplju, a uzorak od 48 ispitanika koji su trebali liječenje zbog akutne ili kronične zubobolje i bili su u istoj ustanovi ili privatnoj stomatološkoj ordinaciji u Ohridu, činio je još jedan uzastopno odabrani uzorak. Stopa odaziva u populaciji darivatelja krvi bila je 90 %, a svi studenti i pacijenti pozitivno su odgovorili. Opis uzoraka, njihov odabir, način na koji je instrument implementiran i svrha istraživanja prikazani su u tablici 1. Tri upitnika odbačena su zbog nepotpunih podataka, a deset pacijenata prijavilo je poteškoće u razumijevanju jezika jer im makedonski nije materinski jezik.

Table 1 Types of populations, sampling strategies, data collection, and types of tested psychometric properties of the Macedonian version of the 14-item Oral Health Impact Profile questionnaire (OHIP-MAC 14)
Tablica 1. Vrste populacija, strategije uzorkovanja, prikupljanje podataka i vrste testiranih psihometrijskih svojstava makedonske verzije upitnika o profilu utjecaja na oralno zdravlje (OHIP-MAC 14) od 14 stavki

Participants • Ispitanici	Sampling • Uzorkovanje	Data collection technique • Tehnika prikupljanja podataka	Research purpose • Svrha istraživanja
General population • Opća populacija	Random • Randomizirano	Questionnaire • Upitnik	Internal consistency and concurrent validity • Unutarnja konzistentnost i konkurentna valjanost
Students • Studenti	Convenience • Progodno	Questionnaire • Upitnik	Internal consistency and test-retest reliability • Unutarnja dosljednost i pouzdanost test-retest
Prosthodontic patients • Protetički pacijenti	Consecutive • Konzekutivno	Interview • Intervju	Internal consistency and responsiveness • Unutarnja konzistentnost i responzivnost
Toothache patients • Pacijenti sa zuboboljom	Consecutive • Konzekutivno	Interview • Intervju	Internal consistency and responsiveness • Unutarnja konzistentnost i responzivnost

Instrument

The short version of the Oral Health Impact Profile (OHIP-14) is a 14-items questionnaire derived from the original version consisting of 49 items, which is based on a the-

Instrument

Kratka verzija upitnika OHIP-14 sastavljena od 14 stavki nastala je iz izvorne verzije koja se sastoji od 49 stavki, a temelji se na teoretskom modelu koji je razvila Svjetska

oretical model developed by the World Health Organization (WHO) (24) and adapted for oral health assessment by Locker (25). The items from Slade's version of the OHIP-14 (13) were derived from the OHIP–MAC 49 version: The following items were included: 2, 6, 10, 16, 20, 23, 29, 32, 35, 38, 42, 43, 47 and 48. Since all items were already translated, they were once again back-translated into the English language by one professional translator and were evaluated by two English native speakers who compared them with the original English version.

All items are statements rated on a Likert-type scale ranging from 0 to 4 (0 = never, 1 =hardly ever, 2 = occasionally, 3 = fairly often, 4 = very often), which resulted in higher scores indicating worse oral health. The highest possible score was X_{max}=56. Additionally, the respondents were also asked to self-assess their overall oral health on a scale from 1 to 5 (1 – poor, 2 – fair, 3 – good, 4 – very good, and 5 – excellent). The questionnaire also included questions on sociodemographic data – age, gender, and ethnicity.

Procedure

The Ethics committee of the Medical School in Skopje approved the study prior to the process of data collection. The examination of the oral status of prosthodontic patients and patients with toothache was performed by three trained dentists and it was in accordance with the WHO criteria (24), before the administration of the questionnaire in the groups. The same dentists provided adequate treatments as well.

Two trained interviewers administered and supervised the questionnaires in the period of January to May 2022. All respondents participated voluntarily. Each respondent received an explanation about the aim of the research, along with the guarantees for confidentiality. Within the samples of students and blood donors (general population), the questionnaires were filled in anonymously by the respondents themselves. Students were asked to write a code (preferably a birth date) for repeated administration. Both groups of patients were interviewed, and the respondents were coded so that two weeks after the treatment the questionnaires could be matched in prosthodontic and in toothache patients. The list related to the identity of the participants with the code was discarded three months after the data collection process. The average duration of administering the instrument was approximately 3-5 minutes, depending on whether it was administered as a self-filled questionnaire or as an interview.

Proposed data analysis

The *reliability* was examined by testing the internal consistency and reproducibility (test-retest). Internal consistency was assessed by obtaining Cronbach`s alpha coefficients and item-total correlation whereas the reproducibility was assessed by calculating the intraclass correlation coefficient (ICC) for all items, using the Shrout and Fleiss two-way random model (absolute agreement). While the internal consistency coefficients were obtained for all included subgroups, due to practical limitations, the test-retest was performed only in the sample of students and prosthodontic patients. Be-

zdravstvena organizacija (SZO) (24), a za procjenu oralnoga zdravlja prilagodio ju je Locker (25). Stavke iz Sladeove verzije OHIP-a 14 (13) izvedene su iz verzije OHIP–MAC 49. Uključene su sljedeće stavke: 2, 6, 10, 16, 20, 23, 29, 32, 35, 38, 42 , 43, 47 i 48. Budući da su sve stavke već bile prevedene, još jedanput ih je preveo na engleski jezik profesionalni prevoditelj, a ocijenila su ih dva izvorna govornika engleskoga jezika te ih usporedili s izvornom engleskom verzijom.

Sve su stavke tvrdnje ocijenjene na ljestvici Likertova tipa u rasponu od 0 do 4 (0 = nikad, 1 = rijetko, 2 = povremeno, 3 = dosta često, 4 = vrlo često), što je rezultiralo višim rezultatima koji upućuju na lošije oralno zdravlje. Najviši mogući rezultat bio je Xmax = 56. Dodatno se od ispitanika tražilo da sami procijene svoje cjelokupno oralno zdravlje na ljestvici od 1 do 5 (1 – loše, 2 – dosta loše, 3 – dobro, 4 – vrlo dobro i 5 – izvrsno). Upitnik je sadržavao i pitanja o dobi, spolu i etničkoj pripadnosti.

Postupak

Etičko povjerenstvo Medicinskog fakulteta u Skoplju odobrilo je istraživanje prije prikupljanja podataka. Ispitivanje oralnoga statusa protetičkih pacijenata i pacijenata sa zuboboljom obavila su tri educirana stomatologa u skladu s kriterijima SZO-a (24) i to prije ispunjavanja upitnika u skupinama. Isti stomatolozi obavili su i odgovarajuće zahvate.

Dva educirana anketara provodila su i nadzirala upitnike u razdoblju od siječnja do svibnja 2022. Svi ispitanici sudjelovali su dobrovoljno. Svaki je dobio objašnjenje o cilju istraživanja, uz jamstvo povjerljivosti. U uzorcima studenata i darivatelja krvi (opća populacija) upitnike su anonimno ispunjavali sami ispitanici. Studenti su zamoljeni da napišu šifru (ako je moguće datum rođenja) za ponavljanje ispunjavanja. Anketirane su obje skupine pacijenata, a ispitanici su kodirani kako bi se dva tjedna poslije terapije mogli upariti upitnici protetičkih pacijenata i onih sa zuboboljom. Popis koji se odnosi na identitet sudionika sa šifrom odbačen je tri mjeseca poslije prikupljanja podataka. Prosječno trajanje ispunjavanja bilo je otprilike od 3 do 5 minuta, ovisno o tome je li se provodilo kao samostalno popunjeni upitnik ili kao intervju.

Predložena analiza podataka

Pouzdanost je analizirana ispitivanjem unutarnje konzistentnosti i ponovljivosti (test-retest). Unutarnja konzistentnost procijenjena je dobivanjem Cronbachovih alfa koeficijenata i ukupne korelacije stavki, a ponovljivost je procijenjena izračunavanjem unutarrazrednoga koeficijenta korelacije (ICC) za sve stavke, korištenjem dvosmjernoga slučajnog modela Shrouta i Fleissa (apsolutno slaganje). Dok su koeficijenti unutarnje konzistencije dobiveni za sve uključene podskupine, zbog praktičnih ograničenja test-retest primijenjen je samo na uzorku studenata i protetičkih pacijenata.

fore the second administration of the instrument (two weeks after the first one), the participants were asked whether they were exposed to any dental treatment or unusual dental condition in the last two weeks. Those who confirmed the absence of such occurrences were included in the analysis of the test-retest. In the group of students, three students were absent in the retest period and their responses were excluded from the analysis.

The ICCs are interpreted as follows: ICCs between 0.40 and 0.75 were considered moderate, between 0.75 and 0.90 very good, whereas above 0.90 as excellent reliability (26). As additional information on time stability, the significance of the difference between the first and the second administration was assessed. The statistically significant difference was considered poor reproducibility.

The *responsiveness* of the instrument, defined as the ability to detect relevant changes over time, was tested by computing pre-intervention and post-intervention mean OHIP-14 scores and performing paired t-test followed by determining the effect-size. The analyses were carried out only for the sample of patients with toothache who asked for and received treatments from experienced dentists, one to two weeks after the treatment. The difference in the OHIP- MAC 14 scores between the baseline (pre-treatment) and the follow-up (post-treatment) was assessed by using a t-test for paired samples, followed by calculating the effect size. The effect sizes were interpreted as small (d = 0.2 – 0.5), medium (d = 0.5 – 0.8), or large (d = above 0.8) as suggested by Cohen (27).

Two aspects of construct *validity* were evaluated: concurrent validity and discriminative validity. To evaluate the concurrent validity of the instrument, we examined the correlation between the self-reported oral health score and the summary score of the OHIP-MAC 14, previously hypothesizing that these measures should be negatively associated. If such an expectation had not been met, the convergent validity would have been considered doubtful. The Spearman's coefficient of correlation was considered the most appropriate statistical method for assessing the association between the OHIP-MAC 14 and self-reported oral health. The sample of students was not included in the validity analysis due to the very low variability of the responses. The known-group comparison (discriminative validity) was used to determine the degree to which the OHIP was able to discriminate between the subgroup of prosthodontic patients with partial and complete removable dentures. It was expected that, on average, the group wearing removable partial dentures would have lower OHIP scores than the group wearing removable complete dentures.

Statistical data analysis was performed by using the software SPSS for Windows 26.

Results

A total of 270 respondents (28.5% female) participated in this study. The composition of the included samples regarding age and gender is presented in Table 2.

Concurrent validity analysis confirmed that the instrument performed well. The assumed negative association be-

Prije druge primjene instrumenta (dva tjedna poslije prve), sudionici su upitani jesu li bili izloženi bilo kakvom stomatološkom zahvatu ili neuobičajenom dentalnom stanju u posljednja dva tjedna. Oni koji su potvrdili nepostojanje takvih pojava uključeni su u analizu test-retesta. U skupini učenika troje nije došlo na ispitni rok te su njihovi odgovori isključeni iz analize.

ICC-i su se tumačili na sljedeći način: ICC između 0,40 i 0,75 smatran je umjerenom pouzdanošću, između 0,75 i 0,90 vrlo dobrom, a iznad 0,90 izvrsnom (26). Kao dodatna informacija o vremenskoj stabilnosti procijenjena je značajnost razlike između prve i druge primjene. Statistički značajna razlika smatrana je slabom ponovljivošću.

Responzivnost instrumenta, definirana kao sposobnost otkrivanja relevantnih promjena tijekom vremena, testirana je izračunavanjem srednjih rezultata OHIP-a 14 prije intervencije i poslije nje te izvođenjem uparenoga t-testa nakon čega je slijedilo određivanje veličine učinka. Analize su obavljene samo na uzorku pacijenata sa zuboboljom koji su zatražili i dobili terapiju kod iskusnih stomatologa tjedan do dva poslije zahvata. Razlika u rezultatima OHIP-MAC-a 14 između početne vrijednosti (prije liječenja) i praćenja (naknadno liječenje) procijenjena je s pomoću t-testa za uparene uzorke, nakon čega se izračunavala veličina učinka. Kako je predložio Cohen, veličina učinka tumačena je kao mala (d = 0,2 – 0,5), srednja (d = 0,5 – 0,8) ili velika (d = iznad 0,8), (27).

Procijenjena su dva aspekta valjanosti konstrukta – konkurentna valjanost i diskriminirajuća valjanost. Kako bismo procijenili istodobnu valjanost instrumenta, ispitali smo korelaciju između rezultata oralnoga zdravlja koje su ispitanici sami prijavili i sažetoga rezultata OHIP-MAC-a 14, pretpostavivši da bi te mjere trebale biti negativno povezane. Ako se to očekivanje nije ispunilo, tada se konvergentna valjanost smatrala upitnom. Spearmanov koeficijent korelacije smatra se najprikladnijom statističkom metodom za procjenu povezanosti između OHIP-MAC-a 14 i oralnoga zdravlja prema samoprocjeni. Uzorak studenata nije uključen u analizu valjanosti zbog vrlo niske varijabilnosti odgovora. Usporedba poznatih skupina (diskriminativna valjanost) korištena je za određivanje stupnja do kojega je OHIP mogao razlikovati podskupinu protetičkih pacijenata s djelomičnom i potpunom mobilnom protezom. Očekivalo se da će u prosjeku skupina koja nosi pomične djelomične proteze imati niže rezultate OHIP-a od one s pomičnim potpunim protezama.

Statistička analiza provedena je u softveru SPSS za Windowse 26.

Rezultati

U istraživanju je sudjelovalo ukupno 270 ispitanika (28,5 % žena). Njihov sastav, s obzirom na dob i spol, prikazan je u tablici 2.

Konkurentna analiza valjanosti potvrdila je da je instrument dobro funkcionirao. Pretpostavljena negativna poveza-

Table 2 Number, age, and gender of participants
Tablica 2. Broj, dob i spol sudionika

Participants • Ispitanici	N	N (% of women) • N (% žena)	M age (SD) • M dob (SD)	Age range • Raspon dobi
General population • Opća populacija	142	25 (17.6)	39.57 (0.91)	21 – 61
Students • Studenti	27	13 (48.1)	23.26 (2.09)	21 – 25
Prosthodontic patients • Protetički pacijenti	53	26 (49.1)	59.57 (1.49)	19 – 82
Toothache patients • Pacijenti sa zuboboljom	48	13 (27.1)	39.19 (1.56)	23 – 61

Table 3 Correlation between self-reported oral health scores and the OHIP-MAK14 questionnaire's scores (concurrent validity)
Tablica 3. Korelacija između rezultata oralnoga zdravlja prema samoprocjeni i rezultata upitnika OHIP-MAC 14 (istodobna valjanost)

Participants • Ispitanici	N	Mean OHIP-14 score • Prosječna OHIP-14 vrijednost	Correlation coefficient • Koeficijent korelacije
General population • Opća populacija	142	1.41	-0.55**
Excellent • Izvrsno	123	0.85	
Very good • Vrlo dobro	14	4.00	
Good • Dobro	4	9.50	
Fair • Dosta loše	/	/	
Poor • Loše	/	/	
Prosthodontic patients • Protetički pacijenti	53	28.96	-0.54**
Excellent • Izvrsno	/	/	
Very good • Vrlo dobro	14	23.14	
Good • Dobro	15	27.67	
Fair • Dosta loše	14	30.61	
Poor • Loše	10	36.60	
Toothache patients • Pacijenti sa zuboboljom	48	13.06	-0.69**
Excellent • Izvrsno	7	4.57	
Very good • Vrlo dobro	16	10.50	
Good • Dobro	14	11.64	
Fair • Dosta loše	8	22.85	
Poor • Loše	3	27.00	

Table 4 Discriminative validity (known group difference) of the OHIP-MAC 14 tested on prosthodontic patients with partial and complete dentures
Tablica 4. Diskriminacijska valjanost (poznata grupna razlika) OHIP-MAC-a 14 testiranoga na protetičkim pacijentima s djelomičnom i potpunom protezom

	N	M	SD	SE Mean • Prosječna standardna pogreška	CI95% • 95 % IP	T	p
Removable partial dentures • Mobilne parcijalne proteze	35	26.40	7.73	1.30	-12.02 - -3.06	-3.38	<0.01
Removable complete dentures • Mobilne potpune proteze	18	33.94	7.64	1.80			

tween the overall OHIP-MAC 14 summary score and the self-reported oral health score was confirmed in all samples which were included in the analysis (Table 3).

Known group validity (discriminative validity), determined by testing the expectation that the instrument would be able to demonstrate the difference between prosthodontic patients wearing partial and complete removable dentures, was also confirmed (Table 4). Patients with complete dentures reported significantly lower oral health-related quality of life.

The *test-retest reliability* was evaluated by calculating the intraclass correlation coefficients (ICC) using the summary OHIP-MAC 14 scores from the repeated administration of the tests. As mentioned before, the group of students and prosthodontic patients were submitted to the administration

nost između ukupnoga OHIP-MAC-a 14 i rezultata oralnoga zdravlja prema samoprocjeni potvrđena je u svim uzorcima koji su bili uključeni u analizu (tablica 3.).

Potvrđena je i poznata grupna valjanost (diskriminacijska valjanost) određena ispitivanjem očekivanja da će instrument moći pokazati razliku između protetičkih pacijenata koji nose djelomičnu mobilnu protezu i onih s potpunom (tablica 4.). Pacijenti s potpunom protezom prijavili su značajno nižu kvalitetu života povezanu s oralnim zdravljem.

Pouzdanost test-retesta procijenjena je izračunavanjem unutarrazrednih koeficijenata korelacije (ICC) korištenjem sažetih rezultata OHIP-MAC-a 14 iz ponovljene primjene testova. Kao što je već spomenuto, skupina studenata i protetičkih pacijenata podvrgnuta je ispitivanju dva puta u razdoblju od dva tjedna. Svi su izjavili da u tom razdoblju nisu

Table 5 Internal consistency (Cronbach alpha) and test-retest reliability (Interclass coefficient) of OHIP-MAC 14
Tablica 5. Unutarnja konzistentnost (Cronbachoova alfa) i pouzdanost test-retesta (međurazredni koeficijent) OHIP-MAC-a 14

Participants • Ispitanici	N	Cronbach α • Cronbachova α	Average inter-item correlation • Prosječna korelacija među stavkama	ICC	Mean differ. • Prosječna razlika	95% CI • 95 % IP	P
General population • Opća populacija	142	0.81	0.24				
Students • Studenti	27/24	0.80	0.25	0.78	-0.04	-0.39 – 0.47	0.861
Prosthodontic patients • Protetički pacijenti	53	0.86	0.28	0.84	0.07	-0.13 -0.28	0.455
Toothache patients • Pacijenti sa zuboboljom	48	0.85	0.38				
All participants • Svi ispitanici	270	0.96	0.59				

Table 6 Responsiveness of OHIP-14 MAC ested in patients with toothache (N=48) before and after the treatment
Tablica 6. Odgovor na OHIP-14 MAC ispitan kod pacijenata sa zuboboljom (N = 48) prije i poslije terapije

	M	Range • Raspon	95% CI • 95 % IP	Effect size coefficient • Koeficijent veličine učinka	P
Baseline • Početna vrijednost	13.06	2-39	6.59-11.19	1.43	<0.001
Follow-up • Praćenje	4.17	1-7			

of the instrument twice within a period of two weeks. All of them provided information that they had not been subjected to any dental treatment in that timeframe. The *internal consistency* evaluation was performed by calculating the Cronbach alpha coefficients and providing information on the average inter-item correlation for the samples. Both ICC statistics and Cronbach alpha coefficients shown in Table 5 indicate the appropriate reliability of the instrument.

The *responsiveness* of the OHIP-MAC 14 was assessed by testing its ability to detect expected changes in the toothache patients between the two administrations of the questionnaire; the first time before the treatment (baseline score), and the second time after the dental intervention (follow-up score). Two weeks after the treatment, the toothache patients were asked to provide responses using the same instrument. The comparison of the two scores (t-test for paired samples) revealed significantly lower scores after the intervention, as expected (Table 6). The effect size of the change was large, and it was 1.43.

Discussion

The evaluation of the OHIP-14 translated into the Macedonian language demonstrated acceptable psychometric properties. The evaluation of the psychometric properties mostly relied on the protocol used in the assessment of the Croatian and Slovenian versions of the OHIP14 (28). A thorough comparison with the jointly presented results of the Croatian (OHIP-CRO 14) and Slovenian (OHIP-SVN 14) short versions of the instrument led to the conclusion that they generated similar psychometric performance, which in addition to the performed approach, could be confidently ascribed to the language and cultural proximities. The OHIP-MAC 14 on the other hand, exhibited somewhat lower internal consistency than the OHIP-MAC 49 (6), especially for the general population and students, which could reasonably be expected on the basis of the reduced number of items (29).

The strong correlations between the self-rated oral health and the OHIP-MAC 14 scores indicated that the instrument

bili ni na kakvom nikakvom stomatološkom zahvatu. Procjena unutarnje konzistentnosti provedena je izračunavanjem Cronbachovih alfa koeficijenata i pružanjem informacija o prosječnoj korelaciji između stavki za uzorke. I ICC statistika i Cronbachovi alfa koeficijenti prikazani u tablici 5. pokazuju odgovarajuću pouzdanost instrumenta.

Odaziv na OHIP-MAC 14 procijenjen je testiranjem njegove mogućnosti da otkrije očekivane promjene kod pacijenata sa zuboboljom između dvaju ispunjavanja upitnika – prvi put prije terapije (*baseline score*), a drugi put poslije stomatološke intervencije (*follow-up score*). Dva tjedna nakon terapije pacijenti sa zuboboljom zamoljeni su da daju odgovore koristeći se istim instrumentom. Usporedba dvaju rezultata (t-test za uparene uzorke) otkrila je značajno niže rezultate poslije intervencije, kao što se i očekivalo (tablica 6.). Veličina učinka promjene bila je velika i iznosila je 1,43.

Rasprava

Procjena OHIP-a 14 prevedena na makedonski jezik pokazala je prihvatljiva psihometrijska svojstva. Procjena psihometrijskih svojstava najvećim se dijelom oslanjala na protokol korišten u procjeni hrvatske i slovenske verzije toga upitnika (28). Temeljita usporedba sa zajednički prikazanim rezultatima hrvatske (OHIP-CRO 14) i slovenske (OHIP-SVN 14) kratke verzije instrumenta rezultirala je zaključkom da su generirali slične psihometrijske performanse što se može pripisati jezičnoj i kulturnoj bliskosti. S druge strane, OHIP-MAC 14 pokazao je nešto nižu unutarnju konzistentnost od OHIP-MAC 49 (6), posebno kad je riječ o općoj populaciji i studentima, što je bilo razumno očekivati na temelju smanjenoga broja stavki (29).

Snažna korelacija između samoprocjene oralnoga zdravlja i rezultata OHIP-MAC-a 14 pokazala je da je instrument imao odgovarajuću valjanost u testiranim skupinama. Dodatni pokazatelj njegove valjanosti bila je potvrda pretpo-

had adequate concurrent validity in the tested groups. An additional indication of its validity was the confirmation of the hypothesized difference between the known groups. The evidence of its validity is yet to be enriched within future research. We propose further studies on known groups, as well as an examination of their internal structure based on the exploratory and confirmatory factor analysis (23).

The findings of the changes between the baseline and follow-up scores in patients who asked for a treatment and who received the treatment (significantly lower scores after the treatment), demonstrated satisfactory responsiveness of the OHIP-MAC 14, particularly the large effect size.

The study has several *limitations* among which the most salient is the process of sample selection. Although it is not unusual to consider blood donors similar in their relevant characteristics to the general population (28, 30), in this study the sample of blood donors was composed of mostly male subjects. In addition, the two samples (students and blood donors) were left to fill in the questionnaire by themselves, which might have introduced irrelevant differences in the responses compared to the participants who were interviewed.

Finally, yet importantly, this study does not provide information on the dimensionality of the instrument. Further research should be directed towards obtaining data on larger samples which will enable performing both exploratory factor analysis (EFA) aimed at describing the internal latent structure of the instrument as well as confirmatory factor analysis (CFA) which will provide empirical evidence of whether OHIP-MAC14 fits adequately into the originally proposed factorial structure of the OHRQoL (3,13), or not. The necessity of this step stems from the fact that there are different proposals for factorial structures for the OHIP-14 (23). At least two studies, one using a sample of the general adult population (31) and the other carried out on dental patients (32) have generated statistical evidence in support of the adequacy of its original factorial structure. However, there was no other evidence in some other studies to confirm the aforementioned (15, 18, 19, 21), which raised the question of whether the instrument can preserve the latent concept that it should perform measurements in different contexts and with different samples.

Conclusion

According to the results of this study, the OHIP-MAC 14 questionnaire has acceptable psychometric properties and can be safely used in assessments of patient's perception of the impact of oral disorders on their quality of life. Further research aimed to reveal the factorial structure of the instrument is highly recommended since its previous use in different samples was not able to guarantee the same dimensionality across various cultures and subpopulations.

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stavljene razlike između poznatih skupina. Dokazi o njegovoj valjanosti tek će se obogatiti u budućim istraživanjima. Predlažemo daljnja istraživanja o poznatim skupinama te ispitivanje njihove unutarnje strukture na temelju eksplorativne i potvrdne faktorske analize (23).

Nalazi promjena između početnih i kontrolnih rezultata kod pacijenata koji su zatražili liječenje i izliječeni su (značajno niži rezultati poslije liječenja), pokazali su zadovoljavajući odgovor u OHIP-MAC-u 14.

Istraživanje ima nekoliko ograničenja među kojima je najistaknutiji proces odabira uzorka. Iako nije neuobičajeno smatrati da su darivatelji krvi prema relevantnim karakteristikama slični općoj populaciji (28, 30), u ovom istraživanju njihov uzorak činili su uglavnom muškarci. Uz to, dva uzorka (studenti i davatelji krvi) ostavljena su da sami popune upitnik, što također može unijeti nebitne razlike u odgovorima u odnosu prema ispitanim sudionicima.

Konačno, ali važno, ovo istraživanje ne daje informacije o dimenzionalnosti instrumenta. Daljnja istraživanja trebala bi biti usmjerena na dobivanje podataka od većih uzoraka koji će omogućiti provedbu eksplorativne faktorske analize (EFA) usmjerene opisivanju unutarnje latentne strukture instrumenta, kao i potvrdne faktorske analize (CFA) koja će pružiti empirijski dokaz o tome uklapa li se OHIP-MAC 14 u izvorno predloženu faktorijalnu strukturu OHRQoL-a (3, 13). Nužnost ovog koraka proizlazi iz činjenice da postoje različiti prijedlozi faktorskih struktura za OHIP-14 (23). Najmanje dva istraživanja, jedno koje je provedeno na uzorku opće odrasle populacije (31) i drugo na stomatološkim pacijentima (32), stvorila su statističke dokaze koji podupiru primjerenost izvorne faktorske strukture. No to nije potvrđeno u nekim drugim istraživanjima (15, 18, 19, 21) zbog čega se postavlja pitanje može li instrument sačuvati latentni koncept da treba mjeriti u različitim kontekstima i s različitim uzorcima.

Zaključak

Prema rezultatima ovog istraživanja, upitnik OHIP-MAC 14 ima prihvatljiva psihometrijska svojstva i može se sigurno upotrebljavati u procjeni pacijentove percepcije utjecaja oralnih poremećaja na kvalitetu života. Preporučuju se daljnja istraživanja usmjerena na otkrivanje faktorske strukture instrumenta s obzirom na to da njegova prethodna uporaba u različitim uzorcima nije mogla jamčiti istu dimenzionalnost u različitim kulturama i subpopulacijama.

Zahvala

Autori nisu dobili nikakvu potporu za provedbu istraživanja, ni za objavu rada.

Conflict of interest

None declared

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Sukob interesa

Nije naveden.

Doprinos autora: **N. K. –** dizajn istraživanja, analiza i interpretacija podataka, pisanje nacrta teksta, konačno odobrenje verzije, ugovor o preuzimanju odgovornosti za sve aspekte rada: **K. S. I. – p**rikupljanje i interpretacija podataka, kritička revizija, konačno odobrenje verzije, ugovor o preuzimanju odgovornosti za sve aspekte rada: **J. K. –** koncept istraživanja, prikupljanje podataka, kritička revizija, konačno odobrenje verzije, ugovor o preuzimanju odgovornosti za sve aspekte rada

Sažetak

Svrha istraživanja: S obzirom na to da je oralno/dentalno zdravlje važan dio općega zdravlja te dobrobiti i kvalitete života pojedinca, ističe se potreba za odgovarajućim instrumentima za procjenu kvalitete života povezane s oralnim zdravljem. Cilj ovog istraživanja bio je procijeniti psihometrijska svojstva upitnika o kvaliteti života povezanog s oralnim zdravljem koji se sastoji od 14 pitanja među odraslim osobama koje govore makedonskim jezikom (OHIP-MAC 14). **Materijali i metode:** U istraživanju je sudjelovalo ukupno 270 odraslih osoba. Pouzdanost upitnika analizirana je ispitivanjem unutarnje konzistentnosti i ponovljivosti (test-retest). Responzivnost instrumenta testirana je izračunavanjem rezultata OHIPa-14 prije intervencije i poslije nje korištenjem uparenoga t-testa nakon čega je slijedilo određivanje veličine učinka. Procijenjena su dva aspekta valjanosti konstrukta – konkurentna valjanost i diskriminirajuća valjanost. **Rezultati:** Konkurentna analiza valjanosti potvrdila je da je instrument dobro funkcionirao. Diskriminacijska valjanost također je potvrdila dobra psihometrijska svojstva ($P < 0,01$). ICC statistika i Cronbachovi alfa koeficijenti upućivali su na odgovarajuću pouzdanost instrumenta za uključene skupine sudionika. Pokazujući veliku veličinu učinka od 1,43, responzivnost upitnika također je bila prihvatljiva ($P < 0,01$). **Zaključak:** OHIP 14 MAC pokazao je prihvatljiva psihometrijska svojstva i može se preporučiti kao vrijedan instrument u procjeni kvalitete života povezane s oralnim zdravljem u Republici Sjevernoj Makedoniji.

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