# z d r a v s t v e n o MARSTVENO

## ZDR VARST 2024 • LETNIK 63 • ŠTEVILKA 4

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## NIJZ Nacionalni inštitut za javno zdravje

## nacionalni inštitut za javno zdravje national institute of public health

Trubarjeva 2, si-1000 ljubljana

Zdravstveno varstvo ISSN 0351-0026

#### Izdajatelj/Publisher:

Nacionalni inštitut za javno zdravje generalni direktor: Branko Gabrovec

**Odgovorni urednik/Editor in Chief:** Igor Švab

**Izvršna urednica/Executive Editor:** Saša Zupanič

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#### Lektoriranje slovenščine/Proofreading for Slovenian:

Mihaela Törnar

Lektoriranje angleščine/Proofreading for English: AMIDAS d.o.o., Ljubljana

Prevajanje anglelščine/English translation AMIDAS d.o.o., Ljubljana

Naslov uredništva/Adress of the Editorlal Office: Zdravstveno varstvo - Slovenian Journal of Public Health, Trubarjeva 2, 1000 Ljubljana, p.p. 260

#### Elektronski naslov uredništva/E-mail Address:

Zdrav.Var@nijz.si

#### Domača stran na internetu/Internet Home Page:

https://nijz.si/objave/revije/revija-zdravstveno-varstvo/

in https://sciendo.com/journal/SJPH

#### Transakcijski račun/Current Account:

011006000043188, UJP

Zdravstveno varstvo izhaja praviloma štirikrat letno v nakladi 250 izvodov. Naročnino zaračunavamo z računom za predplačilo v začetku leta. Upoštevamo le pisne odpovedi do 1. decembra za naslednje leto. Vsako spremembo naslova sporočite naročniški službi pravočasno.

Revija Zdravstveno varstvo je pri Ministrstvu za kulturo RS vpisana v razvid medijev pod zaporedno številko 608.

Izid revije je finančno podprla ARRS iz sredstev državnega proračuna iz naslova razpisa za sofinanciranje domačih znanstvenih periodičnih publikacij.

Letna naročnina/Year subscription rate: 52,50 EUR (z vključenim 5 % DDV/including 5% VAT). Naročniška služba: zdrav.var@nijz.si

Gradivo navaja predvsem poglede avtorjev, za katere ni nujno, da se ujemajo z načelnimi stališči stroke oziroma uredniškega odbora.

Naklada: 250 Likovna oprema ovitka: Jurij Kocbek Grafično oblikovanje in prelom: Urška Stariha Tisk: Tisk Žnidarič d.o.o., Laze 7, 4000 Kranj IF(2023)=1.6

Stepanović A, Švab I, Đukić B, Škrbić R. The evolution and challenges of academic family medicine: Insights from the Banja Luka declaration. Zdr Varst. 2024;63(4):160-163. doi: 10.2478/sjph-2024-0021.

## THE EVOLUTION AND CHALLENGES OF ACADEMIC FAMILY MEDICINE: INSIGHTS FROM THE BANJA LUKA DECLARATION

RAZVOJ IN IZZIVI AKADEMSKE DRUŽINSKE MEDICINE: SPOZNANJA IZ BANJALUŠKE DEKLARACIJE

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Received: Jul 07, 2024 Accepted: Aug 23, 2024 Invited editorial

#### ABSTRACT

#### Keywords:

Family medicine Academic medicine Primary healthcare Southeast Europe WHO Academic medicine encompasses education, research and clinical practice, and plays a crucial role in advancing medical science and training physicians. However, the field faces a crisis, with fewer graduates pursuing academic careers.

Family medicine emerged as an academic discipline in the second half of the 20th century, contributing significantly to science and primary healthcare. Despite its recognised status, the World Health Organization has yet to formally define it as an academic discipline. Nevertheless, the discipline must continually update its academic dimension in order to address future challenges.

The international conference in Banja Luka, attended by deans or representatives of Medical Faculties in Southeast Europe, emphasized family medicine's role in primary healthcare and academic medicine, adopting the Banja Luka Declaration to promote family medicine as an independent academic discipline. The conference aims to inspire global support for family medicine as an academic discipline.

#### IZVLEČEK

Ključne besede: družinska medicina akademska medicina osnovna zdravstvena dejavnost SZO Akademska medicina zajema izobraževanje, raziskave in klinično prakso ter ima ključno vlogo pri napredku medicinske znanosti in usposabljanju zdravnikov. Kljub temu se sooča s krizo, saj se manj diplomantov odloča za akademsko kariero.

Družinska medicina se je kot akademska disciplina pojavila v drugi polovici 20. stoletja in pomembno prispevala k znanosti in primarnemu zdravstvenemu varstvu. Kljub priznanemu statusu Svetovna zdravstvena organizacija še ni formalno opredelila družinske medicine kot akademske discipline. Vseeno pa mora ta stroka nenehno posodabljati svoje akademsko področje, da se sooči z izzivi, ki so pred njo.

Mednarodna konferenca v Banja Luki, katere so se udeležili dekani in predstavniki iz jugovzhodne Evrope, je poudarila vlogo družinske medicine v primarnem in akademskem zdravstvenem varstvu ter sprejela Banjaluško deklaracijo za spodbujanje družinske medicine kot neodvisne akademske discipline. Cilj konference je spodbuditi globalno podporo za akademsko družinsko medicino.

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#### **1 THE CHALLENGES OF ACADEMIC FAMILY MEDICINE**

Academic medicine is an area of medicine that focuses on education, research and clinical practice. It plays a crucial role in introducing new medical technologies and diagnostic tools, improving healthcare delivery and training new generations of physicians, making it a driving force for the development of medical science and the profession. For more than a decade, the medical profession has been concerned that academic medicine is facing challenges and that fewer and fewer top graduates are opting for an academic career. There are several reasons for this, two of which are particularly important. Academic institutions have often failed to respond to the needs of society and have become isolated in their narrow thinking as a result. In addition, young people have not pursued academic careers for economic reasons. In Slovenia, this crisis is reflected in the excessive focus on the routine management of healthcare challenges. A specific issue is that academic medicine in Slovenia is located between the health and education systems and is regulated by both (1).

Since the second half of the last century at the latest, family medicine has emerged as an academic discipline that contributes to science (2). In 2002, the World Organization of Family Doctors (WONCA) defined family medicine as an academic and scientific discipline with its own educational content, research, evidence-based clinical activity and clinical specialty focused on primary healthcare, and has maintained this position ever since (3, 4).

The importance of family medicine for the various dimensions of family medicine has been summarised in policy documents. The importance of teaching has been emphasised in recent EURACT documents (5). EQUIP, the organisation of the WONCA Network for Quality, has also emphasised the importance of a specific approach to the quality of healthcare (6). The need for development in training and research is considerable, as the European General Practice Research Network (EGPRN) has documented in detail in a series of articles (7, 8).

The academic reputation of general practice is a key factor in assessing its status in different countries. In countries with developed primary healthcare, family medicine is considered an established academic discipline with proven health benefits. However, the World Health Organisation (WHO) has not yet issued a declaration defining family medicine as an academic discipline (9).

Family medicine is constantly evolving and adapting to the needs of the times and society. It is therefore essential that it constantly updates and adapts academically to ensure the best possible training and practice for future generations of doctors. The future challenges in family medicine concern training, research and the quality and safety of clinical work.

Studies are needed to demonstrate quality and safety in GP practice. The academic community should work with other stakeholders and policy makers at an international level to ensure sufficient funding to conduct high quality research. Challenges in clinical practice include ensuring high quality care for all patients, managing the increase in remote consultations, ensuring safety and dealing with the shortage of medical staff. New models of working will emerge and the role of academic family medicine will be to guide and prioritise the benefits of these new organisational models.

The European Academy of Teachers in General Practice (EURACT) has issued several recommendations for training in this area. None of these challenges can be addressed without the support of family medicine as an academic discipline with a strong foundation in universities (10).

The development of academic family medicine is a long process that is not yet complete. In the Southeast Europe region, Slovenia serves as an example for other countries in this respect. Two medical faculties have independent departments of family medicine, both of which teach family medicine to medical students and are integrated into the faculties' curricula. Family physicians attain the highest academic titles and hold leading positions in science and research, both at home and abroad (11, 12). Family medicine is also taught at all medical faculties in the region, but its position within the undergraduate curriculum varies considerably. Most countries have introduced specialist training in family medicine according to EU standards, and actively participate in international academic organisations for family medicine.

#### 2 BANJA LUKA DECLARATION

From 21 to 22 March 2024, an international conference was convened on the initiative of the deans of the medical faculties of Ljubljana and Banja Luka to address these challenges. The conference was attended by 18 deans and representatives of family medicine departments of medical faculties from seven countries in Southeast Europe, as well as representatives of WHO and UNICEF. The aim of this meeting was to emphasise the role of family medicine as the basis of primary healthcare and to recognise this profession as an academic discipline that has its place in the curricula of medical faculties. The adopted declaration emphasises the importance of harmonising the curricula of the different medical faculties in the region in order to facilitate the exchange of students and staff. The importance of primary healthcare is also reflected in the reports of WHO and UNICEF (13).

At the meeting, the Banja Luka Declaration was adopted, which emphasises the importance of academic family medicine for the development of the field of family medicine and medical faculties in the region. By signing the declaration, the deans reaffirmed their commitment to the promotion of family medicine as an independent medical specialisation with its specific competences, quality standards and research areas. They agreed that family medicine is equal to other medical disciplines, i.e. it is also a scientific and academic discipline with its own approaches to undergraduate and postgraduate education. Family medicine has the potential to actively support the academic development of faculties.

In order to achieve these goals, five initiatives were proposed in the Banja Luka Declaration. These are: Promoting research initiatives in family medicine at the national and international level; Mutual support in providing mentorship for academic development, including doctoral programmes; Facilitating faculty and student exchanges; Promoting interdisciplinary learning and improving the exchange of ideas at all levels of study; and Mutual support in policy dialogues to provide policy makers with collective expertise for effective health policy making.

Although the declaration was signed by academic representatives from South-Eastern European countries, it has the potential to support the wider development of academic family medicine worldwide. This opportunity was recognised by WHO, whose representatives attended the conference. The WHO Regional Director for Europe, Hans Kluge, emphasised the importance of the conference for WHO and stressed that academic family medicine is one of the pillars for the future development of family medicine. Faculties must provide students and trainees with knowledge, skills and attitudes related to the core values of family medicine.

Hopefully, this conference will motivate other countries and medical faculties around the world to join the initiative. For this reason, information about the conference has been sent to WONCA Europe and WHO to disseminate the declaration within their networks.

#### CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

#### FUNDING

The study was not financed.

#### ETHICAL APPROVAL

Since it is an editorial article with no research, we did not ask for ethical approval.

#### AVAILABILITY OF DATA AND MATERIALS

Since it is an editorial article with no research, we do not have data and materials

#### LLM STATEMENT

During the preparation of this article the authors used the GPT language model to:

- review and amend grammatical and spelling mistakes,
- ensure linguistic consistency and coherence,
- test and fine-tune the article's wording,
- format the references.

After using this model, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Petrič M, Kurnik Mesarič K, Kodrič J, Janjušević P. Psychometric validation of the Slovenian version of the Revised Child Anxiety and Depression Scale child and parent versions (RCADS and RCADS-P). Zdr Varst. 2024;63(4):164-171. doi: 10.2478/sjph-2024-0022.

## PSYCHOMETRIC VALIDATION OF THE SLOVENIAN VERSION OF THE REVISED CHILD ANXIETY AND DEPRESSION SCALE -CHILD AND PARENT VERSIONS (RCADS AND RCADS-P) PSIHOMETRIČNA VALIDACIJA SLOVENSKE RAZLIČICE REVIDIRANE

LESTVICE ANKSIOZNOSTI IN DEPRESIJE ZA OTROKE -OBLIKA ZA OTROKE (RCADS) IN STARŠE (RCADS-P)

### Mojca PETRIČ<sup>1</sup>, Katja KURNIK MESARIČ<sup>2,3\*</sup>, Jana KODRIČ<sup>3,4</sup>, Peter JANJUŠEVIĆ<sup>5</sup>

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Received: Feb 20, 2024 Accepted: Jun 10, 2024

ABSTRACT	<b>Objective:</b> Anxiety and depression are common disorders in children and adolescents and can have a negimpact on their lives. The Revised Child Anxiety and Depression Scale - Child and Parent versions (F					
Keywords: RCADS RCADS-P	and RCADS-P) are widely used standardized measurement tools, but the Slovenian versions have not yet been validated. The aim of the present study was to examine the psychometric properties of the Slovenian version of RCADS and RCADS-P in a representative Slovenian school sample.					
Anxiety Depression Psychometric	<b>Methods:</b> We examined the psychometric properties (factor structure, internal reliability, short-term stability, inter-rater agreement and convergent validity) of the Slovenian version of the RCADS and the RCADS-P in 754 primary and secondary school students and parents of 485 students. The short-term stability of anxiety and depressive symptoms in youth was assessed in a subsample of 117 children and adolescents.					
Children Adolescents	<b>Results:</b> Confirmatory factor analysis showed an acceptable fit of the 6-factor model with CFI=0.92, TLI=0.92 and RMSEA=0.056 for RCADS and with CFI=0.93, TLI=0.92 and RMSEA=0.047 for RCADS-P. Cronbach's $\alpha$ and McDonald's $\omega$ ranged from 0.70 to 0.95 for the total scale and the six subscales. The subscales correlated significantly positively with the total Child Anxiety Life Interference Scale score.					
	<b>Conclusion:</b> The results affirm the good psychometric properties of the Slovenian versions of RCADS and RCADS-P within a school-based sample. There is a need in the future to examine psychometric properties in clinical samples and to provide normative data.					
IZVLEČEK Ključne besede: RCADS RCADS-P anksiozne motnje depresije psihometrične lastnosti otroci mladostniki	<b>Namen</b> : Anksiozne motnje in depresija sodijo med pogostejše težave z duševnim zdravjem pri otrocih in mladostnikih. Revidirana lestvica anksioznosti in depresivnosti za otroke - oblika za otroke (RCADS) in starše (RCADS-P) je v svetu pogosto uporabljen, standardiziran merski pripomoček za ocenjevanje anksioznosti in depresivnosti pri otrocih in mladostnikih, ki pa v Sloveniji še ni bil psihometrično preverjen. Namen raziskave je bil preveriti psihometrične značilnosti slovenske oblike lestvic RCADS in RCADS-P na reprezentativnem vzorcu slovenskih osnovnošolcev in srednješolcev.					
	Metoda: Na vzorcu 754 otrok in mladostnikov ter 485 staršev smo preučevali psihometrične značilnosti (faktorsko strukturo vprašalnika, notranjo zanesljivost, kratkoročno stabilnost - retestno zanesljivost, strinjanje med ocenjevalci in konvergentno veljavnost) slovenske oblike vprašalnikov RCADS in RCADS-P. Kratkoročna stabilnost anksioznih in depresivnih simptomov je bila ocenjena v podvzorcu 117 otrok in mladostnikov.					
	<b>Rezultati:</b> Konfirmatorna faktorska analiza je pokazala sprejemljivo ustreznost šest-faktorskega modela z indeksi prileganja CFI = 0,92, TLI = 0,92 in RMSEA = 0,056 za obliko za otroke in mladostnike (RCADS), ter z indeksi prileganja CFI = 0,93, TLI = 0,92 in RMSEA = 0,047 za obliko za starše (RCADS-P). Koeficienti notranje zanesljivosti (Cronbachova a in McDonaldova $\omega$ ) so se gibali med 0,70 in 0,95 za celotno lestvico in podlestvice. Podlestvice so bile pomembno pozitivno povezane s skupnim rezultatom lestvice CALIS, ki ocenjuje vpliv tesnobe na življenje otrok, mladostnikov in njihovih staršev.					
	Zaključek: Rezultati potrjujejo ustrezne psihometrične lastnosti slovenskih oblik lestvic RCADS in RCADS-P pri šolskem vzorcu otrok in mladostnikov. V prihodnosti bi bilo potrebno lestvici preveriti tudi pri kliničnih vzorcih otrok ter zagotoviti normativne podatke za rabo lestvic.					

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#### Zdr Varst. 2024;63(4):164-171

#### **1 INTRODUCTION**

Internalising disorders affect a substantial number of children and adolescents and are a major health priority because of their negative impact on later health, education and well-being (1-3). An increase in internalising symptoms and disorders in children and adolescents had already begun before the COVID-19 pandemic (4-6), and the prevalence of anxiety and depression disorders in children and adolescents increased significantly during the pandemic (7). A meta-analysis revealed an overall pooled prevalence of anxiety and depression of 32% in children and adolescents after the COVID-19 pandemic (8). There is high comorbidity between anxiety and depression (2, 9). Internalising disorders in childhood and adolescence are associated with impaired social functioning, peer difficulties, academic difficulties and underachievement, as well as psychopathology in adulthood (anxiety disorders, depression, substance abuse), and represent a severe social and economic burden (10-15). Early identification and treatment of internalising disorders in childhood and adolescence is important for reducing the negative impact of such disorders. One of the barriers to early identification of internalising symptoms and assessment of the treatment outcomes is the lack of comprehensive, consensus and valid measurement tools (16, 17).

The Revised Child Anxiety and Depression scale (RCADS and RCADS-P (18)) is currently one of the most widely used assessment tools in clinical and nonclinical settings for screening, differentiating and monitoring anxiety and depression symptoms in young people, which allows for the collection of data from multiple informants. Both child and parent versions measure symptoms of anxiety and depression that are included in the DSM criteria for separation anxiety disorder (SAD), social phobia (SP), generalized anxiety disorder (GAD), panic disorder (PD), obsessive-compulsive disorder (OCD), and major depressive disorder (MDD). Although obsessive compulsive disorder is categorized as Obsessive-Compulsive and Related Disorders rather than an anxiety disorder in DSM-5, it is clinically appropriate to continue to assess for OCD along with the anxiety disorders included in the RCADS measure, because of high comorbidity and common treatment components (19).

Favourable reliability, validity and a six-factor structure consistent with DSM-IV criteria for anxiety disorders and depression, have been proven for RCADS and RCADS-P in clinical and nonclinical groups of English-speaking children and adolescents and their parents (19-22). The RCADS has been translated into 26 languages and the RCADS-P into 20 languages. The translations are available on the official website (https://rcads.ucla.edu/versions). Sound psychometric properties have been replicated in clinical and nonclinical samples for both versions (17, 23-32).

In Slovenia, there are two comprehensive assessment tools for internalizing and externalizing disorders in children and adolescents: the Achenbach System of Empirically Based Assessment (Child Behaviour Checklist - CBCL; Youth Self Report - YSR, Teacher Report Form - TRF) (33) and Strengths and Difficulties Questionnaire - SDQ (34). They have not yet been psychometrically examined in the Slovenian sample. Given the increase in symptoms of internalising disorders in children and adolescents. there is a need for reliable and valid assessment tools for internalising problems in childhood and adolescence. The RCADS is a freely available, valid tool, with the option of multiple informant assessment, and can serve not only as a screening tool but also as a diagnostic and treatment monitoring/assessment tool (35). The RCADS is available to users who read and agree to the terms of use, which are provided in the User's Guide (18). The RCADS may be used for educational, professional and research purposes. The aim of the study was to investigate the psychometric and structural properties of the Slovenian versions of RCADS and RCADS-P in a nonclinical sample of children and adolescents aged 10 to 18 years. Based on previous research we hypothesized that the results of this study would confirm the reliability and validity of the six-factor Slovenian RCADS and RCADS-P. A secondary aim of the study was to assess parent-child agreement and shortterm reliability of the child version of the RCADS.

#### 2 METHOD

#### 2.1 Participants

For our study we considered primary and secondary school students (female and male), aged from 10 to 18 years from all the Slovenian regions and their parents. We reached out to Slovenian public primary and secondary schools. Sample characteristics are described in the results in section 3. 1.

#### 2.2 Measures

The Revised Child Anxiety and Depression Scale (RCADS) (18,36) and the Revised Child Anxiety and Depression Scale - Parent Version (RCADS-P) (18,36) are questionnaires with 47 items that were developed to assess anxiety and depression symptoms in children and adolescents aged 8 to 18 years. The items are rated on a 4-point Likert-scale. It comprises 6 subscales: separation anxiety disorder (SAD), social phobia (SP), generalized anxiety disorder (GAD), panic disorder (PD), obsessive compulsive disorder (OCD), and major depressive disorder (MDD). The sum of all six subscales results in the Total Internalizing Scale.

The RCADS and the RCADS-P were translated into Slovenian with the permission of the authors and according to the translation terms and author's instructions (https://rcads.ucla.edu/node/15). The translation was approved by the

authors. The Slovenian versions of the RCADS and RCADS-P are available at https://rcads.ucla.edu/versions.

The Child Anxiety Life Interference Scale (CALIS) (37) is a measure of the interference of anxiety on the lives of children and parents. The child version consists of 9 items, divided into two subscales (Outside home interference and Inside home interference) and total score. The parent version consists of 16 items divided into three subscales (Outside home interference, Inside home interference and Parent life interference) and total score. All items are rated on a five-point Likert scale (37). In the present study, we used the official translation, which was made according to the author's terms and guidelines (38) and was approved by the authors. The CALIS demonstrated strong psychometric properties in other languages (37, 39-41). The internal consistencies in our sample were for the children version  $\omega$ =0.89 for total score,  $\omega$ =0.86 for Outside home interference and 0.75 for Inside home interference. For the parent version, the internal consistencies were  $\omega$ =0.93 for total score,  $\omega$ =0.87 for Outside home interference,  $\omega$ =0.80 for Inside home interference, and  $\omega$ =0.90 for Parent life interference.

#### 2.3 Procedure

The Ethics Committee of the Faculty of Arts at the University of Ljubljana approved the present study. We ensured that all participants - children, adolescents and their parents - were fully informed about the study, and they signed informed consent.

Drawing on data from the Statistical Office of the Republic of Slovenia regarding the number of students by gender in the Eastern and Western Cohesion Regions of Slovenia, we contacted sixteen primary and eleven secondary schools across both Slovenian regions (quota sampling). Out of the schools contacted, 12 primary and 11 secondary schools agreed to participate. School counsellors informed all students and their parents about the study and invited them to participate. However, only those students who themselves and their parents provided informed consent were enrolled in the study. Parents received questionnaires from children and completed them at home. The children completed the questionnaires in their classrooms, where a school counsellor was present to assist with any questions. Attrition rates are described in Results, section 3. 1.

After a three-month interval, a re-assessment was conducted with children from three schools (one elementary and two secondary) that agreed to participated in this step. A total of 129 questionnaires (17% from the original sample) were sent to schools to be distributed to all children and parents from these three schools. The questionnaires were completed in schools or at home. Attrition rates are described in Results, section 3. 1.

#### 2.4 Statistical analysis

The confirmatory factor analysis (CFA) was performed with MPlus version 7.7. (42) to assess how well the empirical data fit a theoretical six-factor model confirmed in previous studies (17, 18, 24, 25, 27, 29, 30, 36). Three alternative models identified from the literature (43) that represent various competing conceptualizations of the relations among internalizing symptoms were tested as well (a single-factor model of internalising disorders, correlated two-factor model of anxiety and depression and five-factor model, combining GAD and MDD into a single factor). The analysis was conducted separately for child and parent versions of the questionnaire. We treated the 4-item Likert scale as categorical and therefore chose weighted least squares with mean and variance adjustment (WLSMV) as the estimation method for analysis. Goodness of fit was assessed using a chi-square statistic (x2), Comparative Fit Index (CFI) (44), Tucker-Lewis Index (TLI) (45) and Root Mean Square Error of Approximation (RMSEA) (46) with 90% confidence interval. CFI and TLI values between 0.90 and 0.95 indicate an adequate model fit, and CFI and TLI values above 0.95 indicate a good fit. RMSEA values above 0.05 and below 0.08 indicate an adequate fit and values below 0.05 indicate a good fit (47, 48).

All other statistical analyses were performed using IBM SPSS Statistics for Windows, version 29. Missing data across all RCADS subscales were managed in accordance with the questionnaire authors' recommendations, with calculations performed for each scale only if it contained fewer than two missing items (18, 36). The internal consistency of the questionnaire was assessed using Cronbach's Alpha ( $\alpha$ ) (49) and McDonald's omega ( $\omega$ ) (50). Reliability values above 0.70 are acceptable and above 0.80 are high (51). For the retest reliability analysis, an interclass correlation coefficient (ICC) was used with a two-way mixed-effects model with an average measure unit and absolute agreement definition. ICCs of 0.70 or higher are adequate (52).

To assess the convergent validity, we examined the correspondence between RCADS total scores and subscale scores and CALIS total scores. We assumed that the correlations between the RCADS and CALIS scores would be positive and significant, which could confirm the convergent validity of the Slovenian RCADS.

#### **3 RESULTS**

#### 3.1 Sample description

Of the 878 children and adolescents and their parents who agreed to participate, 754 (86%) children and adolescents and 485 (64% of those whose children responded) parents returned the questionnaires. The sample consisted of 456 (60.5%) female and 289 (39.5%) male primary and secondary school students, aged 10-18 years (M 13.27, SD

2.08). 532 (70.6%) of the participants attended primary school and 222 (29.4%) attended secondary school. The average age of the boys was 13.19 (SD=2.08) and of the girls 13.32 (SD=2.07). Of those who were invited in the follow-up after three months, 117 children and adolescents (91%) and 36 parents (31% of those whose children responded) returned the questionnaires.

#### 3.2 Factor structure

First, the factor structure of the RCADS was investigated. Table 1 presents the fit statistics for competing models, separately for child version (RCADS) and parent version (RCADS-P). As seen in Table 1, the original six-factor model showed

acceptable fit with the data for both child and parent versions. All factor loadings were significant and ranged from 0.43 to 0.86 for the child version and from 0.42 to 0.89 for the parent version. Poorer model fit was observed for one-, two- and five-factor models in comparison to the six-factor model.

#### 3.3 Descriptive statistics, reliability and validity

#### 3.3.1. Descriptive statistics

The means, standard deviations, medians, skewness, kurtosis and internal consistency coefficients for the RCADS child and parent versions for the entire sample are shown in Tables 2 and 3.

Table 1. Statistics for competing models, for child version (RCADS) and parent version (RCADS-P).

Model	X²	df	р	CFI	TLI	RMSEA	90% CI (RMSEA)
RCADS							
6 factor	3436.856	1019	0.000	0.922	0.918	0.056	0.054- 0.058
5 factor	3653.978	1024	0.000	0.916	0.911	0.058	0.056-0.060
2 factor	4520.724	1033	0.000	0.888	0.883	0.067	0.065-0.069
1 factor	4728.787	1034	0.000	0.880	0.875	0.069	0.067-0.071
RCADS-P							
6 factor	2119.913	1019	0.000	0.927	0.923	0.047	0.044-0.050
5 factor	2261.578	1024	0.000	0.918	0.914	0.050	0.047-0.053
2 factor	2572.491	1033	0.000	0.898	0.893	0.055	0.053-0.058
1 factor	2703.374	1034	0.000	0.890	0.885	0.058	0.055-0.060

Note:  $\chi^2$ =chi-square; df=degrees of freedom; CFI=comparative fit index; TLI=Tucker-Lewis fit index; RMSEA=root mean square error of approximation; CI=90 % confidence interval for RMSEA

Table 2. Descriptive statistics for RCADS.

	M (SD)	Med	Skew.	Kurt.	M (SD) Girls (N=465)	M (SD) Boys (N=289)	α	ω
Total	37.64 (21.8)	35.0	0.93	0.90	42.77 (21.93)	29.96 (17.43)	0.95	0.95
SAD	3.77 (3.27)	3.0	1.09	0.99	4.44 (3.42)	2.68 (2.66)	0.71	0.70
GAD	5.72 (3.46)	5.0	0.81	0.51	6.44 (3.48)	4.56 (3.08)	0.82	0.82
PD	5.65 (4.77)	4.0	1.28	1.51	6.63 (5.17)	4.08 (3.35)	0.86	0.86
SP	10.85 (5.43)	10.0	0.51	-0.03	12.11 (5.37)	8.78 (4.88)	0.86	0.86
OCD	4.56 (3.25)	4.0	0.93	0.88	5.03 (3.34)	3.81 (2.95)	0.74	0.74
MDD	7.30 (5.07)	6.0	1.06	1.03	8.11 (5.31)	5.99 (4.34)	0.87	0.86

Note: RCADS=RCADS Child; RCADS-P=RCADS Parent: Total=Total RCADS Score; GAD=Generalised Anxiety; SP=Social Phobia; SAD=Separation Anxiety Disorder; PD=Panic Disorder; OCD=Obsessive Compulsive Disorder; MDD=Major Depressive Disorder.

	M (SD)	Med	Skew.	Kurt.	M (SD) Girls (N=313)	M (SD) Boys (N=172)	α	ω
Total	23.60 (13.45)	22.0	0.81	0.65	24.05 (13.01)	22.79 (14.22)	0.93	0.94
SAD	2.72 (2.72)	2.0	1.48	2.76	2.76 (2.57)	2.63 (2.98)	0.72	0.72
GAD	3.84 (2.54)	3.0	0.78	0.33	3.97 (4.51)	3.6 (2.58)	0.79	0.81
PD	2.19 (2.35)	4.0	2.16	7.87	2.34 (2.53)	1.93 (1.96)	0.74	0.73
SP	8.55 (4.18)	8.0	0.55	0.69	8.78 (4.18)	8.14 (4.16)	0.83	0.83
OCD	1.79 (2.09)	1.0	2.07	6.74	1.73 (1.87)	1.88 (2.44)	0.71	0.70
MDD	4.61 (3.38)	4.0	0.82	0.76	4.61 (3.30)	4.6 (3.52)	0.80	0.81

Table 3. Descriptive statistics for RCADS-P.

Note: RCADS=RCADS Child; RCADS-P=RCADS Parent: Total=Total RCADS Score; GAD=Generalised Anxiety; SP=Social Phobia; SAD=Separation Anxiety Disorder; PD=Panic Disorder; OCD=Obsessive Compulsive Disorder; MDD=Major Depressive Disorder

#### 3.3.2 Internal consistency

Good internal consistency was found for all subscales and for total score of the child and parent versions. Tables 2 and 3 show the Alpha and Omega coefficients.

#### 3.3.3 Retest reliability

Short-term stability was good with ICC's>0.75 and statistically significant (p<0.001) for the child version (ICC<sub>sad</sub>=0.82; ICC<sub>gad</sub>=0.82; ICC<sub>pd</sub>=0.79; ICC<sub>sP</sub>=0.90; ICC<sub>ocd</sub>=0.77; ICC<sub>mdd</sub>=0.87; ICC<sub>tot</sub>=0.88).

#### 3.3.4 Inter-rater reliability

Interclass correlations (ICC) were conducted between parent and child ratings on the RCADS (sub)scales. Parent-child agreement was low for most subscales (below 0.50) and statistically significant for all subscales (p<0.001): ICC<sub>sad</sub>=0.54; ICC<sub>gad</sub>=0.44; ICC<sub>pd</sub>=0.27; ICC<sub>sp</sub>=0.49; ICC<sub>ocd</sub>=0.23; ICC<sub>mdd</sub>=0.44; ICC<sub>tot</sub>=0.40.

There were no significant differences in the mean results for children and adolescents with or without parental reports ( $p_{tot}$ =0.24;  $p_{sad}$ =0.09;  $p_{gad}$ =0.42;  $p_{pd}$ =0.53;  $p_{sp}$ =0.29;  $p_{ocd}$ =0.44;  $p_{mdd}$ =0.31).

#### 3.3.5 Convergent validity

RCADS total score and CALIS total score correlated statistically significantly (p<0.001) for children (r=0.59) and for parents (r=0.66).

Subscales for children correlated:  $r_{sad}$ =0.48;  $r_{gad}$ =0.50;  $r_{pd}$ =0.45;  $r_{sp}$ =0.51;  $r_{ocd}$ =0.47;  $r_{mdd}$ =0.55. Subscales for parents correlated:  $r_{sad}$ =0.44;  $r_{gad}$ =0.54;  $r_{pd}$ =0.46;  $r_{sp}$ =0.52;  $r_{ocd}$ =0.52;  $r_{mdd}$ =0.62.

#### **4 DISCUSSION**

The original factor structure of the RCADS was confirmed in our sample (18, 36). The results indicate that the sixfactor structure provides satisfactory fit for both the child version and the parent version of the RCADS. The sixfactor structure was also validated in various nonclinical samples, including French (25), Danish(23), Dutch (24), German (28), Irish (21), Norwegian (17) and Chinese (31) populations, as well as in a Turkish clinical sample (29). In addition, the six-factor structure for the parent version was confirmed in a Spanish school sample (27), in the original sample (43), in a Turkish clinical sample (30), and in a sample of youth with ADHD (53). The fit indexes for the child version were similar to those reported in the literature. Previous studies showed a CFI for the child version between 0.83 and 0.92 (17, 23-25, 29, 31, 32) and for the parent version from 0.87 to 0.94 (27, 30, 43, 53), and RMSEA for the child version between 0.034 and 0.052 (17, 23-25, 29, 31, 32) and for the parent version from 0.040 to 0.079 (27, 30, 43, 53). The internal consistency of the total scale was excellent for both the child and parent versions and was consistent with previous studies from several countries (54). The internal consistency of the subscales for the child and parent versions was good. Short-term reliability was good and statistically significant, and the ICC coefficients were like the short-term reliability of the Danish sample (24). Convergent validity was supported by statistically significant positive correlations of RCADS total and subscale scores with CALIS total scores suggesting that higher levels of internalizing symptoms in youth significantly affect their everyday functioning as well as the everyday functioning of parents.

The mean score of the total RCADS scale was higher in our sample than in other nonclinical samples, where scores ranged from 22.3 to 32.3 (23, 24, 28), except for the Norwegian sample, where the mean score for the total scale was higher - 50.7 (17). The mean score of the RCADS-P total scale was comparable to other studies in nonclinical samples (27, 43).

As can be seen from Tables 2 and 3, the parents reported a lower level of symptoms on all scales compared to the children. For most (sub)scales, agreement between parents and children was low (below 0.50), except for the SAD subscale, where agreement was moderate. Agreement was higher than in a previous study with a nonclinical sample, in which coefficients ranged from 0.14 to 0.39; in that study, agreement was also highest for the SAD subscale (43). The results suggest that parentchild agreement differs for different types of anxiety. In a clinical sample of adolescents, the agreement between adolescents and parents was slightly higher than in our sample; the coefficients ranged from 0.26 to 0.61 (55). Our results are consistent with the findings of a systematic review of previous studies, showing low to moderate agreement between children and parents in internalising disorders, which are not always easily detected by parents. (56).

The RCADS and RCADS-P are freely available, valid, and valuable measurement tools for assessing anxiety and depression symptoms in children and adolescents. RCADS was chosen with international consensus on a standard set of outcome measures for child and youth anxiety and depression (16). RCADS is aligned with DSM criteria and can be used to identify individuals who are at higher risk for developing an internalizing disorder and to offer them appropriate early intervention or treatment. RCADS allows for the simultaneous assessment of anxiety and depression which has very important clinical implications, as anxiety and depression are highly comorbid disorders (2, 9). Another potential use of RCADS is to assess treatment efficacy (35), which would be very valuable as we do not have psychometrically validated measures for this use in Slovenia. In clinical samples, both the RCADS and the RCADS-P also show good psychometric properties. They can be used to identify young people with anxiety and depression, and they are useful to clarify additional areas for assessment (20, 55, 57). The RCADS-P has been shown to be diagnostically efficient, sensitive, and fairly specific in diagnosing internalizing disorders in a clinical sample of children and adolescents with ADHD (53). It has also been shown to be useful in assessing internalizing problems in young people with autism spectrum disorders (58).

The present study has both strengths and limitations. We aimed for a high degree of generalizability of the results for our study. The sample was carefully selected in terms of representativeness of population; we took into account factors such as gender, age, geographical distribution and inclusion of different school types. In our study, we considered the assessment of contextual variations through a multi-informant assessment involving children, adolescents and parents. To ensure the reliability of our results, we repeated the assessment three months later and conducted a retest with a subsample of participants. One of the main limitations of our study is use of a nonclinical population. To gain an insight into the value of the RCADS for clinical use, a replication of the present study in a clinical sample would be necessary in the future. Another limitation is limited assessment of validity, which could be extended by using other measures of anxiety and depression in children and adolescents and by investigating discriminant validity. In our sample, there was a gender imbalance - the sample had more girls (60.5%) than boys and that could have an impact on our results. A suggestion for future research would be to examine the psychometric properties of RCADS and RCADS-P in clinical samples. It would also be beneficial to compare the results of RCADS and RCADS-P with those of other pure measures of anxiety and depression and with clinical interviews. Further research is required to assess the effectiveness of RCADS and RCADS-P in predicting clinical diagnoses of anxiety and depressive disorders within the Slovenian population. Additionally, to utilize RCADS and RCADS-P for screening purposes, it is essential to determine whether the original cut-off scores are appropriate for the Slovenian population.

There is a need for valid and psychometrically robust tools in the Slovenian language. In recent years, significant progress has been made in this area, with an increasing number of questionnaires from various fields being adapted and psychometrically validated (59-61). This study aims to contribute to this progress by providing a psychometric validation of RCADS and RCADS-P.

#### **5 CONCLUSION**

In conclusion, the Slovenian version of RCADS and RCADS-P has adequate psychometric properties. The factor structure favours a six-factor model, and internal consistency and convergent validity are high. The Slovenian version of RCADS and RCADS-P are valid and reliable instruments for measuring anxiety and depression symptoms. Further research is needed for validation in a clinical setting and for providing normative data for both school and clinical samples.

#### ACKNOWLEDGMENTS

We thank psychologists Lidija Magajna, Daša Vervega and Mateja Hudoklin from the Counselling Centre for Children, Adolescents, and Parents Ljubljana for their invaluable help with the data collection, and psychologists Gaja Zager Kocjan and Luka Komidar from the University of Ljubljana for their consultations. Our sincere thanks also go to all participating children, adolescents, parents, schools and school psychologists for their important contributions to this study.

#### CONFLICTS OF INTEREST

The authors declare that they have no competing or potential conflicts of interest.

#### FUNDING

KKM is funded by the Slovenian Research Agency under the Young Researcher Programme and is a PhD student at the University of Ljubljana.

#### ETHICAL APPROVAL

The Ethics Committee of the Faculty of Arts, University of Ljubljana approved the study. The children, adolescents and parents were informed verbally and in writing about the study, and written informed consent was obtained.

#### AVAILABILITY OF DATA AND MATERIALS

The data presented in this study can be obtained upon request from the corresponding author.

#### CONTRIBUTORSHIP

All authors were involved in writing the paper and gave final approval of the submitted and published versions.

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Poklar Vatovec T, Jakus T, Pucer P, Prunk Franetič B, Stubelj M. The results of the "My Challenge" camp in addressing childhood obesity. Zdr Varst. 2024;63(4):172-179. doi: 10.2478/sjph-2024-0023.

## THE RESULTS OF THE "MY CHALLENGE" CAMP IN ADDRESSING CHILDHOOD OBESITY

## REZULTATI TABORA »MOJ IZZIV« PRI OBRAVNAVI PREKOMERNO HRANJENIH OTROK

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Received: Feb 20, 2024 Accepted: Jun 10, 2024 Original scientific article

ABSTRACT	Introduction: This article presents the development, implementation and results of the project "An interdisciplinary approach to the treatment of overweight children" under the name "My Challenge" camp. It is a
Keywords: Diets Food Nutrition Health promotion Childhood obesity Overweight	2-week multidisciplinary programme involving a physician, a dietitian, a psychologist, an occupational therapist or physiotherapist and a kinesiologist. The children stay in camp for 2 weeks and are actively involved in the daily preparation of healthy meals, participate in cooking workshops and interactive nutrition lessons, and are active outdoors throughout the programme.
	Methods: The study included 117 overweight or obese children, aged 7-18 years, 66 girls and 51 boys from ten camps between 2017 and 2023. Completed dietary questionnaires and anthropometric measurements were compared at baseline, after 2 weeks, and after 1 month.
	Results: Changes in children's diets include an increase in meal frequency, in higher vegetables, fish, and seafood consumption, lower consumption of fried food and reduced consumption of sugary drinks. Boys more

frequently consume fried food than girls and less frequently consume milk and dairy products. After one month, there was a decrease in body fat percentage, waist circumference and waist-to-height ratio in both genders. **Conclusions:** The "My Challenge" camp demonstrates promising outcomes in combating childhood obesity. Through a two-week multidisciplinary programme, significant improvements in dietary habits and anthropometric

**Conclusions:** The "My Challenge" camp demonstrates promising outcomes in combating childhood obesity. Through a two-week multidisciplinary programme, significant improvements in dietary habits and anthropometric measures were observed. The findings underscore the importance of preventive education programmes for children in addressing the long-term health consequences of obesity. Further research and continued implementation of such initiatives are warranted to effectively tackle this public health issue.

#### IZVLEČEK

Ključne besede: diete hrana prehrana spodbujanje zdravja debelost v otroštvu prekomerna telesna masa **Uvod**: Debelost v otroštvu ima številne negativne fiziološke in psihološke posledice za zdravje, ki se lahko prenašajo tudi v odraslo dobo. Preventivni izobraževalni programi in programi osveščanja za otroke lahko pomagajo omiliti te negativne posledice. Ta članek predstavlja razvoj, izvajanje in rezultate projekta »Interdisciplinarni pristopi pri obravnavi prekomerno hranjenih otrok in mladostnikov« pod imenom tabor »Moj izziv«. Gre za 2-tedenski multidisciplinarni program, ki vključuje zdravnika, dietetika, psihologa, delovnega terapevta ali fizioterapevta ter kineziologa. Otroci so v taboru dva tedna in so aktivno vključeni v vsakodnevno pripravo zdravih obrokov, sodelujejo v kuharskih delavnicah in interaktivnih izobraževanjih o prehrani ter so aktivni na prostem ves čas programa. Program vključuje tudi aktivno prisotnost staršev ali skrbnikov med vikendom. Vsi udeleženci imajo dostop do e-materialov o prehrani, receptih in jedilnikih, tudi ko se vrnejo v domače okolje.

**Metode:** V študijo je bilo vključenih 117 otrok s prekomerno telesno maso ali debelostjo, starih od 7 do 18 let, 66 deklic in 51 dečkov iz desetih taborov med leti 2017 in 2023. Izpolnjene vprašalnike o prehrani in antropometrične meritve smo primerjali na začetku, po dveh tednih in po enem mesecu. Poleg tega smo ugotavljali razlike v prehranjevalnih vzorcih med deklicami in dečki.

**Rezultati:** Opazne spremembe v prehrani otrok vključujejo povečanje pogostosti uživanja obrokov na več kot dva na dan, večjo pogostost uživanja zelenjave, rib in morskih sadežev, manjšo pogostost uživanja ocvrte hrane ter manjšo pogostost uživanja sladkih pijač. Dečki bolj pogosto kot deklice uživajo ocvrto hrano in manj pogosto uživajo mleko in mlečne izdelke. Po enem mesecu se je zmanjšal odstotek telesnega maščevja, obseg pasu in razmerje med obsegom pasu in višino pri obeh spolih.

Zaključki: Interdisciplinarni pristop, ki je bil izveden v taboru »Moj izziv«, kaže obetavne rezultate pri boju proti otroški debelosti. S pomočjo dvo-tedenskega multidisciplinarnega programa, ki vključuje strokovnjake s področja zdravstva, smo opazili pomembne izboljšave v prehranjevalnih navadah in antropometričnih meritvah. Ugotovitve poudarjajo pomen preventivnih izobraževalnih programov za otroke pri zmanjševanju dolgoročnih zdravstvenih posledic debelosti. Nadaljnje raziskave in nadaljnja izvajanja takšnih izobraževanj je potrebnih, da se učinkovito spopademo s tem javnozdravstvenim problemom.

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#### **1 INTRODUCTION**

Childhood obesity is the most important public health issue of the 21st century. It signals a higher risk of developing various chronic non-communicable diseases such as diabetes, cardiovascular disease, certain types of cancer and osteoporosis (1). It is a complex condition with multiple factors, defined as non-modifiable factors such as genetics, ethnic differences, gestational weight and intrauterine conditions, as well as modifiable factors such as socioeconomic status, diet, physical activity, sleep and parental factors (2, 3). Obesity can affect children's psychological health, social and emotional well-being, and self-esteem (4). Nutrition education can play an important preventive role here, as a healthy and balanced diet is not only important for each individual, but also influences the physical health of future generations (5). Overall, any nutritional education equips children with the knowledge and skills necessary to make informed decisions about their dietary choices, leading to better health outcomes both in childhood and throughout their lives (6-10). Research indicates that Slovenian children have unhealthy eating habits. An international study on health-related behaviours during the school years revealed that only 39.8% of children consume fruit daily, and even worse, only 35.9% consume vegetables every day. The consumption of sugary drinks has decreased over the years, but is still too frequent. Their consumption is more widespread among boys and increases with the age of children (11,12). Worrying data have directed public health efforts in Slovenia to the development of programmes that address these problems (13).

This article presents the development, implementation and results of the "My Challenge" camp project initiated by the RCS health resort at Debeli Rtič, co-financed by the Ministry of Health of the Republic of Slovenia (13). The project included nutrition and cooking education focusing on content characteristic of changing poor eating habits. The objective of this study was to investigate the effects of an intervention on changes in weight, body mass index (BMI), body fat percentage, waist circumference and waistto-height ratio (WHtR) in boys and girls over a period of 1 month. In addition, changes in eating habits and genderspecific differences were analysed.

#### 2 METHODS

#### 2.1 Study design

A one-group pretest-posttest design was used to assess anthropometric changes and changes in eating patterns after 2 weeks and 1 month. In addition, gender differences in these changes were analysed. The project was developed in collaboration with various experts, including a physician, a dietitian, a psychologist, an occupational therapist or physiotherapist and a kinesiologist. It is part of the measures provided for in the Slovenian Government's national plan to combat childhood obesity (13). It took place under the name "My Challenge" camp in the health resort of RCS Debeli Rtič. The recruited children stay at the camp for two weeks and are actively involved in the preparation and portioning of their meals. They have a cooking workshop twice a day where they prepare and eat two meals. They also have interactive nutrition lessons twice a day, where the dietitian combines nutrition education with didactic games. All activities were supervised by an experienced dietitian. During the main meal (lunch), dietitians and dietetics students supervised the children (individually) as they selected meals at the resort's self-service restaurant and helped them determine portion sizes, choose more appropriate foods and balance the ratio of vegetables to starchy foods. They had no access to other foods during their two weeks at the camp. The two-week camp is followed by a measurement after one month.

#### 2.2 Participants

Based on the criteria of professional Slovenian guidelines (14), personal paediatricians referred children to the camp. The programme includes overweight or obese children aged 7-18 with: a) obesity; b) overweight, where a 6-month intervention at the primary level has not been successful; c) overweight, with complications. A total of 10 camps were held from 2017 to 2023 and 148 children were recruited for the camp. However, 31 children were missing at the third measurement (after 1 month) due to Covid-19, other diseases and unknown reasons. We excluded them from this study due to incomplete data. A total of 117 children completed all measurements.

#### 2.3 Cooking workshops

The cooking workshops are divided into theoretical and practical parts. In the theoretical part of workshop, participants learn how to prepare healthy meals, how to handle kitchen utensils, how to use kitchen scales, measuring cylinders and adhering to hand hygiene rules. In the practical part, they receive a booklet with recipes for all the dishes they have prepared, focusing on the inclusion of vegetables, fruit, and grains. Under the guidance of a dietitian, they cut, cooked and decorated various dishes. They then prepared the dining room and ate the prepared meals together.

#### 2.4 Nutrition lessons and didactic games

The nutrition lessons cover the following topics: food groups, nutrient and energy values of selected foods, healthy plate, eating fruits and vegetables, health benefits of eating fruits and vegetables, reading food labels, planning breakfast, determining portion sizes, fluid intake, salt in the diet and composition of foods. As part of nutritional education, six didactic games were utilized. Simple games contents were prepared and conducted by a dietitian.

#### 2.5 Screening questionnaire

The screening questionnaire included 11 items on eating habits, which can be categorized as unhealthy depending on the answer and are defined as risk factors in Slovenia (15). The statements were: I eat two or fewer meals a day: I never eat breakfast; I consume milk and dairy products less than once a day; I eat fruit less than once a day; I eat vegetable less than once a day; I eat red meat 3 times a week or more; I eat fish and seafood 3 times a month or less; I eat whole grain products/meals (cereals or porridge) 3 times a month or less; I eat fried food 1 time per week or more often; I consume soft drinks and beverages with added sugar (carbonated sweet beverages, flavoured water, fruit syrup) 1-3 times a week or more often; I eat margarine, butter, cream or lard every day. The answer "yes" means an unhealthy eating habit and is scored as zero, the answer "no" means a healthy eating habit and is scored as one point. The higher the total value, the better the eating habits. The highest healthy eating score is 11 points.

#### 2.6 Anthropometric measurements

Height, waist circumference and body composition were measured in all children on arrival at the camp, after 2 weeks and after 1 month. All measurements were taken between 7:00 and 9:00 a.m. under standardized conditions by the same dietitian after the children had fasted overnight. The height of the children was measured to the nearest 0.1 cm while standing, without shoes, using the Leicester height meter (Invicta Plastics Limited, Oadby, England). The children's body weight (kg) was measured with an accuracy of 0.1 kg. BMI was calculated using the following formula: Weight (kg)/Height (m2). The BMI z-score was calculated according to the WHO reference for growth standards for children aged 5-19 years (16). Waist circumference (WC) was measured with a tape measure in a standing position. WHtR was calculated: WC (cm)/Height (cm) (17). Body composition, total body fat mass and fatfree mass were determined using the Tanita BC 418MA bioelectrical impedance analysis (BIA) (Tanita Corporation, Arlington Heights, IL) and the data were analysed using GMON Pro 3.2.1 software from the same manufacturer.

#### 2.7 Statistical analyses

To describe the basic characteristics of the participants, we used descriptive statistics, including mean and standard deviation (SD). Independent-Samples T Test was used to compare the children's characteristics by gender. To determine statistically significant differences between baseline, after 2 weeks and 1 month, we paired descriptive statistics with the results of inferential statistics. Given that some of the data groups were not normally distributed, we used the Wilcoxon signed-rank test and Mann-Whitney U test and the paired samples t-test for normally distributed groups of data.

All statistical analyses were conducted using the IBM SPSS 29 (Statistical package for the Social Sciences). The study protocol was approved by the National Medical Ethics Committee of Slovenia (No. 0120-631/2017/2).

#### **3 RESULTS**

## 3.1 Anthropometric measurements and healthy eating score

A total of 117 children participated in the study, with 66 (56%) girls and 51 (44%) boys. The anthropometric measurements and healthy eating score at baseline, after 2 weeks and after 1 month are shown in Table 2 for girls and Table 3 for boys. Boys weighed 79.0 kg initially, reducing to 75.9 kg after 2 weeks (p<0.001), and girls started at 71.1 kg, reaching 68.4 kg after 2 weeks (p<0.001). After 1 month, boys weighed 75.2 kg (p<0.001), and girls 67.7 kg (p<0.001). In boys, initial BMI decreased from 31.0 kg/ m<sup>2</sup> to 29.6 kg/m<sup>2</sup> (p<0.001) after 2 weeks and reached 29.0 kg/m<sup>2</sup> after 1 month (p<0.001). The girls' average BMI started at 28.9 and decreased to 27.7 kg/m<sup>2</sup> after 2 weeks (p<0.001), reaching its lowest value after 1 month at 27.3 kg/m<sup>2</sup> (p<0.001). Initial WHO BMI-for-age z-score for boys decreased from 3.24 to 2.99 after 2 weeks and reached 2.90 after 1 month. Initial WHO BMI-for-age z-score for girls decreased from 2.69 to 2.49 after 2 weeks, reaching its lowest value after 1 month at 2.39. Fat percentage in boys decreased from an average of 38.3% at the beginning to 36.5% after 2 weeks (p<0.001), and further to 35.1% after 1 month (p<0.001). In girls, the percentage of body fat started at 37.4%, decreased to 36.8% after two weeks (p<0.001), and reached its lowest value after 1 month at 35.7% (p<0.001). Lean body mass was 45.9 kg at the beginning, reducing to 44.9 kg after 2 weeks (p<0.001), and reaching 45.3 kg after 1 month (p=0.001). In boys, lean body mass decreased from 48.5 kg to 47.9 kg after 2 weeks (p=0.002) and remained at 48.5 kg after 1 month (p=0.292). Girls started at 43.9 kg, decreased to 42.5 kg after 2 weeks (p<0.001), and reached 42.8 kg at the end of followup (p<0.001). The mean waist circumference decreased from 95.9 cm at the beginning to 91.9 cm after 2 weeks (p<0.001) and further to 86.9 cm after 1month of followup (p<0.001). In boys, the initial waist circumference of 99.8 cm decreased to 95.6 cm after 2 weeks (p<0.001) and further to 89.7 cm after 1 month (p<0.001). Girls' waist circumference decreased from an initial 92.9 cm to 88.9 cm after 2 weeks (p<0.001), with the mean value reaching its lowest at 84.6 cm after 1 month (p<0.001). In girls, the initial WHtR was 0.60, decreasing to 0.57 after 2 weeks (p<0.001) and reaching 0.54 at the end of the one-month follow-up (p<0.001). In boys, the baseline WHtR was 0.63, decreasing to 0.60 after 2 weeks (p<0.001) and further to 0.56 after 1 month (p<0.001). The score for healthy eating was 6.6 at the beginning of the study, increasing to 8.9 after 2 weeks (p<0.001) and reaching 7.3 points after 1 month (p<0.001). Boys started at 6.3 points, increasing to 8.8 after 2 weeks (p<0.001) and remaining at 6.9 points after 1 month (p<0.001). Girls scored 6.8 points initially, reaching 8.9 points after 2 weeks (p<0.001) and remaining at 7.6 points after 1 month (p<0.001). The only significant difference between genders was observed in the healthy eating score after one-month (U=1289.5, p<0.028).

#### 3.2 Gender differences in eating patterns

Table 3 shows gender differences in eating patterns. A higher percentage of boys compared to girls, 37% versus 20% (p=0.035), never eat breakfast. After one month, the percentage of boys who never eat breakfast was still higher, but not statistically significant. However, we found statistically significant differences in milk and dairy products consumption. More boys than girls, 47% versus 24% (p=0.010), consumed milk and dairy products less than once a day. Similarly, more boys than girls, 51% vs. 30% (p=0.024), consumed fried foods once a week or more often.

Table 1. Anthropometric measurement and healthy eating score at baseline, after 2 weeks and after 1 mor	th for girls.
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Girls	Baseline	After 2 weeks			After 1 month		
66 (36.4%)	Mean±SD	Mean±SD	t	р	Mean±SD	t	р
Body mass (kg)	71.1±20.7	71.1±20.7	-17,573	<0.001	67.7±19.72	-12,435	<0.001
Body height (cm)	155.1±12.87	155.1±12.87			155.8±12.44	4,384	<0.001
WC (cm)	92.9±12.60	92.9±12.60	-8,898	<0.001	84.6±12.15	-6,951	<0.001
Fat mass (kg)	27.3±10.88	27.3±10.88	-9,224	<0.001	27.3±10.88	-9,972	<0.001
Fat percentage (%)	37.4±5.21	37.4±5.21	-3,351	<0.001	35.7±5.74	-6,62	<0.001
Fat free mass (kg)	43.9±10.88	43.9±10.88	-6,038	<0.001	42.8±10.43	-4,719	<0.001
BMI (kg/m²)	28.9±4.74	28.9±4.74	-20,021	<0.001	27.3±4.71	-12,768	<0.001
WHtR	0.60±0.06	0.60±0.06	-8,718	<0.001	0.54±0.06	-7,030	<0.001
Healthy eating score	6.8±1.90	6.8±1.90	13,460	<0.001	7.6±1.81	4,293	<0.001

Legend: WC, waist circumference; BMI, body mass index; WHtR, waist to height ratio; Healthy eating score was calculated from answers yes or no; Yes, means an unhealthy eating habit and is scored as zero, the answer no means a healthy eating habit and is scored as one point. The higher the total value, the better the eating habits. Statistical significance: p<0.05.

Table 2. Anthropometric measurement and healthy eating score at baseline, after 2 weeks and after 1 month for boys.

Boys	Baseline	After 2 weeks			After 1 month		
51 (43.0%)	Mean±SD	Mean±SD	t	р	Mean±SD	t	р
Body mass (kg)	79.0±21.52	75.9±21.06	-22,470	<0.001	75.2±20.72	-15,092	<0.001
Body height (cm)	158.8±11.48	158.8±11.48			159.7±11.52	6,885	<0.001
WC (cm)	99.8±11.82	95.6±12.09	-8,713	<0.001	89.7±15.45	-6,100	<0.001
Fat mass (kg)	30.5±10.86	28.0±10.19	-22,470	<0.001	26.7±9.59	-9,819	<0.001
Fat percentage (%)	38.3±6.75	36.5±5.90	-4,618	<0.001	35.1±6.07	-7,659	<0.001
Fat free mass (kg)	48.5±13.43	47.9±12.74	-3,573	<0.001	48.5±13.36	-1,053	0.292
BMI (kg/m²)	31.0±4.92	29.6±4.89	-10,337	<0.001	29.0±4.76	-11,115	<0.001
WHtR	0.63±0.06	0.60±0.06	-8,745	<0.001	0.56±0.09	-6,093	<0.001
Healthy eating score	6.3±1.93	8.8±1.27	15,286	<0.001	6.9±1.69	3,521	<0.001

Legend: WC, waist circumference; BMI, body mass index; WHtR, waist to height ratio; Healthy eating score was calculated from answers yes or no; Yes, means an unhealthy eating habit and is scored as zero, the answer no means a healthy eating habit and is scored as one point. The higher the total value, the better the eating habits. Statistical significance: p<0.05.

Statements	Boys baseline 51 (43.6%)	Girls baseline 66 (56.4%)			Boys baseline 51 (43.6%)	Girls baseline 66 (56.4%)		
	%	%	U	р	%	%	U	р
l eat two or fewer meals a day	12	11	1663.5	0.844	12	5	1561.5	0.148
l never eat breakfast	37	20	1387.5	0.035	31	17	1435.5	0.062
l consume milk and dairy products less than once a day	45	33	1485.0	0.197	47	24	1299.0	0.010
l eat fruit less than once a day	45	33	1485.0	0.197	25	29	1627.5	0.693
I eat vegetable less than once a day	43	48	1593.0	1.000	35	30	1599.0	0.569
l eat red meat 3 times a week or more	47	42	1605.0	0.618	47	39	1554.0	0.408
I eat fish and seafood 3 times a month or less	69	74	1588.5	0.505	63	62	1672.5	0.945
l eat whole grain products/meals (cereals or porridge) 3 times a month or less	39	23	1405.5	0.054	35	24	1497.0	0.194
l eat fried food once a week or more often	59	42	1407.0	0.080	51	30	1335.0	0.024
l consume soft drinks and beverages with added sugar 1-3 times a week or more often	45	41	1612.5	0.651	25	26	1678.5	0.974
I eat margarine, butter, cream or lard every day	43	55	1491.0	0.223	41	55	1458.0	0.153

Table 3. Gender differences from a screening questionnaire, percentage of answers "Yes".

Legend: Statistical significance: p<0.05.

#### **4 DISCUSSION**

Our study examined the results of the "My Challenge" camp by determining changes in measuring anthropometric parameters and eating patterns at baseline, after 2 weeks and after 1 month. The participants were 117 children, 66 girls and 51 boys. A total of 10 camps were held from 2017 to 2023. Key findings of this study were: (a) reduction in weight and BMI; (b) reduction in body fat percentage; (c) decrease in waist circumference and WHtR; (d) improvement in healthy eating score; (e) gender differences in eating habits. The camp aimed to provide theoretical and practical knowledge to the children through cooking workshops and interactive nutrition lessons. The impact of nutrition education on the nutritional knowledge and habits of children and adolescents has been studied by many researchers. Kostanjevec (18) conducted an extensive study among ninth grade primary school students. The aim of the study was to analyse students' eating habits and assess their knowledge, attitudes and intentions regarding healthy eating before and after the implementation of nutrition education. The research results showed that formal nutrition education is effective, as students' nutrition knowledge improved after the training, but it has no effect on changing dietary habits. Contrary to these results, some research (19, 20) confirms the effectiveness of nutrition education and shows that those who participate in nutrition education are more likely to consume the recommended amounts of fruit and vegetables. As nutrition education plays a crucial role in establishing appropriate dietary habits, children should be equipped with appropriate nutritional knowledge (21, 22). In our study, however, the participants acquired appropriate nutritional knowledge during the culinary workshops in the morning and afternoon, which were led by a dietitian. Nutritional knowledge and skills were acquired also with the help of computer programmes and desktop learning games. The use of educational games to teach nutritional content stimulate attention more than traditional methods and allowed for repetition and reinforcement of data, facts and acquiring more knowledge while having fun (23).

Although we did not test knowledge, we noted differences in food intake. We found that children after 2 weeks acquired more appropriate eating patterns. Of course, the results were to be expected, as the children had reduced their access to junk food, fried food and sweet drinks during this 14-day period. They therefore had time to get to know new types of vegetables and to focus intensively on healthy eating. Children and young people cite the relatively easy access and good taste of disappointing foods as the main barrier to eating healthy foods (24). Because of these obstacles, children and young people need to discover new and different flavours of the recommended foods, especially by actively participating in their preparation. At camp, the children prepared healthy and appealing snacks as part of the practical training and discovered different foods and new, unfamiliar flavours. For example, we prepared various spreads from cooked fish, which the children liked better due to their consistency and they therefore ate more fish. Perhaps this was also a result of the children's education, similar to what Mahmudiono et al. report (25). However, we wanted to know whether the effect would still be visible after a month. We found that even after one month, a greater proportion of children were eating more than two meals a day, eating more fish and seafood dishes, eating less fried food and drinking fewer sugary drinks. Interestingly, we did not see a higher proportion of vegetables in the daily diet after 14 days, but the results showed up later. After one month, 68% of the children included at least one portion of vegetables per day. This is much better than other Slovenian children who in a much lower percentage (35.9%) consume vegetables every day (11). It is interesting to note that even at the beginning of the camp a high proportion of children ate breakfast every day (73%). This has improved to 77%, which we are pleased about as breakfast is a very important meal to prevent obesity (26). The healthy eating scores after 1 month (Table 1 for girls and Table 2 for boys) also show improvements. However, girls were more successful, as they had a better healthy eating score than boys. Our results are consistent with the HBSC survey (11), which shows that a higher percentage of girls consume fruit and vegetables more often and sweet drinks less often, but according to the HBSC survey, a higher percentage of boys regularly consume breakfast, which was shown to be the opposite in our survey. Nevertheless, we only found statistically significant differences in the consumption of milk and dairy products. More boys than girls, 47% compared to 24%, consume milk and dairy products too rarely, and more boys than girls, 51% compared to 30%, consume fried food too frequently. We also observed a decrease in body weight, although the children increased in height in both sexes. There were statistically significant changes - decrease in fat mass, increase in fat-free mass and improvement in WHtR. Of course, the encouraging results are not only due to the change in dietary intake, but also to the physical activity that the children did every day at the camp, and perhaps they were also more active at home.

The study by Howard et al. (27) indicates that children are more receptive to new tastes when they experience them together with high-energy foods. The preparation of meals for the children in the camp was also based on this fact, i.e., the combination of different types of vegetables with energy-rich foods such as cream, parmesan, peanut butter and similar foods. Parents were also partly involved in nutritional education and have a considerable influence on establishing appropriate eating habits in childhood (28). Therefore, the effectiveness of programmes and approaches to change dietary habits can be further improved by involving parents. Other similar interventions have also shown that nutrition interventions can improve dietary intake, however evidence of the long-term sustainability of these impacts is limited (29). Interventions that modify the environment may be effective in improving children's dietary patterns, both in the short and long term (30). There are interesting results in the research of Strączek et al. (31) and Ranucci et al. (32), who found, similar to our research, significant improvements in body weight, waist and hip circumference, WHtR and positive effects also on changing eating habits in children. When developing the "My Challenge" programme, we reviewed and took into account the British recommendations for dealing with childhood obesity (33) as well as programmes that are already being implemented in Slovenia (34), but there is still a gap in the area of intensive cooking education. Research shows that such programmes have a positive impact on children's eating habits (35, 36).

Nevertheless, it is important to recognise the limitations associated with this study. The data we used in our study covers a short period of time for the children and the study was a one-group pretest-posttest design. Another limitation is that the children were individually supported in their food choices by a dietitian, which could have an overly suggestive influence on the children's dietary choices. A limitation of our study is also the screening method for (un)healthy eating, which is based on dichotomous responses and a limited number of dietary factors. However, the results of this study are important for the conclusions and further design of similar public health projects in this area, as childhood obesity is a major public health problem. It is crucial to note that our research group consisted only of children who completed all measurements, leading to a possible bias as their continued participation could indicate greater motivation.

#### **5 CONCLUSION**

The described study provides insight into a public health intervention implemented in Slovenia as part of the national plan of the Republic of Slovenia to combat childhood obesity (13). In the study, we have highlighted short-term results that are very encouraging, as well as the challenges that experts working with children see in the funding and approval of programmes. The 2-week intervention had an impact on children's anthropometric measurements and eating habits after one month, with clear gender differences observed for certain eating habits. Further research and continued implementation of such initiatives are warranted to effectively tackle this public health issue.

#### ACKNOWLEDGMENT

The authors would like to thank all those who took part in the survey.

#### CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

#### FUNDING

The project "An interdisciplinary approach to the treatment of overweight children" under the name "My Challenge" camp was funded by the Republic of Slovenia, Ministry of Health. Public call for co-financing of programmes in the field of nutrition and physical activity for health for the years 2017, 2018 and 2019, No. C2711-17-708312, dated 20 March 2017, published by the Ministry of Health. Public call for co-financing of programmes in the field of nutrition and physical activity for health until 2022, No. 181-122/2019/1, of 28 May 2017, published by the Ministry of Health. Public call for co-financing of health protection and strengthening programmes until 2025, No. C2711-22-185024 of 12.12.2022 (Official Gazette of the Republic of Slovenia, No. 74/22).

#### ETHICAL APPROVAL

The study protocol was approved by the Slovenian National Medical Ethics Committee (No. 0120-631/2017/2). Written informed consent was obtained from all subjects who participated in the study. The questionnaire was anonymous and the data collected was used only for the purposes of the research. Informed Consent Statement: All participants included in "My Challenge" camp project consented to publication. No additional individual person's data in any form (details, images or videos) were used.

#### AVAILABILITY OF DATA AND MATERIALS

All data and materials used in this study are available upon reasonable request.

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## SMOKERS' CHARACTERISTICS ASSOCIATED WITH SUCCESSFUL SMOKING CESSATION UNDERGOING PHARMACOTHERAPY IN SLOVENIA

ZNAČILNOSTI KADILCEV, POVEZANE Z USPEŠNIM OPUŠČANJEM

KAJENJA S FARMAKOTERAPIJO V SLOVENIJI

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Received: Mar 21, 2024 Accepted: Jul 22, 2024 Original scientific article

#### ABSTRACT

#### Keywords:

Tobacco use Tobacco use disorder Smoking cessation Drug therapy **Introduction:** Tobacco use is a major global health problem, contributing to premature death and disability. In Slovenia, the prevalence of smoking is higher than the EU average, emphasizing the need for effective tobacco control measures. The aim of this study was to identify the characteristics of patients most likely to benefit from pharmacotherapy for smoking cessation.

**Methods:** We performed cross-sectional analysis of factors associated with successful smoking cessation using pharmacotherapy for Slovenian smokers. A total of 176 (24.6%) smokers with an average age of 50 years agreed to receive pharmacotherapy for their smoking cessation attempt and were enrolled in the study. Participants were followed up at 4-week intervals during treatment and for 24 weeks after completion of pharmacotherapy.

**Results:** Attempts to quit smoking with prescription medications were successful in 24.4% of those willing to try. Female smokers, older persons, those with more children, with a lower self-perception of health, a higher number of cigarettes per day and a higher nicotine dependence were more likely to attempt to quit smoking. However, the strongest predictors of smoking cessation success were lower nicotine dependence, which was tested using the Fagerström test for nicotine dependence, and higher adherence to pharmacotherapy.

**Conclusion:** Nicotine dependence and adherence to pharmacotherapy are the strongest predictors of a successful smoking cessation attempt. Identification of potential responders, prescription of pharmacotherapy and follow-up are applicable in the primary healthcare setting.

#### IZVLEČEK

Ključne besede: uporaba tobaka odvisnost od nikotina opuščanje kajenja farmakoterapija **Uvod**: Kajenje je pomemben svetovni zdravstveni problem, ki prispeva k prezgodnji smrti in invalidnosti. Slovenija ima višjo razširjenost kajenja v primerjavi s povprečjem EU, kar poudarja potrebo po učinkovitih ukrepih za nadzor tobaka. Namen te študije je bil ugotoviti značilnosti bolnikov, ki jim bo farmakoterapija pri opuščanju kajenja najverjetneje koristila.

**Metode:** Opravili smo presečno analizo dejavnikov, povezanih z uspešno opustitvijo kajenja z uporabo farmakoterapije pri slovenskih kadilcih. 176 kadilcev s povprečno starostjo 50 let se je strinjalo z uporabo farmakoterapije za poskus opustitve kajenja in so bili vključeni v študijo. Udeležence smo spremljali v 4-tedenskih intervalih med zdravljenjem in 24 tednov po zaključku farmakoterapije.

**Rezultati:** Poskus opustitve kajenja z zdravili na recept je bil uspešen pri 24,4 % kadilcev. Kadilke, starejše osebe, z več otroki, z nižjo samooceno zdravja, večjim številom pokajenih cigaret na dan in večjo odvisnostjo od nikotina so pogosteje poskušale opustiti kajenje. Vendar pa je bilo ugotovljeno, da sta manjša odvisnost od nikotina, preizkušena s Fagerströmovim testom za odvisnost od nikotina, in višja adherenca farmakoterapiji najmočnejša napovedna dejavnika uspeha pri opuščanju kajenja.

**Zaključek**: Odvisnost od nikotina in upoštevanje farmakoterapije sta najmočnejša napovedna dejavnika uspešnega poskusa opustitve kajenja. Tako identifikacija možnih odzivnikov in predpisovanje farmakoterapije kot nadaljnje spremljanje se lahko izvajajo v osnovnem zdravstvenem varstvu.

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#### **1 INTRODUCTION**

Tobacco use is a leading preventable risk factor for noncommunicable chronic diseases and premature death worldwide, leading to more than eight million deaths and 170.9 million disability-adjusted life-years lost each year (1). In 2019, more than one billion individuals worldwide were tobacco users. In Slovenia, the prevalence of smoking is 27.9%, which is higher than the EU average of 26.1% (2). According to the Global Burden of Disease study, in 2019 smoking was the second most important risk factor for female deaths and most important factor for male deaths worldwide (3). There is strong scientific evidence that tobacco use inflicts harm on almost every organ in the human body and has detrimental effects on overall health throughout one's lifetime (4), but tobacco users are most at risk for developing lung cancer, chronic obstructive pulmonary disease (COPD) and ischemic heart disease due to smoking (5). Therefore, reducing tobacco use is essential for improving public health and limiting the tobacco epidemic (6).

Smoking also represents a heavy economic burden for healthcare systems throughout the world (3). This includes direct costs (costs of inpatient care, outpatient visits, drugs and diagnostic tests, transportation costs) and indirect costs (productivity lost, the cost of premature retirement and morbidity costs) (7). There are different approaches to limiting tobacco consumption and lowering the cost of treating patients for the effects of tobacco use. These efforts include various non-pharmacological smoking cessation programmes (8), the use of nicotine substitutes and pharmacotherapy (9). Thus smokers in the European Union (EU) approach smoking cessation differently (8-10). In Slovenia, the screening for smoking and tobacco use is carried out by registered nurses who are part of the family medicine (FM) team. Smokers are invited to attend individual or group smoking cessation programmes in Health Promotion Centres. In countries where prescription medicines are available, smokers may be offered this therapy to support the smoking cessation process.

In recent literature, successful smoking cessation has been correlated to factors such as age, gender, education level, cigarette consumption, past quitting attempts, selfefficacy in quitting, presence of smoking family members, household smoking restrictions and nicotine dependency (11-14). Identifying potential respondents for smoking cessation pharmacotherapy based on nicotine dependency involves assessing the level of nicotine dependency of individuals. The two most used questionnaires used to evaluate nicotine dependency are the Fagerström Test for Nicotine Dependence (FTND) and Heaviness of Smoking Index (HSI). FTND and HIS questionnaires had substantial agreement in measuring high levels of nicotine dependency (15). There is strong scientific evidence that FTND score is associated with smoking cessation success (16-18). However, the association of nicotine dependency and the role of pharmacotherapy to support the smoking cessation process has not yet been studied in Slovenia. Therefore, the aim of this study was to explore the association between the smokers' characteristics and the success of pharmacotherapy for smoking cessation in Slovenian smokers.

#### 2 METHODS

#### 2.1 Study design

The data used in this study come from part of a multicentre prospective non-inferiority clinical intervention supported by the Global Research Awards for Nicotine Dependence foundation (GRAND) (19). In this paper we describe the cross-sectional analysis of factors associated with successful smoking cessation using pharmacotherapy. The data for this analysis derived only from the Slovenian arm of the GRAND study and therefore reflect the setting and the population of Slovenian smokers.

#### 2.2 Setting

FM practices in Slovenia were invited to recruit patients for participation in the study, and purposive sampling was applied. Email invitations to the practices were sent using two databases: The Association of Family Medicine Doctors, which has 351 email addresses, and the Praktik. Um family medicine physicians' union, which has 725 email addresses. The first 24 responding practices were included in the study. The average number of registered patients per FM practice in Slovenia is approximately 1,600 patients, hence the FM practices included in the study reached out to approximately 38,400 appointed patients.

#### 2.3 Study population

The research sample consisted of tobacco users identified in the FM practice by their appointed FM specialist or registered nurse. Convenience sampling was used for recruiting the patients. A total of 715 consecutive tobacco users were asked if they were willing to attend a smoking cessation programme using pharmacotherapy. Out of these, 176 patients agreed to receive pharmacotherapy for their smoking cessation attempt and were enrolled in the study. Enrolment in the study took place from 14 July 2020 to 4 November 2022.

The inclusion criteria for participants were a) active smoking, defined by smoking more than 1 cigarette per day in the 30 days prior to inclusion, b) self-declared motivation for quitting smoking, c) having an appointed FM specialist and d) consent to participate in the study. Exclusion criteria were a) age below 18 years, b) cognitive impairment that results in not being able to answer the questionnaire, c) hypersensitivity or contraindications to pharmacotherapy for smoking cessation, specifically to cytisine or varenicline.

Participants were enrolled in the study on a voluntary basis, were fully informed about the research procedures before signing the informed consent and were able to withdraw from the study at any point without explanation or consequence. The study was approved by the Slovenian National Medical Ethics Committee (KME 0120/133/2019/4).

#### 2.4 Study protocol

176 smokers who expressed motivation to quit smoking using pharmacotherapy were randomly prescribed one of the two smoking cessation medications that were available at the time of the study (varenicline or cytisine). The envelope technique was used for randomization. Neither doctor nor patient knew what the allocated medication was, until opening the envelope. Participants were followed at 4-week intervals during treatment and for 24 weeks after completion of pharmacotherapy, i.e. a total of 28 weeks for cytisine and 36 weeks for varenicline due to the difference in treatment duration. There was no control group and no follow-up for smokers who did not receive pharmacotherapy.

#### 2.5 Data collection

All smokers were invited to complete the set of questionnaires: The baseline interview questionnaire on smoking habits, FTND and sociodemographic information. The Slovenian version of FTND has been previously used in publications (20) issued by the Slovenian National Institute of Public Health (NIJZ). The FTND questionnaire is presented in supplement 1.

Variables age, gender, education level, cigarette consumption, past quitting attempts, self-efficacy in quitting, presence of smoking family members, household smoking restrictions and scores on the FTND scale were included in the data analysis. Self-assessment of "general health" was subjectively rated by the subjects in five categories from 1 (excellent) to 5 (poor). Adherence to pharmacotherapy was operationally defined as taking  $\geq$ 80% of the prescribed medication until completion of the treatment regimen.

#### 2.6 Data analysis

The sample was calculated to ensure a representative cross-section of smokers in Slovenia utilising Cochran's formula. According to data from the Statistical Office of the Republic of Slovenia, the prevalence of adult smokers in 2019 was 17.4% (n=233922). Therefore, a representative sample of smokers necessitated a minimum of 384 participants (e=95%; z=5%). We anticipated that about 40% of smokers would express interest in pharmacotherapy to assist their smoking cessation attempt, therefore our target was to enroll at least 150 smokers for the analysis. The study utilised Research Electronic Data Capture (REDCap) database management technology for real-time data monitoring. Statistical analysis was performed using the IBM Statistical Package for the Social Sciences (SPSS) Statistics 29. Descriptive statistics, including frequencies, means and standard deviations or ranges and medians, were used to summarize demographic characteristics and FTND items. Variables associated with smoking cessation success were identified through univariate analysis. Furthermore, a multivariate logistic regression model between successful smoking cessation and potential predictors was constructed. A statistical significance level of p<0.05 was assumed for the hypothesis test.

Prior to the analysis, multicollinearity was evaluated by calculating the tolerance values and the variance inflation factor (VIF). In all cases, the VIF values were in the range of 1 to 2, indicating that there was no multicollinearity between the variables.

In total, the data set contained 1.71% missing values, which affected only four variables, with no discernible pattern. To compensate for these missing values and obtain unbiased estimates, multiple imputation was performed. The assumption of normal distribution was checked using a Kolmogorov-Smirnov test with a random sample.

#### **3 RESULTS**

#### 3.1 Demographic characteristics

A total of 715 smokers were invited to participate in the study. Of these, 24.6% were willing to attempt smoking cessation (responders), and the majority did not attempt smoking cessation (non-responders). The demographic and clinical characteristics of responders and non-responders are presented in Table 1.

## 3.2 Factors associated with successful smoking cessation

Potential predictors in successful smoking cessation using pharmacotherapy are presented in Table 2. Fewer cigarettes per day, lower nicotine dependence and higher adherence to pharmacotherapy were associated with successful smoking cessation.

 Table 1. Demographic and clinical characteristics of responders and non-responders (n=715).

Characteristics	Responders n (%)	Non-responders n (%)	P value
No. of smokers	176 (24.6)	539 (75.4)	<0.01
Age, mean (SD)	50.9 (11.7)	47.2 (14.2)	
Range in years	23-73	18-84	
Missing values		11 (2.0)	
Gender			
Female	96 (54.5)	242 (45.8)	< 0.05
Male	80 (45.5)	297 (54.2)	
Education			
Primary school or less	38 (21.6)	103 (19.1)	0.83
Completed secondary school	118 (67.0)	362 (67.2)	
Completed university	20 (11.4)	64 (11.9)	
Missing values		10 (1.9)	
Marital status			
Married	82 (46.6)	205 (38.0)	0.16
In relationship	54 (30.7)	162 (30.1)	
Single	24 (13.6)	90 (16.7)	
Widowed/divorced	16 (9.1)	71 (13.2)	
Missing values		11 (2.0)	
No. of children, mean (SD)	1.65 (1.1)	1.34 (1.0)	< 0.01
Missing values		14 (2.6)	
General health, mean (SD)	3.1 (1.0)	2.70 (0.97)	<0.01
Missing values		11 (2.0)	
No. of cigarettes per day, mean (SD)	19.2 (8.8)	15.7 (9.1)	<0.01
Missing values		21 (3.9)	
Age at start of smoking, mean (SD)	19.5 (3.3)	18.9 (5.0)	0.69
Missing values		8 (1.5)	
Dependence (FTND, 0-10), mean (SD)	4.72 (2.1)	3.89 (2.0)	<0.01
Missing values		15 (2.8)	

Legend: FTND - Fagerström Test for Nicotine Dependence; SD - standard deviation.

Variables	OR	95% CI	P value
Age	1.02	0.99-1.05	0.17
Gender	0.95	0.47-1.88	0.87
Education (ref. Primary School) Completed secondary school Completed university	0.47 0.42	0.15-1.49 0.16-1.15	0.19 0.09
Partnered (yes/no)	1.23	0.55-2.74	0.61
No. of children	1.00	0.73-1.36	0.99
Age of starting to smoke	1.04	0.97-1.11	0.28
No. of cigarettes per day	0.96	0.91-1.00	0.04
No. of quit attempts	1.08	0.98-1.20	0.13
Confidence in quitting (0-10)	0.97	0.97-1.29	0.19
Other family members smoking (no/yes)	1.69	0.84-3.38	0.14
Household smoking restrictions (ref. smoking everywhere)			
Nobody smokes inside Smoking in some areas	2.92 2.67	0.62-13.70 0.56-12.74	0.17 0.22
Dependence (FTND, 0-10)	0.73	0.31-0.74	<0.01
Adherence	2.55	1.20-5.38	<0.01
Treatment type (Varenicline/Cytisine)	0.69	0.34-1.38	0.29
General health (0-5)	0.73	0.51-1.04	0.08

 Table 2.
 Univariate analysis exploring potential predictors in successful smoking cessation (n=176).

Legend: FTND - Fagerström Test for Nicotine Dependence; OR - odds ratio; CI - Confidence interval.

A multivariate logistic regression model between successful smoking cessation and potential predictors was constructed (Table 3). Dependence and adherence were proven to be the statistically significant predictors for successful smoking cessation.

 Table 3. Multivariate logistic regression between successful smoking cessation and potential predictors (n=176).

Variables	OR	95% CI	P value
Age	1.04	0.99-1.08	0.06
Education (ref. Primary School) Completed secondary school Completed university	0.60 1.61	0.21-1.69 0.38-6.81	0.32 0.52
Other family members smoking (no/yes)	1.02	0.44-2.35	0.96
Household smoking restrictions (ref. smoking everywhere) Nobody smokes inside	2.47	0.45-13.61	0.30
No. of days of smoking	0.96	0.85-1.08	0.50
No. of cigarettes per day	1.00	0.95-1.06	0.97
No. of quit attempts	1.00	0.88-1.14	0.94
Confidence in quitting (0-10)	1.09	0.92-1.28	0.33
Dependence (FTND, 0-10)	0.75	0.58-0.96	0.02
Adherence	3.53	1.47-8.51	<0.01
General health (0-5)	0.70	0.43-1.16	0.17

Legend: FTND - Fagerström Test for Nicotine Dependence; OR - odds ratio; CI - Confidence interval.

The model was found to be statistically significant (p<0.01), overall showing a good model fit. The predictors explained by the model were better explained in the group that did not successfully complete the treatment (97% correct prediction). Nevertheless, the model was able to explain 24% of the variability of the dependent variable.

#### **4 DISCUSSION**

This study showed that almost a quarter of smokers undergoing pharmacotherapy successfully quit smoking for a 24-week interval. The statistically significant predictors of smoking cessation success were nicotine dependence and adherence to pharmacotherapy.

The cross-sectional analysis that was performed aimed to investigate factors associated with the success of smoking cessation facilitated by pharmacotherapy. Out of 715 invited participants, 24.6% opted to attempt smoking cessation using prescription medications, specifically cytisine and varenicline, with a success rate of 24.3% over the 24-week observation period.

The univariate analysis among 715 invited participants (Table 1) showed that female smokers, older smokers and smokers with a higher number of children were more likely to try to quit smoking. In addition, those who reported poorer general health, higher daily cigarette consumption and higher nicotine dependence were more likely to engage in smoking cessation initiatives.

A multivariate logistic regression model between successful smoking cessation and potential predictors was constructed (Table 3). Dependence and adherence were proven to be the statistically significant predictors for successful smoking cessation.

In 176 patients who used prescription medicine, univariate analysis identified dependence, adherence and lower daily cigarette consumption to be correlated with the smoking cessation. However, lower daily cigarette consumption did not prove significant in the multivariate model. In this study, the FTND served as a critical measure for assessing nicotine dependence and showed a robust association with the effectiveness of smoking cessation using the prescribed medications studied. The results of our study also show that treatment adherence to non-NRT pharmacological therapy is essential for smoking cessation, regardless of the medication used (cytisine or varenicline).

Our findings align with prior research indicating that various demographic factors correlate with the likelihood of successfully quitting smoking through pharmacotherapy. These factors include age, gender, level of education, marital status, presence of children and self-assessment of health status (11, 12, 21, 22). However, after adjusting for other variables in the multivariate regression model, only nicotine dependence and adherence to pharmacotherapy protocols were found to be statistically significant predictors of smoking cessation success. A larger sample size would probably confirm or reject the significance of previous sociodemographic variables. This observation is consistent with several studies indicating that FTND scores are an indicator of successful smoking cessation (16-18). Indeed, Fagerström's study has shown that higher FTND scores correlate with a lower probability of being abstinent at week 24 (16). Our study confirms this relationship in the context of pharmacotherapeutic interventions. Furthermore, our results highlight the utility of FTND scores in the assessment phase in identifying smokers at increased risk of non-adherence to subsequent treatment sessions (23). Studies on adherence to nicotine replacement therapy (NRT) have shown that adherence doubles the rate of successful smoking cessation (24), and there is a positive correlation between adherence to treatment and tobacco abstinence, with early abstinence experience being a strong driver of adherence (25). Several studies have found a strong relationship between the number of cigarettes smoked and smoking cessation (26, 27), and a longitudinal study of 17,155 persistent smokers who were followed over a six-year period showed that higher daily cigarette consumption, shorter intervals before the first cigarette of the day and regular daily smoking patterns resulted in a lower probability of smoking cessation (13). Regarding prescription medications, Noor et al. showed that lower daily cigarette consumption is associated with a higher likelihood of becoming smokefree in people undergoing varenicline treatment (28). However, in the multivariate logistic model of our study, this variable was no longer recognized as a significant factor associated with smoking cessation. It is possible that FTND and adherence to treatment might mediate or moderate the relationship between daily cigarette consumption and smoking cessation.

Among other factors investigated, including age, gender, self-perceived general health and number of children, none emerged as a predictive factor for smoking cessation success in our study population, although they were associated with a higher likelihood of attempting smoking cessation. Several other predictors for both trying to quit and successful cessation were described in the literature (29), but none demonstrated statistical significance in our population. There are several possible reasons for this outcome, including complex interactions between variables that could not be fully explored due to a limited sample size.

The pharmacological approach to smoking cessation is widely acknowledged as safe and efficacious, warranting consideration for all individuals committed to quit smoking (9, 19). Notably, varenicline, cytisine treatment and NRT are all effective methods for smoking cessation (30). Although a trial by Courtney et al. failed to demonstrate noninferiority of cytisine compared with varenicline regarding smoking cessation (31), the standard 4-week cytisine treatment was shown to be less effective than the standard 12-week varenicline treatment for smoking cessation in the trial by Orešković et al. (19).

Our study has several notable strengths. While references demonstrate the importance of nicotine dependence for smoking cessation success, the significance of adherence to smoking cessation medications is novel in this context. Our study's key advantage is demonstrating how medication adherence can improve smoking cessation effectiveness in real-world clinical settings. The biggest strength of our research is its practical application in a real family medicine setting. The tools we used to identify candidates for smoking cessation medication can be easily integrated into routine primary care. Additionally, using two different types of smoking cessation medications underscores the thoroughness of our study.

However, our study also has some limitations. First, the small sample size limits the statistical robustness required for an individualized analysis of the efficacy of each medication. Nonetheless, the observed similarity in outcomes between the two medications supports the generalisability of our findings to different pharmacotherapeutic approaches to smoking cessation. There was no control group and no follow-up for smokers who did not receive pharmacotherapy. Furthermore, because we rely on cross-sectional data, we are limited in our ability to establish definitive causal relationships or temporal sequences between smoking cessation success and associated factors. This limitation underscores the need for future longitudinal studies to elucidate the dynamic interplay of these variables over time.

There was no connection with real participant data, which limited the interpretation of results, particularly concerning non-respondents in the context of mental health, previous addiction diseases and socioeconomic status, all of which heavily influence continued smoking according to findings from previous studies (21). Also, the success of quitting smoking can be affected by the condition during or after treatment and by recovering from a serious illness (32, 33). Moreover, it is possible that more motivated FM enrolled patients participated in the study, and this can also be reflected in the population of their patients. While we have not included these variables in our data collection, we want to emphasize their importance and acknowledge their potential impact on the outcomes.

#### **5 CONCLUSION**

This study highlights the central role of reduced nicotine dependence and higher adherence to pharmacotherapy as robust predictors of smoking cessation success when using pharmacotherapy. This finding enables the identification of potential responders to pharmacotherapeutic interventions and facilitates targeted prescribing and follow-up in primary healthcare. Moving forward, it is imperative to investigate the efficacy and outcomes of targeted pharmacotherapy prescription for smoking cessation through further research efforts. Such investigations will not only improve our understanding of the role of pharmacotherapy in smoking cessation, but will also enable the development of tailored interventions to optimise smoking cessation outcomes more broadly (20).

#### ACKNOWLEDGMENT

We would like to acknowledge and thank all subjects participating in the survey.

#### CONFLICTS OF INTEREST

The study was financed by Global Research Awards for Nicotine Dependence, WI231434/Pfizer. Janez Rifel was lead investigator for the Slovenian arm of this research. The funding sources had no role in the study design, collection, analysis or interpretation of data, writing of the report or the decision to submit the article for publication. Other authors have no conflict of interest to declare.

#### FUNDING

The study was financed by Global Research Awards for Nicotine Dependence, WI231434/Pfizer.

#### ETHICAL APPROVAL

The authors of this paper hereby declare that the study complies with the Declaration of Helsinki and has been approved by the Slovenian National Medical Ethics Committee (KME 0120/133/2019/4).

#### AVAILABILITY OF DATA AND MATERIALS

Access to the data is subject to approval and a data-sharing agreement.

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Original scientific article

Harhaji S, Tomori S, Nakov V, Chihai J, Radic I, Mana T, Stoychev K, Esanu A, Pirlog MC. Stigmatising attitudes towards mental health conditions among medical students in five South-Eastern European countries. Zdr Varst. 2024;63(4):188-197. doi: 10.2478/sjph-2024-0025.

## STIGMATISING ATTITUDES TOWARDS MENTAL HEALTH CONDITIONS AMONG MEDICAL STUDENTS IN FIVE SOUTH-EASTERN EUROPEAN COUNTRIES STIGMATIZIRAJOČI ODNOS DO DUŠEVNEGA ZDRAVJA MED ŠTUDENTI

## MEDICINE V PETIH DRŽAVAH JUGOVZHODNE EVROPE

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Received: Apr 10, 2024 Accepted: Aug 02, 2024

ABSTRACT Keywords:	<b>Introduction:</b> Stigmatising attitudes towards mentally ill people are present among healthcare professionals. The aim of the study was to evaluate medical students' attitudes in five medical schools from Albania, Bulgaria, Moldova, Romania and Serbia and to determine if psychiatry clerkship improves these attitudes.
Stigmatisation Medical students Mental disorders Psychiatry	<b>Methods:</b> In the first stage, the study included students from the first and final years of medical school; in the second stage, only final-year students were included; The Mental Illness Clinicians' Attitude Scale (MICA-2) and the Attribution Questionnaire (AQ-9) were used in this study. The total sample comprised 1,526 medical students in the first stage and 614 in the second stage.
Mental health	<b>Results:</b> The analysis of the average AQ-9 and MICA-2 scores between countries revealed significant differences (p<0.05). Multivariable analysis showed that female students were 30% more likely to have elevated AQ-9 scores than male students (p=0.029). Final-year students had a significantly lower chance of having a higher MICA-2 score compared to first-year students (OR=0.7; p<0.05).
	<b>Conclusions:</b> Psychiatry clerkship contributes to a decrease in the level of stigmatising attitudes among medical students. Further research is required to assess the curricula to achieve better results in reducing stigma among future doctors.
IZVLEČEK Kliučne besede:	<b>Uvod</b> : Stigmatizirajoči odnos do duševno bolnih ljudi je prisoten tudi med zdravstvenimi delavci. Namen študije je bil oceniti stališča študentov medicine na petih medicinskih fakultetah v Albaniji, Bolgariji, Moldaviji, Romuniji in Srbiji ter ugotoviti, ali praksa na psihiatriji ta stališča izboljša.
stigmatizacija študenti medicine duševne motnje psihiatrija duševno zdravje	<b>Metode:</b> V prvi fazi je študija vključevala študente prvega in zadnjega letnika medicinske fakultete, v drugi fazi pa samo študente zadnjega letnika; v tej študiji sta bila uporabljena lestvica stališč zdravnikov do duševnih bolezni (MICA-2) in vprašalnik o atribuciji (AQ-9). Skupni vzorec je obsegal 1526 študentov medicine v prvi fazi študije in 614 v drugi fazi.
	<b>Rezultati</b> : Analiza povprečnih rezultatov AQ-9 in MICA-2 med državami je pokazala pomembne razlike (p < 0,05). Multivariatna analiza je pokazala, da je bila verjetnost, da bodo imele študentke za 30 % višji rezultat AQ-9 kot študenti (p = 0,029). Študenti zadnjega letnika so imeli v primerjavi s študenti prvega letnika bistveno manj možnosti za višji rezultat MICA-2 (OR = 0,7; p < 0,05).
	<b>Zaključki</b> : Psihiatrična praksa prispeva k zmanjšanju stopnje stigmatizirajočega odnosa med študenti medicine. Potrebne so nadaljnje raziskave za oceno učnih načrtov za doseganje boljših rezultatov pri zmanjševanju stigmatizacije med bodočimi zdravniki.

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#### **1 INTRODUCTION**

According to WHO data, in 2019 over 12% of the world's population suffered from a mental health condition (1), a rate which increased during the COVID-19 pandemic, especially regarding depressive and anxiety disorders (2). In this context, the effects of stigma associated with mental illnesses became more significant, necessitating new and more effective strategies to address it.

Defined by Erving Goffman, stigma comprises socially discrediting attributes, behaviours, or reputations leading individuals to be perceived as undesirable or abnormal (3). Stigma towards mentally ill people has two main forms: public stigma, often described as the general population's reaction to mental health conditions, and self-stigma where individuals internalise societal prejudices (4, 5).

Public stigma is also prevalent among healthcare professionals (6, 7), with a special note on psychiatrists (8, 9) and medical students (10, 11). Medical students are an important target of anti-stigma campaigns, although the effectiveness of interventions varies (12-15). There are studies that have shown that medical students' attitudes towards mental illnesses prior to psychiatric clerkship are similar to the general population in terms of negative beliefs and attitudes (16-19). There is data regarding the positive outcome of psychiatry clerkship (20-25). Other studies have shown that post-clerkship attitudes of students worsened based on newly gained beliefs about patients' aggression and their unpredictable and dangerous behaviour, considering them as having poor prognosis or even being incurable, while working as a psychiatrist is too stressful and emotionally overwhelming (25-28).

Albania, Bulgaria, Moldova, Romania and Serbia share similar characteristics, not just their geographical location. Over the past three decades, both the healthcare and education systems in these countries have undergone continuous and slow reform (29). In the realm of mental health research, there is a scarcity of comparative studies focusing on the stigmatising attitudes of medical students towards individuals with mental illnesses in the contexts of these five countries. The length and content of psychiatry clerkship were quite similar across all countries involved in the research, consisting on average of 90 academic hours per semester of lectures and practice in clinical psychiatry settings, without differences in content between the two stages of the study.

The aim of the study was to measure and compare medical students' attitudes towards people with mental health conditions in the aforementioned countries, and to assess changes in these attitudes following psychiatric clerkships. We initially hypothesized that there would be no difference in stigmatising attitudes among medical students from these countries and that improved knowledge about mental health conditions would reduce negative attitudes.

#### 2 METHODS

#### 2.1 Study settings

The study was conducted at faculties of medicine in five South-Eastern European countries as follows: Tirana Medical University, Albania; Pleven Medical University, Bulgaria; State Medical and Pharmaceutical University Nicolae Testemitanu, Chisinau, Moldova; University of Medicine and Pharmacy of Craiova, Romania; University of Novi Sad, Serbia.

#### 2.2 Study stages

The study consisted of two stages: (I) the first, during academic year 2015/2016, included medical students from the first year of medical faculties and students in their final year; (II) the second, during academic year 2020/2021, included only final-year medical students. Students surveyed in the second stage were mostly the same students included in the first stage when they were in the first year of their studies.

#### 2.3 Study sample

In the initial stage of the research, we collected two convenience samples from each medical faculty: one comprising 860 first-year students and the other consisting of 666 final-year students. During the second stage, the study included only final-year students, with 614 participants, after they had completed the psychiatry clerkship.

The inclusion criteria for first-year students were being registered and attending the medical faculty, while the additional criterion for final-year students was the completion of the psychiatry clerkship. There were no exclusion criteria at any stage of the study.

In the initial stage, printed questionnaires were distributed to students by their teachers during lectures or practical lessons on a voluntary basis. Response rates ranged from 81.1% in Serbia to 44.8% in Albania. The second stage was conducted online due to the constraints imposed by the COVID-19 pandemic. Students received links to the webbased questionnaire through their associations. Response rates decreased in all countries except Bulgaria, where the rate was 97.1%. The lowest response rate in the second stage was 16.2% in Moldova.

Participation in the study was voluntary, with students being informed of their right to decline involvement, as well ensuring the confidentiality and anonymity of both students and their responses. The study received approval from the ethics committees of the participating universities.

#### 2.4 Study measures

The questionnaire collected basic sociodemographic data, including age, gender and year of study. To assess stigmatising attitudes, two instruments were used: the Attribution Questionnaire (AQ-9) and The Mental Illness Clinicians' Attitudes (MICA-2).

The AQ-9 measures medical students' stigma by addressing nine stereotypes about individuals with mental illness, using a Likert scale ranging from 1 to 9. Higher scores indicate more stigmatising attitudes (30, 31).

The MICA-2 is a 16-item scale that measures attitudes towards psychiatry and mental health, perceptions of recovery and the dangerousness of individuals with mental illness, comfort levels around these individuals and discriminatory behaviour. Scores range from 1 to 6, with higher total scores indicating more stigmatising attitudes (32).

Both questionnaires underwent back-translation into the national languages of the countries involved (Albanian, Bulgarian, Romanian and Serbian), ensuring linguistic and cultural relevance. Cronbach's alpha values were satisfactory across three measurements, indicating acceptable internal consistency.

#### 2.5 Statistical analysis

Standard methods of descriptive and inferential statistics were used. Numerical data were presented as mean (M) and standard deviation (SD), while categorical characteristics were depicted through frequency distributions. Univariate analyses were performed using Pearson's  $\chi^2$  test, Student's t-test, and one-way analysis of variance (ANOVA).

Binary logistic regression (Enter method) was used to assess the relationship between stigma and independent variables (gender, year of study and country). Crude and adjusted Odds Ratios (OR and AOR) were calculated. The independent variables, such as gender and year of study, were selected for the multivariable analysis model based on empirical variable selection, while the country variable was included based on the study's objectives. The AO-9 score and MICA-2 scores as dependent variables were dichotomized around the median of the total sample into two categorical variables: AO-9 scores were classified as low (9-35) or high (36 and above), and MICA-2 scores were classified as low (16-51) or high (52 and above). This analysis focused on the initial stage of the research (academic year 2015/2016) and Serbia was selected as the reference country due to its lowest average AQ-9 and MICA-2 scores.

Significance level was set at p<0.05. Statistical analyses were conducted using IBM SPSS Statistics 23.

#### **3 RESULTS**

The study initially involved 1,526 students, with 614 students participating in the subsequent stage. Women comprised the majority in both stages, representing 72.0% and 74.4% of the participants, respectively (Table 1).

#### Table 1. Characteristics of the study samples.

Characteristics	Albania n (%)	Bulgaria n (%)	Moldova n (%)	Romania n (%)	Serbia n (%)	Total n (%)
2015/2016						
Gender						
Men	52 (22.0)	68 (28.0)	74 (23.6)	127 (31.9)	106 (31.6)	427 (28.0)
Women	184 (78.0)	175 (72.0)	240 (76.4)	271 (68.1)	229 (68.4)	1099 (72.0)
Year of study						
First	126 (53.4)	111 (45.7)	229 (72.9)	207 (52.0)	187 (55.8)	860 (56.4)
Final	110 (46.6)	132 (54.3)	85 (27.1)	191 (48.0)	148 (44.2)	666 (43.6)
Total	236 (100.0)	243 (100.0)	314 (100.0)	398 (100.0)	335 (100.0)	1526 (100.0)
Age (years, M±SD)	21.5±2.7	22.2±3.2	20.8±2.6	21.8±2.9	21.3±2.5	21.5±2.8
2020/2021						
Gender						
Men	21 (18.4)	45 (44.6)	24 (27.0)	40 (19.7)	27 (25.2)	157 (25.6)
Women	93 (81.6)	56 (55.4)	65 (73.0)	163 (80.3)	80 (74.8)	457 (74.4)
Total	114 (100.0)	101 (100.0)	89 (100.0)	203 (100.0)	107 (100.0)	614 (100.0)
Age (years, M±SD)	24.3±1.6	24.1±2.0	25.0±2.0	24.9±1.4	25.3±1.7	24.8±1.7

In the first stage, the average AQ-9 score for first-year students across all countries was 35.2, compared to 35.0 for final-year students. In the second stage, the average score was 32.7. Regarding gender, a significant difference was observed among Moldovan students in their final year of 2015/2016 (p=0.011), which was not observed in other countries. Analysis by research year revealed that finalyear students had lower AQ-9 scores compared to first-year students in Albania (p<0.05) and Bulgaria (p<0.001) during the first stage. Conversely, Moldovan final-year students had significantly higher scores in the first stage (p<0.001). Additionally, a comparison between AQ-9 scores of firstyear students in 2015/2016 and those who completed a psychiatry course in 2020/2021 showed a significant decrease in Bulgaria (from 42.1 to 33.2, p<0.001) and Romania (from 37.1 to 33.1, p<0.001) (Table 2).

In the first stage, the average MICA-2 score for firstyear students across all countries was 50.6, while for final-year students it was 49.1. In the second stage, the average score decreased to 45.6. Significant gender-based differences were found in Serbia in the second stage, with female scores being significantly lower than male scores (34.5 vs. 39.2; p=0.007). During the first stage, significant differences between first and final-year students were observed in Albania, Bulgaria and Romania. When comparing MICA-2 scores between first-year students in 2015/2016 and those in their final year in 2020/2021, significant differences were detected in all countries except Albania (Table 2).

Table 2. AQ-9 and MICA-2 scores measured among medical students.

Characteristics		AQ-9			MICA-2	
	M	SD	p *	M	SD	p *
Albania						
First year (2015/2016)	32.6	10.4	0.440	54.5	6.1	0.485
Men	34.3	10.0		55.3	5.1	
Women						
Final year (2015/2016)	30.2	8.8	0.668	52.3	6.3	0.714
Men	31.2	9.4		52.8	6.0	
Women						
Final year (2020/2021)	33.8	9.8	0.727	54.7	4.5	0.645
Men	32.9	11.2		54.1	5.5	
Women						
First year (2015/2016)	33.9	10.1	0.022	55.1	5.4	<0.001
Final year (2015/2016)	31.0	9.2		52.7	6.0	
First year (2015/2016)	33.9	10.1	0.550	55.1	5.4	0.187
Final year (2020/2021)	33.1	10.9		54.2	5.3	
Bulgaria						
First year (2015/2016)	42.4	10.8	0.888	59.2	7.0	0.929
Men	42.0	10.0		59.0	9.0	
Women						
Final year (2015/2016)	35.8	7.3	0.393	57.5	8.7	0.179
Men	37.0	8.4		55.8	5.5	
Women						
Final year (2020/2021)	32.3	8.2	0.352	50.6	7.4	0.288
Men	33.9	9.2		52.3	7.6	
Women						
First year (2015/2016)	42.1	10.1	<0.001	59.1	8.7	0.010
Final year (2015/2016)	36.6	8.0		56.5	6.9	
First year (2015/2016)	42.1	10.1	< 0.001	59.1	8.7	<0.001
Final year (2020/2021)	33.2	8.7		51.5	7.5	
Moldova						
First year (2015/2016)						
Men	35.5	10.6	0.477	52.9	6.4	0.181
Women	34.4	9.5		51.6	6.1	
Final year (2015/2016)						
Men	34.3	12.8	0.011	52.2	5.2	0.682

Characteristics		AQ-9			MICA-2	
	M	SD	p *	M	SD	p *
Women	41.7	11.0		51.7	5.2	
Final year (2020/2021)						
Men	32.7	11.1	0.259	43.8	11.5	0.101
Women	35.9	12.0		47.8	9.6	
First year (2015/2016)	34.7	9.8	< 0.001			
Final year (2015/2016)	39.8	11.9		51.9	6.2	0.887
First year (2015/2016)	34.7	9.8	0.787	51.8	5.2	
Last year (2020/2021)	35.0	11.8		51.9	6.2	< 0.001
				46.7	10.2	
Romania						
First year (2015/2016)						
Men	36.9	9.4	0.805	52.2	8.4	0.100
Women	37.3	9.1		50.1	9.0	
Final year (2015/2016)						
Men	37.5	11.0	0.850	47.4	9.5	0.703
Women	37.8	10.5		46.9	8.3	
Final year (2020/2021)						
Men	34.1	10.9	0.517	43.7	7.2	0.292
Women	32.9	10.4		42.4	6.5	
First year (2015/2016)	37.1	9.2	0.550	50.8	8.9	< 0.001
Final year (2015/2016)	37.7	10.6		47.0	8.7	
First year (2015/2016)	37.1	9.2	<0.001	50.8	8.9	< 0.001
Final year (2020/2021)	33.1	10.5		42.7	6.7	
Serbia						
First year (2015/2016)						
Men	32.3	8.1	0.058	41.7	7.8	0.148
Women	29.6	9.6		40.1	6.7	
Final year (2015/2016)						
Men	28.6	7.0	0.092	41.1	5.7	0.921
Women	31.2	9.3		41.0	7.8	
Final year (2020/2021)						
Men	31.4	9.9	0.108	39.2	10.4	0.007
Women	28.6	7.1		34.5	6.5	
First year (2015/2016)	30.5	9.2	0.924	40.6	7.0	0.589
Final year (2015/2016)	30.4	8.6		41.0	7.2	
First year (2015/2016)	30.5	9.2	0.280	40.6	7.0	<0.001
Final year (2020/2021)	29.3	8.0		35.7	7.8	

\*p-Independent samples t-test

Analysis of AQ-9 scores across different academic years and countries indicated significant differences (p<0.05) between study stages. Notably, the highest stigma levels, as measured by AQ-9, were observed among first-year students in Bulgaria (42.1), whereas the lowest score was found among final-year students in Serbia during the 2020/2021 academic year (29.3) (Table 3). Comparative analysis of average MICA-2 scores across countries revealed significant differences in both research stages (p<0.001). Initially, Bulgarian first-year students had the highest score (59.1), while in the subsequent stage, the highest score was observed among Albanian students (54.2). In both research stages, the lowest MICA-2 scores were observed in Serbia (Table 3).

Year of Study		Alba	ania	Bulg	garia	Molo	lova	Rom	ania	Ser	bia	р*
		Μ	SD	Μ	SD	Μ	SD	Μ	SD	М	SD	
AQ-9												
2015/2016	First Final	33.9 31.0	10.1 9.2	42.1 36.6	10.1 8.0	34.7 39.8	9.8 11.9	37.1 37.7	9.2 10.6	30.5 30.4	9.2 8.6	<0.001 <0.001
2020/2021	Final	33.1	10.9	33.2	8.7	35.0	11.8	33.1	10.5	29.3	8.0	0.002
MICA-2												
2015/2016	First Final	55.1 52.7	5.4 6.0	59.1 56.5	8.7 7.0	51.9 51.8	6.2 5.2	50.8 47.0	8.9 8.7	40.6 41.0	7.0 7.2	<0.001 <0.001
2020/2021	Final	54.2	5.3	51.5	7.5	46.7	10.2	42.7	6.7	35.7	7.8	<0.001

Table 3. AQ-9 and MICA-2 scores between countries.

\* p-ANOVA

Univariate analysis revealed that men had a higher prevalence of low AQ-9 scores (57.1%) compared to women (51.2%). Bulgarian students had the highest prevalence of AQ-9 scores above the median (62.1%), while Serbian students had the lowest (29.9%). Significant differences were observed in the prevalence of both low and high AQ-9 and MICA-2 scores between countries (Table 4).

The logistic regression analysis showed significant findings. Women had higher AQ-9 scores than men, with a significant crude odds ratio (OR=1.3, p=0.037). Final-year students had notably lower odds for high MICA-2 scores compared to first-year students (OR=0.8, p=0.021) (Table 5).

The multivariable regression analysis confirmed that female students were 30% more likely to have elevated AQ-9 scores compared to male students (p=0.029). However, no significant association was found between gender and MICA-2 scores. Completing psychiatry courses was associated with a 30% reduced likelihood of higher MICA-2 scores compared to first-year students (Table 6).

Table 5.	Association between gender, year of study, country
	and AQ-9/MICA-2 scores in the first stage of the
	research (logistic regression—unadjusted OR).

Year	AQ-9 Sc	ore	MICA-2 Score			
of Study	OR (95% CI)	p	OR (95% CI)	p		
Gender Men Women	1 1 3 (1 0-1 6)	0.037	1 1 1 (0 9-1 4)	0 291		
Year of study First year Final year	1 1.0 (0.8-1.2)	0.853	1 0.8 (0.6-1.0)	0.021		
<b>Country</b> Serbia Albania Bulgaria Moldova Romania	1 1.4 (1.0-2.0) 3.9 (2.7-5.5) 2.3 (1.7-3.2) 3.1 (2.2-4.2)	0.079 <0.0001 <0.0001 <0.0001	1 35.2 (21.6-57.5) 75.0 (43.7-128.7) 14.7 (9.4-23.0) 9.1 (5.9-14.0)	<0.0001 <0.0001 <0.0001 <0.0001		

\* p-Logistic Regression

Table 4. A	ssociation between ge	ender, year of study,	country and AQ-9/MICA-2	scores in the first stage of	the research.
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Year of Study		AQ-9	Score			MICA-2 Score				
-	Lo	w	High			Low		High		-
-	n	%	n	%	р	n	%	n	%	Р
Gender										
Men	244	57.1	183	42.9	0.040	238	55.7	189	44.3	0.332
Women	563	51.2	536	48.8		582	53.0	517	47.0	
Year of study										
First	453	52.7	407	47.3	0.877	444	51.6	416	48.4	0.063
Final	354	53.2	312	46.8		376	56.5	290	43.5	
Country										
Albania	149	63.1	87	36.9	<0.001	74	31.4	162	68.6	< 0.001
Bulgaria	92	37.9	151	62.1		39	16.0	204	84.0	
Moldova	158	50.3	156	49.7		155	49.4	159	50.6	
Romania	173	43.5	225	56.5		239	60.1	159	39.9	
Serbia	235	70.1	100	29.9		313	93.4	22	6.6	

\* p-Chi-Square Test

Year of Study	AQ-9 Sco	ore	MICA-2 Score			
	AOR (95% CI)	р	AOR (95% CI)	р		
Gender						
Men	1		1			
Women	1.3 (1.0-1.6)	0.029	1.0 (0.7-1.3)	0.805		
Year of study						
First year	1		1			
Final year	1.0 (0.8-1.2)	0.657	0.7 (0.5-0.9)	0.002		
Country						
Serbia	1		1			
Albania	1.3 (0.9-1.9)	0.104	32.3 (19.3-54.1)	< 0.001		
Bulgaria	3.9 (2.7-5.5)	< 0.001	79.8 (45.8-139.2)	< 0.001		
Moldova	2.3 (1.6-3.1)	<0.001	13.9 (8.5-22.6)	< 0.001		
Romania	3.1 (2.3-4.2)	<0.001	9.7 (6.0-15.7)	<0.001		

# Table 6.Association between gender, year of study, country<br/>and AQ-9/MICA-2 scores in the first stage of the<br/>research (logistic regression—adjusted OR).

#### 4 DISCUSSION

The level of stigmatising attitudes measured among firstyear medical students was not as high as expected (16, 25, 33), aligning with recent research findings from South Africa (34). Across all countries, the mean AQ-9 score for first-year students was 35.2, while in the second stage, the average score among final-year students decreased to 32.7, which is similar to a Portuguese study, where the AQ-9 score was 33.6 (35).

No significant difference in AQ-9 scores between genders was found across countries (except in Moldova), aligning with one previous study (35) but contradicting other studies that indicated lower stigma levels among female medical students (36-37). However, multivariable analysis of the initial stage revealed a higher likelihood for female students to show more pronounced stigmatising attitudes than their male counterparts, which was unexpected. One possible explanation for this difference is that females experience more internalised stigma compared to men (38), potentially leading to higher stigmatising attitudes toward others. Another factor could be that females are more likely to acknowledge and report psychological distress (39), which might result in a less positive attitude toward mental illnesses. Future research should explore these potential factors to better understand the underlying reasons for gender differences in stigmatising attitudes across countries involved in the study.

The average MICA-2 score for first-year students across all countries in the first stage of the study was 50.6, while for final-year students in the second stage, it was 45.6, indicating a significant difference. Several studies reported lower average MICA-2 scores compared to our findings. In Malaysia, the average score was 43.4 (40), while in Portugal, it ranged from 38.2 to 36.7 before and after psychiatry and psychology courses (41). An Australian study showed an average score of 36.8 (42), while in India the average MICA-2 score was 42.4 (43). A study comparing various programmes in Spain and Chile found a MICA score of 40.2 among medical students, who exhibited more negative attitudes towards mental disorders compared to students in nursing, psychology, and occupational therapy programmes (44). Medical schools in Poland recorded a score of 41.1, with no significant difference based on psychiatry attendance (45).

In our study, Bulgarian students had the highest average MICA-2 score in the first stage, regardless of their year of study, while students from Albania recorded the highest average score in the second stage. The most substantial decrease in MICA-2 score between stages was observed in Romania (from 50.8 to 42.7). Multivariable analysis showed that final-year students had a significantly lower likelihood of having higher MICA-2 scores compared to first-year students (OR=0.7), which is similar to an Australian study, where the baseline MICA-2 score was 48.2 and decreased to 43.5 after psychiatry classes (20). Other studies also support this, indicating that increased knowledge and exposure to patients with mental disorders positively affect stigma levels (22, 40, 41).

Furthermore, existing literature suggests that educational interventions aim to foster positive shifts in medical students' attitudes toward psychiatry, indicating that clerkships generally have a beneficial impact on students' attitudes in this field. This shift in attitude is evidenced by an increasing perception among students of psychiatry as a scientifically growing area of medicine, with significant effectiveness in psychiatric treatments (46).

In contrast to our findings, research conducted among medical university students in 65 countries worldwide reported an average MICA-2 score of 40.5, with no statistically significant difference based on attendance in psychiatry lectures (47).

Regarding gender, a significant difference in MICA-2 score was observed only in Serbia during the second stage of our research, with males exhibiting higher scores than females. Some studies confirm more stigmatising attitudes among men (43, 44), others report no significant gender differences (40, 41), while in Australia female students had higher scores compared to males (42).

Based on our findings and the existing literature, future research on stigmatising attitudes among healthcare professionals, particularly medical students, should explore several key areas: longitudinal comparative studies, examining attitude shifts across various stages of medical education and within different geographical and educational settings, as well as the inclusion of more variables that might influence student attitudes. Additionally, our study suggests that psychiatric training during medical school has a noticeable positive influence on attitudes, an effect that could be further enhanced by incorporating specific lectures focused on stigma into the curriculum.

#### 4.1 Limitations of the study

The selection of medical faculties was based on established research collaborations, which may not represent the overall student population in these five countries, thereby limiting the generalisability of the results. The relatively low response rates, particularly in Albania and Moldova, could be attributed to the strictly voluntary nature of our study, cultural differences and external factors such as COVID-19 restrictions. These response rates may affect the sample's representativeness, potentially introducing bias if respondents differ from non-respondents. Due to data collection constraints, we were unable to conduct a nonrespondent analysis. These limitations highlight the need for future research on a larger and more representative sample.

Variations in the psychiatry curriculum, including the timing of students' attendance of psychiatry classes, led to differing intervals between psychiatry rotations and data collection periods. The preservation of anonymity prevented more detailed correlation analyses between first-year students from the initial stage and students from the subsequent stage of the research. Another limitation of our study is the potential bias introduced by self-report measures, such as social desirability and subjective interpretation. In order to reduce this bias, we used valid instruments with good internal consistency, provided clear instructions to participants and ensured anonymity. One factor that could potentially influence the results of the study is the different modes of data collection used in the two study stages (mode effect). In the first stage we used printed questionnaires, while the second stage employed an online survey method due to the COVID-19 pandemic restrictions. If the second stage of the research had been postponed to maintain consistency in the survey method, the students who were in their first year during the initial stage of the research would have been missed. The hybrid nature of psychiatry classes during the COVID-19 pandemic might have affected the quality and scope of the classes, as well as contact with patients, potentially impacting the level of stigma among students in the second stage of the research.

While our study provides insights into stigmatising attitudes among medical students from five South-Eastern European countries, future research could include broader populations of other future healthcare professionals (e.g. dentists, pharmacists, nurses) or different settings to enhance the generalisability of the results.

#### **5 CONCLUSIONS**

Our study revealed significant differences in stigmatising attitudes towards individuals with mental health conditions among medical students from the five countries involved. Despite initially high levels of stigma, psychiatry clerkships generally had a positive impact, improving attitudes towards individuals with mental health conditions. Early recognition of existing stigmatising attitudes and intervention during medical education can help develop strategies to reduce stigma, fostering compassionate and informed care. Further research is crucial for analysing and comparing psychiatry curriculum content across these countries and for identifying areas for reducing stigma among medical students, including the introduction of tailored training programmes to address this issue.

#### CONFLICTS OF INTEREST

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

#### FUNDING

The authors received no financial support for the research, authorship and/or publication of this article.

#### ETHICS APPROVAL

This study was approved by the Committee of Ethics and Academic and Scientific Deontology of the University of Medicine and Pharmacy of Craiova, Romania (approval no. 15) on February 26, 2016. This research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

#### AVAILABILITY OF DATA AND MATERIALS

All data and materials used in this study are available upon reasonable request.

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## THE VAPER'S PERSPECTIVE: A QUALITATIVE STUDY OF E-CIGARETTE USERS AND SMOKERS IN SLOVENIA

»VEJPANJE«: KVALITATIVNA RAZISKAVA UPORABNIKOV IN KADILCEV E-CIGARET V SLOVENIJI

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Received: Jun 05, 2024 Accepted: Aug 08, 2024 Original scientific article

#### ABSTRACT

Keywords: E-cigarettes Vaping Less harmful alternative Qualitative studies Slovenia **Background:** The use of e-cigarettes has been rapidly expanding in recent years. The reasons people in Slovenia chose to use electronic cigarettes have not been studied to date. This study examines e-cigarette users' attitudes regarding their health risks.

**Objectives:** The aim of the study was to examine the users' standpoint towards e-cigarettes and their understanding of the impact on people's health.

**Methods:** This qualitative study consists of 15 semi-qualitative interviews. Fifteen active or former tobacco smokers and/or e-cigarette users were interviewed using semi-structured interviews between 1 December 2019 and 30 April 2020. Data were analysed using qualitative content analysis. The employed inductive analysis consisted of coding, creating categories and abstraction; that is, framing a general description of the research topic through generating categories.

**Results:** Data show that the interviewees do not have a unified opinion regarding the use and harmful effects of e-cigarettes. They agree that e-cigarettes are less harmful than regular cigarettes, but do not believe that they completely eliminate harmful effects for people that smoke regularly. The results also show that vaping is typical of young people, who use e-cigarettes as an important element of their subculture.

**Conclusions:** The use of e-cigarettes in Slovenia is still a matter of public debate, because the advantages and harmful effects of using e-cigarettes are not yet well known. National guidelines for reducing the harmful effects of e-cigarettes are needed.

#### IZVLEČEK

Ključne besede: e-cigarete vejpanje manj škodljive alternative kvalitativne študije Slovenija

Izhodišča: Uporaba e-cigaret se v zadnjih letih hitro širi. Razlogi, zakaj se ljudje v Sloveniji odločajo za uporabo elektronskih cigaret, do danes niso bili raziskani. Ta raziskava preučuje odnos uporabnikov e-cigaret do njihovih zdravstvenih tveganj.

Cilji: Namen raziskave je bil preveriti stališče uporabnikov do e-cigaret in njihovo razumevanje vpliva na zdravje ljudi.

**Metode**: Kvalitativna študija je sestavljena iz 15 pol-kvalitativnih intervjujev. Med 1. decembrom 2019 in 30. aprilom 2020 je bilo s pol-strukturiranimi intervjuji anketiranih 15 aktivnih ali nekdanjih kadilcev tobaka in/ ali uporabnikov e-cigaret. Podatki so bili analizirani s kvalitativno vsebinsko analizo. Uporabljena induktivna analiza je bila sestavljena iz kodiranja, ustvarjanja kategorij in abstrakcije; to je oblikovanje splošnega opisa raziskovalne teme z ustvarjanjem kategorij.

**Rezultati:** Podatki kažejo, da anketiranci nimajo enotnega mnenja glede uporabe in škodljivosti e-cigaret. Strinjajo se, da so e-cigarete manj škodljive od navadnih cigaret, vendar ne verjamejo, da popolnoma odpravijo škodljive učinke za ljudi, ki redno kadijo. Rezultati tudi kažejo, da je vejping značilen za mlade, ki uporabljajo e-cigarete kot pomemben element svoje subkulture.

Zaključek: Uporaba e-cigaret je v Sloveniji še vedno predmet javne razprave, saj prednosti in škodljivosti uporabe e-cigaret še niso dobro poznane. Potrebne so nacionalne smernice za zmanjšanje škodljivih učinkov e-cigaret.

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#### **1 INTRODUCTION**

The use of electronic cigarettes (e-cigarettes) has been rapidly expanding worldwide in recent years (1). Although both tobacco cigarettes and e-cigarettes serve as nicotine delivery systems, they differ fundamentally in their composition, health risks, regulatory frameworks and social perceptions. E-cigarettes are often promoted as a less harmful alternative to conventional cigarettes; however, to date the commercialisation (sale, import, distribution or manufacture) of e-cigarettes as consumer products has not been proven to benefit public health. Instead, alarming evidence about their adverse health effects on the population is mounting. The WHO Study Group on Tobacco Regulation has published a number of reports that contain evidence-based recommendations on electronic nicotine delivery systems and electronic nonnicotine delivery systems (ENDS and ENNDS), colloquially referred to as e-cigarettes (2, 3). The use of e-cigarettes has dramatically increased over the last four years, particularly among young people (4). Etter (5) reported that 7.5 million people in the European Union currently use e-cigarettes. E-cigarettes have been marketed as a new method for smoking cessation or decreasing cigarette consumption because they are cheaper than normal cigarettes and they taste and smell better than normal cigarettes (6). The evidence base for e-cigarettes is certainly still emerging, particularly in relation to their effectiveness as quitting aids and the health impacts for long-term users (7). A study by Chen et al. (8) reported that most participants believed e-cigarettes had influenced their cigarette smoking behaviour, and stated that e-cigarettes had helped them temporarily cut back on smoking. They also added that e-cigarettes serve as a replacement for normal cigarettes and help alleviate their craving. Pokhrel et al. (9) found that e-cigarettes were perceived as an effective way to cut back on or quit smoking. On the other hand, adolescents that use e-cigarettes are more than twice as likely to later use conventional cigarettes, and there is a pattern of dual or multiple tobacco and nicotine product use among youth (10).

Some studies have shown that participants that used e-cigarettes failed to quit smoking, and, instead, many ended up using e-cigarettes in addition to normal cigarettes (11). Etter (5) concluded that 66% of vapers had no intention of stopping vaping. Buckell and Sindelar confirmed this and found that e-cigarettes encouraged participants that prefer vaping to keep vaping instead of quitting (12). Moreover, Coleman et al. (13) highlighted that adult e-cigarette users that wanted to reduce or quit normal cigarette smoking were less likely to say they would stop using e-cigarettes in the short or long term. Skelton et al. (14) found that less than half of their study participants believed that e-cigarettes were helpful for quitting or cutting back on smoking. Coleman et al. (13) found that the most frequently repeated point of discussion regarding e-cigarettes was the lack of stigma surrounding e-cigarette use compared to normal cigarettes; that is, the social acceptability of e-cigarettes. Most of these study participants had positive attitudes about e-cigarettes because e-cigarettes allow them to continue to enjoy the social aspects of smoking. Furthermore, studies by Gorukanti et al. (4) and Aghar et al. (6) revealed that e-cigarette users are more acceptable to their friends because e-cigarettes are considered trendier. It was found that 36.8% use e-cigarettes exclusively for social smoking purposes. The idea of using e-cigarettes to enhance social status was derived from Pokhrel et al. (10), who found that e-cigarette users perceive e-cigarettes as a way to enhance their social interactions, feel that they are more acceptable, believe they can be used around children and that children do not need to be left unattended while users go smoke, believe they allow users to enjoy the company of non-smokers without fear of harmful second-hand exposure, and believe that e-cigarette use could help them meet or get to know new people that also use e-cigarettes. Alexander et al. (15) found that younger users are more likely to use e-cigarettes with others compared to older users.

Although most people know that e-cigarettes contain nicotine, few individuals were able to mention specific ingredients in e-cigarette liquid, revealing a general lack of knowledge about the ingredients other than nicotine (13). In a study by Gorukanti et al. (4), 19.05% agreed that smoke from e-cigarettes is water vapor, and 23.03% thought e-cigarettes are not a tobacco product. Some participants did not know that e-cigarettes could contain nicotine. They were also unsure about the differences between the nicotine in e-cigarettes and the nicotine in normal cigarettes. They believed that normal cigarettes contain natural nicotine, derived from tobacco plants, as opposed to chemically synthesized nicotine in the e-liquid. E-cigarettes generate vapor by heating a liquid that is typically composed of nicotine, a humectant, and flavoring; however, nicotine itself is teratogenic, even in the absence of combustion by-products (8). On the other hand, because the delivery of nicotine in e-cigarettes takes place through heating but not burning the liquid, they do not expose individuals to as many toxins as combustible tobacco products (14).

Tobacco product marketing is prohibited in Slovenia, and the legislation became stricter in 2024. Except for tobacco, all flavourings, including menthol, are prohibited in heated tobacco products and electronic cigarettes. Smoking rooms will be banned by the end of December 2025. The main goal of the tightened restrictions is to prevent and reduce the use of tobacco and related products, especially among adolescents and children, who are the main target of the tobacco industry (16). Koprivnikar notes that after the introduction of effective tobacco control measures in Slovenia there has been a decrease in the prevalence of smoking among adults; currently, approximately one in five adult residents of Slovenia smokes. Due to the tightening of measures, to meet its goal of increasing sales and profits, the industry began marketing various types of products with tobacco or nicotine, such as electronic cigarettes, heated tobacco products and nicotine pouches, which are also present in Slovenia (17). The Slovenian medical profession has already been dealing with the harmful effects of e-cigarettes (18). However, the reasons people choose to use e-cigarettes are not well studied. This study examines e-cigarette users in Slovenia and their attitudes regarding the health risks of vaping. The study investigates how users perceive e-cigarettes and their understanding of the impact on people's health. The primary research questions are why people start using e-cigarettes and whether their reasons are personal or social.

#### 2 METHODS

#### 2.1 Study design

This qualitative study uses semi-structured interviews. Qualitative interviews play an important role in research projects based on participant observation (18). The reasons for using a qualitative approach can be found in the specific characteristics of e-cigarette users, such as their specific reasons for using e-cigarettes (e.g., how useful e-cigarettes are if one wants to quit smoking, the belief that e-cigarettes are not harmful, family and subculture affiliation, etc.). Vaping is a relatively new phenomenon that justifies the use of this exploratory method, which has also been recognized by other researchers (3, 7, 9, 15).

#### 2.2 Participants

The researchers conducted semi-structured interviews with fifteen active e-cigarette users. Some participants used both normal cigarettes and e-cigarettes, and some have given up normal cigarettes and switched to e-cigarettes. Interviews were conducted between 1 December 2019 and 30 April 2020, until saturation was reached (no more new views and opinions were forthcoming). The participants were between 30 and 59 years old. The following criteria were considered when selecting the participants: they are smokers that use e-cigarettes, they are capable of reflection (not biased), they have time available to be interviewed, and they are willing to take part in our study. All the interviews were audio recorded and transcribed verbatim by a trained administrator. The questionnaire was developed in the following manner: after studying the Slovenian and international literature on e-cigarettes and their impact on health and social life, the guestion set was developed. The researchers then discussed this set to narrow down the topics.

#### 2.3 Recruitment and interview process

A literature review was conducted first, which included case reports, comparative studies, datasets, interviews, meta-analysis, reviews and systematic reviews written in English. Following the literature review, the scenario for interviews was developed in three rounds. The next phase was dedicated to training the interviewers in November 2019. These trained interviewers conducted 15 interviews with e-cigarette smokers through purposive sampling. The sample size was determined using theoretical saturation, which is the point in the data collection process when new data no longer offer additional insights for the research question (19-21). The saturation process was applied prospectively, during the course of data collection, which allowed us to stop interviewing after a certain period of time. Under this condition, the final number of interviews conducted was 16. All the interviews were audio recorded and transcribed verbatim.

#### 2.4 Data analysis

Qualitative content analysis (QCA) was used for the systematic examination of the data collected. QCA is a method derived from the communication sciences that is useful for systematic analysis in a wide range of research domains (22), including for e-cigarettes and their health risks (9). This study used inductive content analysis, which includes coding, creating categories and abstraction: framing a general description of the research topic through generating categories (23-25). The interviews were independently coded by two researchers. The study used a data-driven coding scheme and formed codes sorted into logical categories/themes to observe patterns in the data analysed and explain e-cigarette users' attitudes toward health risks. During the coding process, consensus was sought between the two researchers. If consensus was not reached, we tried to achieve intercoder agreement about the differently perceived parts of the text analysed to fit the category created, also known as a "unitizing" process (24, 25).

#### **3 RESULTS**

Three categories were determined using QCA: 1) attitudes and beliefs about e-cigarettes; 2) subcultural determinants; and 3) awareness-raising measures. Themes were named according to the content they illustrate, as well as relying on the literature discussing previous empirical studies.

#### 3.1 Attitudes and beliefs about e-cigarettes

Interviewees' opinions regarding the use of e-cigarettes differed. There is virtually no consensus on whether e-cigarettes are harmful or not. Some of the interviewees believe that e-cigarettes are a "healthier alternative" that can help people quit smoking. They believe that e-cigarettes are less dangerous for smokers (because of the way they deliver nicotine) and for other people in the surrounding area. As an example, they emphasise improved breathing and reduced symptoms of cough or phlegm. Here are some typical responses:

- However, having used it for 4 or 5 months, I feel that my breathing is better. (P7)
- E-cigarettes or vapes are a better option or a better alternative to quit normal smoking. They are less dangerous than cigarettes, but still the healthier option would be not smoking at all. So this was a healthier–I mean not healthy, but less dangerous–alternative to normal cigarettes. (P12)
- If you smoked normal cigarettes in the past, what were the reasons for switching to e-cigarettes? There are two: that's what health is, definitely. When, after so many years, you start to worry a little, even though the medical examinations, thank God, have always been fine. On the other hand, there's also a financial reason. (P1)
- For me, this is a better alternative to completely cutting nicotine straight away or going back to cigs. (P13)

Some of our interviewees were less optimistic regarding the damage caused by e-cigarettes, which was associated with nicotine content.

• But for now, I'm still on a minimum amount of nicotine. Otherwise, between normal cigarettes and this, I think that the addiction to normal cigarettes is greater, in my opinion, cigarettes are significantly worse because it's so much harder. . . I've already tried to quit smoking before. It's harder to stop smoking normal cigarettes than this. Here you can still regulate how much nicotine you give yourself. (P2)

#### 3.2 Subcultural determinants

Some of our interviewees described attractive characteristics of e-cigarettes, such as their cool appearance, and attractive packaging and colours, taste and smell. Practically all interviewees were convinced that this appeals to young people, who are the most enthusiastic about e-cigarettes. They are convinced that this is a subcultural element, which is also exploited by the tobacco industry. The visual appeal of these products seems to be more important to young users than the idea of e-cigarettes being less harmful than normal cigarettes. Below are some of the most indicative statements:

 But I think even younger people are more likely to try something like this at all because it's visually appealing. (P1)

- Most people will start using these e-cigarettes because they look cool when people are vaping and stuff. To be honest, I took advice from a few people at work and then chose a nice colour. I can also choose the taste and not stink so much after smoking. (P14)
- I've heard of different shapes and flavours before, and I definitely think this adds to the appeal of these things.
   As people, we tend to get attached to things that we find pleasant, and thus safe. Young people are probably particularly susceptible to this. (P5)
- E-cigarettes are visually more attractive than regular cigarettes. Also, nobody likes to stink, and you can avoid it with an e-cigarette, for example. (P10)

Some interviewees pointed out that e-cigarettes are easier to choose because of the way one finds out what they are. One interviewee mentioned that he decided to switch to e-cigarettes so he would not bother others with the smell at the workplace. He also said that smoking gave him a feeling of belonging, and it helped his social life.

• And also, it didn't stink. Because normal cigarettes stink. E-cigarettes don't stink that much. The smell is annoying. It wasn't for me because I don't want other people, like non-smokers, to be affected by the smell. Because when you have a cigarette and you go back, the smell stays on you, and if the person sitting next to you doesn't smoke, it bothers them. And this doesn't have any smell. It doesn't linger around. It's just like no smoke. (P11)

Some of interviewees pointed out that smoking e-cigarettes gave them the feeling of belonging among peers. Similar to their attitude towards alcohol, young people do not want to be excluded from society, so they choose to have a drink or a cigarette. It means following generational norms and meeting the conformist expectations of youth subculture. In other words, by smoking an e-cigarette you are accepted among your peers.

• Because everyone in your circle of friends is smoking and you're just standing there, and smoke is blowing in your face, and it's just weird like that. Because everyone's doing it, and then you'd be the only one who's just standing there. (P11)

#### 3.3 Awareness-raising measures

Some of our interviewees, as experienced vapers, pointed out the importance of raising awareness about the harmful effects of e-cigarettes and smoking as such. They highlighted the lack of educational programmes that are urgently needed to limit this phenomenon in the long run. They were practically united on the need to draw up national guidelines for raising public awareness about the harmful effects of e-cigarettes. They agreed that a ban on the sale of tobacco products and fines were not optimal.

- My doctors know that I smoke because this is always among the first questions when meeting them here. What else would be of benefit to you in e-cigarette prevention and use? Help with quitting. We're supposed to have assistance service or support available through a facility. (P15)
- How familiar are you with prevention programmes such as Healthy Living workshops and Smoking Cessation workshops? I haven't really heard about those. (P11)
- I'm not familiar with these things, so I haven't been involved in any of these workshops. (P4)

#### **4 DISCUSSION**

The data presented here show that interviewees in Slovenia do not have a unified opinion regarding the use and harmful effects of e-cigarettes. Some of them agree that e-cigarettes are less harmful than regular cigarettes but not completely free of side effects for people that smoke constantly. The interviewees agreed that vaping is typical mainly among young people, which is confirmed by data in Slovenia (26). They attribute the use of e-cigarettes to the subculture and packaging (i.e. marketing) of such products.

Our research findings are in line with those of researchers in other countries. Smoking habits are affected by individual, psychological and social factors such as curiosity, the smoking behavior of friends or family members, and their social environment. At the social level, many factors, such as sales, education and knowledge, influence the use of e-cigarettes (27).

Most interviewees believed that e-cigarettes influenced their cigarette smoking habits, and stated that e-cigarettes temporarily helped them cut back on smoking. They also added that e-cigarettes served as a replacement for normal cigarettes and helped alleviate the craving for them. This is consistent with past research, in which researchers similarly found that e-cigarettes were perceived as an effective way to reduce or quit smoking (28). However, Duarte et al. (11) found that e-cigarette users failed to quit smoking. Furthermore, instead of encouraging smokers to switch from conventional cigarettes to less dangerous e-cigarettes or quitting altogether, e-cigarettes are reducing smoking cessation rates and even expanding the nicotine market by attracting young people (29).

An important finding in our study relates to the youth subculture: smoking e-cigarettes is acceptable among young people. They use e-cigarettes to express their belonging to a peer group. This finding is similar to that of Coleman et al., who found that most participants had positive attitudes towards e-cigarettes because they allow them to continue to enjoy the social aspects of smoking (13). E-cigarette users are better accepted among their friends because they are considered trendier (6). In line with previous results, our interviewees also mentioned a lack of awareness and information about the harmful effects of e-cigarettes. General practitioners play an important role in providing patients with health information, support and treatment to encourage them to quit smoking. Despite conflicting evidence on the effectiveness of e-cigarettes as a smoking cessation aid, there is growing interest in the role e-cigarettes might play as an alternative to smoking tobacco (30). Clear guidance on the role of e-cigarettes is needed to inform and educate general practitioners about e-cigarettes for smoking cessation.

As in other countries, e-cigarettes are relatively new devices in Slovenia, and our interviewees stated that they are not well informed about the harms and benefits of e-cigarettes. They unanimously agreed that national guidelines for reducing the harmful effects of smoking need to be developed in the future, with a special focus on e-cigarettes.

#### 4.1 Limitations

Some methodological limitations of our study could be related to the open research question, and the study's explanatory character may have been hampered by the inductive creation of codes, categories and themes. In this regard, it is important to note that the study is subjective-which is, in fact, the most frequent criticism of qualitative research in general (23). However, all coauthors relied on a careful and deliberate research strategy and respected the basic characteristics of qualitative research at the stage of data collection and analysis. Some of our findings may have also been limited due to the polarised and insufficiently researched area of e-cigarette use in Slovenia (17). As an example of recommendations for guitting e-cigarettes, we cite the publication "Clinical Guidance for E-Cigarette (Vaping) Cessation" in the journal Preventive Medicine Reports (31). In 2020, the Slovenian National Institute of Public Health published Elektronske cigarete - podrobnejše informacije za zdravstvene delavce (Electronic Cigarettes: More Detailed Information for Health Workers) (32).

#### **5 CONCLUSION**

Findings from this qualitative study provide insight into e-cigarette users' standpoints and beliefs about e-cigarettes. Three themes were created based on the interviewees' inputs. Attitudes and beliefs about e-cigarettes included seeing them as a way to reduce or quit smoking. The study also found that e-cigarettes are used for social enhancement. Most interviewees consider e-cigarettes a healthier alternative that improves breathing and is less dangerous. Under subcultural determinants, it was found that the attractive features of e-cigarettes such as taste, smell, colours and appearance, along with being convenient to use, affect smoking behaviours and e-cigarette use. The interviewees especially pointed out the demographic group of young people. Cessation workshops tailored to new findings on e-cigarettes should be offered. Recommendations and guidance should be provided to physicians on e-cigarette cessation.

#### ACKNOWLEDGMENT

We thank all the participating PhD students for taking the time to act as interviewers in our study, above and beyond their regular duties during the pandemic. We dedicate this article to all of them.

#### CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

#### FUNDING

This study did not receive any specific grants from funding agencies in the public, commercial or not-for-profit sectors.

#### ETHICAL APPROVAL

This study was approved by the Ethical Review Board in Slovenia under the number 0120-619/2019/8.

#### AVAILABILITY OF DATA AND MATERIALS

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

#### LLM STATEMENT

During the preparation of this work the authors did not use AI tools.

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## MONITORING THE EFFECT OF VACCINATION ON MUMPS CASES COMPLICATIONS IN THE CZECH REPUBLIC - SURVEILLANCE DATA 2013-2022

SPREMLJANJE UČINKA CEPLJENJA NA ZAPLETE PRI PRIMERIH MUMPSA NA ČEŠKEM - NADZORNI PODATKI 2013-2022

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Received: Mar 01, 2024 Accepted: Aug 26, 2024 Original scientific article

ABSTRACT	Introduction: Mumps data were analysed to assess the effect of vaccination on mumps complications and hospitalisation.
Keywords: Mumps Mumps complications Orchitis Hospitalisation Vaccination Vaccine effectiveness	<b>Methods:</b> The mumps cases reported to the Czech nationwide surveillance system from 2013 to 2022 were analysed using logistic regression with an odds ratio (aOR) adjusted for age, sex, year of onset and administrative region to measure the association between vaccination and complications or hospitalisation. Adjusted vaccine effectiveness (aVE) was calculated: aVE=(1-aOR)x100.
	<b>Results:</b> A total of 11,913 mumps cases were reported, of which 6,885 (58%) were male. The median age of the study participants was 16 (range: 0-89 years). No complications occurred in 91% of patients. Mumps orchitis occurred in 633 (9%) male cases. A total of 946 (8%) patients required hospitalisation. The highest proportion of complications and hospitalisations was in the age group 35-44 years. Two doses of vaccine reduced statistically significantly the risk of any complications and of hospitalisation compared with unvaccinated patients: aOR 0.48 (95% CI: 0.37, 0.62), aVE of 52% (95% CI: 38, 63); and aOR 0.43 (95% CI: 0.33, 0.56), aVE of 57% (95% CI: 44, 67), respectively. Two doses showed statistically significant aVE 50% (95% CI: 32, 64) against orchitis, and 59% (95% CI: 23, 79) against meningitis. Among the two-dose recipients, the proportion of complications increased gradually with the time from the second dose.
	<b>Conclusions:</b> Our findings demonstrated a protective effect of two-dose vaccination against mumps complications and hospitalisation for mumps. We recommend continuing routine childhood mumps vaccination and maintaining high MMR coverage in Czechia.
IZVLEČEK	<b>Uvod</b> : Analizirali smo podatke o mumpsu, da bi ocenili učinek cepljenja na zaplete in hospitalizacijo zaradi mumpsa.
<b>Ključne besede:</b> mumps zapleti	<b>Metode:</b> Primere mumpsa, ki so bili v obdobju 2013-2022 prijavljeni v državni sistem nadzora na Češkem, smo analizirali z logistično regresijo z razmerjem obetov (aOR), prilagojeno glede na starost, spol, leto začetka in upravno regijo, da bi ugotovili povezavo med cepljenjem in zapleti ali hospitalizacijo. Izračunali smo prilagojeno učinkovitost cepiva (aVE): aVE = (1 - aOR) x 100.
hospitalizacija cepljenje učinkovitost cepljenja	<b>Rezultati</b> : Skupaj je bilo prijavljenih 11.913 primerov mumpsa, od tega 6885 (58 %) pri moških. Povprečna starost udeležencev v študiji je bila 16 let (razpon: 0-89 let). Pri 91 % bolnikov ni prišlo do zapletov. Mumps orhitis se je pojavil pri 633 (9 %) moških. Skupaj je 946 (8 %) bolnikov potrebovalo hospitalizacijo. Največji delež zapletov in hospitalizacij je bil v starostni skupini 35-44 let. Dva odmerka cepiva sta statistično pomembno zmanjšala tveganje za nastanek morebitnih zapletov in hospitalizacijo v primerjavi z necepljenimi bolniki: aOR 0,48 (95 % IZ: 0,37, 0,62), aVE 52 % (95 % IZ: 38, 63) in aOR 0,43 (95 % IZ: 0,33, 0,56), aVE 57 % (95 % IZ: 44, 67). Dva odmerka sta pokazala statistično pomembno aVE 50 % (95 % IZ: 32, 64) v primerjavi z orhitisom in 59 % (95 % IZ: 23, 79) v primerjavi z meningitisom. Delež zapletov med prejemniki dveh odmerkov se je postopoma povečeval s časom od drugega odmerka.
	<b>Zaključki</b> : Naše ugotovitve so pokazale zaščitni učinek cepljenja proti zapletom in hospitalizaciji zaradi mumpsa. Priporočamo nadaljevanje rutinskega cepljenja otrok proti mumpsu in ohranjanje visoke stopnje precepljenosti s
	cepivom OMR na Češkem.

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#### **1 INTRODUCTION**

Mumps is a viral respiratory infection caused by an RNA virus of the family Paramyxoviridae, genus Rubulavirus (1). The disease starts with nonspecific prodromal symptoms: malaise, fever, myalgia, headache and anorexia (1). The common course of the disease is acute parotitis in up to 70% of cases. The following complications may occur: orchitis (the most frequent complication), oophoritis, meningitis, encephalitis, pancreatitis, myocarditis, deafness and so forth (1). Asymptomatic and subclinical mumps infections can account for up to 20% of all infections (2). The incubation period is 16-19 days (range 12-25 days) (1). Mumps is transmitted by droplet spread and by direct contact with the saliva of an infected person (1).

It belongs to notifiable diseases only in some countries. The global annual number of reported cases in the years 1999-2022 ranged from 169,799 in 2019 to a maximum of 726,638 in 2011, based on the World Health Organization (WHO) Global Health Observatory data repository (3).

The incidence of mumps per 100,000 population reported in the European Union/European Economic Area (EU/ EEA) in 2013-2021 decreased from 5.9 in 2013 to 0.4 cases in 2021. The most recent EU/EEA data available before the COVID-19 pandemic in 2018 show an incidence of 2.6 cases/100,000 population, and a higher proportion of cases occurred in males in all age groups. Hospitalisations and complications due to mumps in 2018 were rare (4.5% and 6.5%, respectively), with no deaths reported. The Czech Republic (CZ) belonged to those EU/EEA countries with the highest notification rate in 2018 (5.1 cases/100,000 population). In 2021, 1,567 cases of mumps were reported by 27 EU/EEA Member States, with an overall notification rate of 0.4 cases/100,000 population. This was significantly lower than the notification rates reported during the previous four years (range 1.7-4.2). In 2022, 27 EU/EEA countries reported 2,593 mumps cases, with an overall notification rate of 0.7 cases/100,000 population (4).

#### 1.1 Surveillance of mumps in CZ

According to Czech national legislation, mumps is a mandatorily notifiable disease (5). The current mumps surveillance system in CZ is comprehensive, nationwide, case-based and harmonised with the EU case definition 2008 requirements. General practitioners and physicians from hospitals report cases to the Regional Public Health Authority (RPHA). The RPHA collects information on individual mumps cases, performs epidemiological investigation and uploads the data to the electronic nationwide infectious disease notification system. The National Institute of Public Health (NIPH) collaborates on data validation and analyses and reports them to the European Surveillance System and WHO database.

Mumps belongs to vaccine preventable diseases. A twodose mandatory vaccination programme covered by public health insurance began in the former Czechoslovakia in 1987 with a bivalent measles-mumps vaccine. The first dose was given at 15 months of age, the second dose 6-10 months after the first dose. In 1995, the trivalent measlesmumps-rubella (MMR) vaccine was introduced nationwide. Since January 2018, the first dose of MMR vaccine has been administered at 13-18 months of age and second dose at 5-6 years of age (6).

The vaccination coverage (VC) has been evaluated annually by administrative surveys. The VC data from a 2019 survey showed that for children born in 2016 and 2017, one-dose MMR VC was 96.55% and 94.41%, respectively. Coverage with the second dose was not available in CZ in 2019 (7). The latest available one-dose MMR VC figure (for 2022) for children aged 2 years born in 2020 in CZ was 87.0%, based on data from health insurance companies (8).

The aim of the study was to assess the effect of vaccination on mumps complications and the need for hospitalisation based on mumps cases reported to the nationwide surveillance system in 2013-2022. Furthermore, the intention was to evaluate the effect of the time interval from the administration of the second dose of vaccine on the development of complications.

#### 2 METHODS

#### 2.1 Study population and data sources

Pseudonymised data were retrieved from the Czech electronic nationwide infectious disease surveillance systems EpiDat (until 2017) and ISIN (from 2018). The surveillance system contains mumps data reported as confirmed cases (meeting the laboratory criteria), probable cases (meeting the clinical criteria with an epidemiological link) and possible mumps cases (meeting the clinical criteria). All reported mumps cases were included in this study regardless of their case classification (confirmed, probable and possible case). All cases were checked for duplicity and data integrity.

A case was defined as any patient with clinical presentation of mumps reported to the surveillance system under the code "B26" of the 10th Revision of International Classification of Diseases in the ten-year period 2013-2022 according to the date of disease reporting. A case was defined as vaccinated if the patient received at least one dose of mumps vaccine more than 25 days before the symptoms onset, which we decided based on the incubation period and at least partial onset of immunity after vaccination.

Incidence was calculated based on mid-year population data published by the Czech Statistical Office (9, 10).

#### 2.2 Data analysis

Mumps cases were described in terms of age, sex, year of reporting, administrative region (third level of the Nomenclature of Territorial Units for Statistics - "NUTS 3" was used), vaccination history and disease severity by complications and hospitalisation. The vaccination history included vaccination status, number of doses and the date of vaccination. Epidemiological characteristics of the cases were analysed using absolute and relative frequencies. Fisher's exact test was used to examine the significance of the association between the two characteristics.

To assess the effect of vaccination on the occurrence of mumps complications and hospitalisation in those fully vaccinated with two (or three) doses of MMR vaccine, partially vaccinated with one dose of MMR vaccine and unvaccinated mumps cases were compared.

Simple and multiple logistic regression models were used to assess the relationship between vaccination status and selected mumps complications or hospitalisation. They resulted in unadjusted odds ratios (OR) and odds ratios adjusted for age, sex, year of onset and NUTS 3 (aOR). In the case of separation problems related to small numbers of observations in some subcategories, the logistic regression model was fitted using the Firth's bias reduction method (11). The adjusted vaccine effectiveness (aVE) was computed as aVE=(1-aOR)x100. Point estimates for odds ratio and vaccine effectiveness were supplemented with 95% confidence intervals (95% CI). Cases with an unknown vaccination status and vaccinated cases with an unknown number of vaccine doses were excluded from the analytical part of the study.

The risk of mumps complications was evaluated using logistic regression in relation to the time between the date of the vaccination with the second dose of MMR vaccine and the onset of disease and age at the second dose. The time interval from the second dose to disease onset was divided into five-year periods.

Findings with p-values less than 0.05 were considered statistically significant. Statistical analyses were performed in STATA, version 17 (StataCorp LLC, College Station, Texas, USA).

#### **3 RESULTS**

#### 3.1 Descriptive analysis

Over the ten-year study period the mumps cases in CZ were distributed unevenly (Table 1). The incidence of reported mumps cases per 100,000 population ranged from 0.4 to 54.3. The highest morbidity was reported in 2016, followed by a significant decline in subsequent years. The total of 11,913 mumps cases was reported within the study period. Of these, 6,885 (58%) were males. The mean age at disease onset was 18.3 years, median age 16 years

(range 0-89 years). The age groups 10-14 and 15-19 years were the most affected. Cases were reported from all fourteen CZ regions, with the highest incidence in the South Bohemian Region (Table 1).

In total, 40% of all cases of mumps were laboratory confirmed and 35% were epidemiologically linked to a confirmed case. Possible cases were reported based on typical clinical symptoms in 25% of all cases of mumps. Of the total 11,913 analysed cases, 9,714 (81.5%) were vaccinated, 1,673 (14%) unvaccinated and in 526 (4.4%) cases the status was unknown. Ninety-four percent of those vaccinated were vaccinated with two doses (Table 2).

Ninety-one percent of the cases had no clinical complications. The most frequent complication was orchitis, reported in 633 (9.2%) male patients. Of all the cases, meningitis affected 126 (1.1%), pancreatitis 37 (0.3%) and encephalitis 11 (0.1%). Oophoritis was detected in 8 (0.2%) females. Further, there were 88 (0.7%)other complications and 139 (1.2%) cases had unknown information about mumps complications. Of those with a known hospitalisation status (n=11,844), 946 (7.9%) required hospitalisation (Tables 2 and 3). The proportion of hospitalised patients was significantly higher in males (10.2%) than in females (5.0%), p<0.001. Orchitis was the most common complication in males in age groups 25-34 (31%), 15-19 (25%) and 20-24 (19%) years. The highest proportion of mumps complications and hospitalisations was reported in the age group 35-44 years (22.8% and 19.4%, respectively), followed by the age group 25-34 years (17.5% and 17.0%, respectively). Males accounted for 87.5% of all mumps complications (790/903) and 73.5% of hospitalisations (695/946).

## **3.2 Effectiveness of MMR vaccination to prevent mumps complications or hospitalisation**

Among the mumps cases with complications, 59% reported being vaccinated with two doses of MMR vaccine, while among cases without any complications 85% received two doses of vaccine (p<0.001). Among the hospitalised cases, 62% were vaccinated with two doses, while of those nonhospitalised the rate was 85% (p<0.001). Therefore, two doses of vaccine substantially and significantly (p<0.001) reduced the risk of any complications and the need for hospitalisation compared with unvaccinated patients, resulting in an aOR 0.48 (95% CI: 0.37, 0.62) and an aOR 0.43 (95% CI: 0.33, 0.56), which corresponds to aVE of 52% (95% CI: 38, 63) and 57% (95% CI: 44, 67), respectively. Two doses also showed significant aVE of 50% (95% CI: 32, 64) against orchitis in males, and 59% (95% CI: 23, 79) against meningitis in all cases (Table 4).

Even in single-dose vaccinated cases, a significant reduction in the risk of any complications and the need for hospitalisation was demonstrated, p<0.05.

	Number of mumps cases (n=11,913)	Proportion (%)	Incidence of mumps cases per 100,000 population and year
Year of onset			
2013	1,553	13.0	14.8
2014	677	5.7	6.4
2015	1,616	13.6	15.3
2016	5,733	48.1	54.3
2017	1,407	11.8	13.3
2018	537	4.5	5.1
2019	191	1.6	1.8
2020	93	0.8	0.9
2021	38	0.3	0.4
2022	68	0.6	0.6
Distribution of cases by administrative region			
Prague	1,041	8.7	8.1
Central Bohemian	853	7.2	6.3
South Bohemian	2,438	20.5	38.1
Plzeň	446	3.7	7.7
Karlovy Vary	274	2.3	9.3
Ústí nad Labem	386	3.2	4.7
Liberec	602	5.1	13.7
Hradec Králové	649	5.4	11.8
Pardubice	821	6.9	15.8
Vysočina	1,642	13.8	32.2
South Moravian	798	6.7	6.7
Olomouc	381	3.2	6.0
Zlín	240	2.0	4.1
Moravian-Silesian	1,342	11.3	11.1
Gender			
Male	6,885	57.8	13.2
Female	5,028	42.2	9.3
Age group (years)			
0	10	0.1	0.9
1-4	269	2.3	6.0
5-9	1,371	11.5	24.1
10-14	3,417	28.7	64.8
15-19	3,142	26.4	65.5
20-24	1,353	11.4	24.8
25-34	1,479	12.4	10.6
35-44	506	4.2	3.0
45-54	214	1.8	1.5
55-64	95	0.8	0.7
65-74	46	0.4	0.4
75+	11	0.1	0.1

Table 1.	Demographic	characteristics of	mumps cases,	infectious	disease su	rveillance	system,	Czech	Republic,	2013	-2022
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Nearly two thirds of the mumps cases complicated with orchitis (409 men) were hospitalised compared with 3% of those hospitalised among the males without mumps complications (p<0.001).

Of the 126, 37 and 11 mumps cases with meningitis, pancreatitis and encephalitis, respectively, 97%, 46% and 91% were hospitalised. These proportions were significantly higher in all three situations compared with 3% of hospitalised cases among those with no reported mumps complications, p<0.001.

In two-dose vaccine recipients, the proportion of mumps cases with complications increased significantly with the time passed from the second dose of vaccination, p<0.001 (Table 5). Each subsequent category of time period is significantly different from the previous one, except for the last category of 25+ years, which shows no significant difference from the category of 20-24 years.

#### 4 DISCUSSION

This study builds on the work of Czech authors confirming the protective effect of MMR vaccination against mumps complications for data covering the period 2007-2012 (12). In our study, teenagers were the most affected age group. This result is in line with studies which have demonstrated that the highest burden of disease is currently among adolescents and young adults (12-15).

Due to the COVID-19 pandemic, it could not be ruled out that some mild mumps cases have not been detected in CZ. Mumps is a respiratory disease, so the implementation of non-pharmaceutical interventions (NPIs) during the COVID-19 pandemic may have influenced and reduced the number of mumps cases reported in CZ; a similar decrease of mumps cases was reported in other countries (4).

Table 2.	Vaccination and hospitalisation status of mumps
	cases, infectious disease surveillance system, Czech
	Republic, 2013-2022.

	Number of mumps cases	Proportion (%)
Vaccination status (n=11,913)	9,714	81.5
Vaccinated	1,673	14.0
Unvaccinated	526	4.4
Unknown		
Vaccinated by doses (n=9,714)		
1 dose	156	1.6
2 doses	9,134	94.0
3 doses	29	0.3
Unknown number of vaccine doses	395	4.1
Hospitalisation (n=11,913)		
Yes	946	7.9
No	10,898	91.5
Unknown	69	0.6

Several studies confirmed the reduction in the incidence of many communicable diseases, including several vaccine-preventable diseases during the pandemic, most likely due to social distancing, school closures and other NPIs reducing the likelihood of transmission (16-18).

In the last decade, mumps outbreaks were reported in several regions of CZ, with the highest incidence in South Bohemia in 2016 (19). The increase in mumps incidence in the highly vaccinated population in CZ seems to be a consequence of a secondary vaccination failure due to waning immunity over time (20, 21). This view is supported by the fact that in the mumps outbreak in South Bohemia, the age group 15-19 years was the most affected (19-21). The results of the serological surveys from 2013 demonstrated that only 33% of individuals in the age group 15-19 years had mumps antibodies (19, 22). Genotype G, which is predominant in Europe, has also been detected in CZ (20).

The most frequent complication in our study was mumps orchitis, which occurred in 9% of male cases, while in the previous CZ study it was reported in 12% of males. In the current study, a smaller proportion of cases were hospitalised due to the clinical course of the disease (8%) than in the previous CZ study with 12% hospitalised cases (12). We hypothesized that the higher number of hospitalisations in males could be due to the number of reported orchitis cases, which reveals a more severe course of mumps. In a Spanish study, the most frequent complication among hospitalised mumps cases was meningitis (13).

In our study, 19% of the unvaccinated participants had complications, while among one- or two-dose vaccine recipients the rate was about 5%. The reason for that difference is in vaccination status itself.

Table 3.	Mumps complications,	hospitalisation and	vaccination,	infectious dise	ase surveillance syste	em, Czech F	Republic,	2013-2022.
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	Mumps vaccination						
	Three doses	Two doses	One dose	Zero doses	Unknown	Total	
Total number of cases Complications	29	9,134	156	1,673	921	11,913	
None	27	8,608	145	1,339	752	10,871	
Orchitisª	2	312	6	231	82	633	
Meningitis	0	69	0	38	19	126	
Pancreatitis	0	20	0	13	4	37	
Encephalitis	0	3	0	6	2	11	
Oophoritis <sup>b</sup>	0	3	0	5	0	8	
Other	0	54	1	22	11	88	
Unknown	0	65	4	19	51	139	
Hospitalisation							
Yes	2	494	8	297	145	946	
No	27	8,605	147	1,359	761	10,899	
Unknown	0	35	1	17	15	68	

Note: <sup>a</sup>only among males (6,885), <sup>b</sup>only among females (5,028)

Type of complications	Vaccination by number of doses <sup>b</sup>	Number of cases	Number of cases with complications (%)	Unadjusted odds ratio (95% CI)	Adjusted <sup>c</sup> odds ratio (95% CI)	p value	Adjusted <sup>c</sup> vaccine effectiveness % (95% CI)
Any complication	0	1,654	315 (19.0)	Ref	Ref		
	1	152	7 (4.6)	0.21 (0.10, 0.44)	0.42 (0.19, 0.95)	0.036	58 (5, 81)
	2	9,069	461 (5.1)	0.23 (0.20, 0.27)	0.48 (0.37, 0.62)	<0.001	52 (38, 63)
<b>Orchitis</b> <sup>a</sup>	0	967	231 (23.9)	Ref			
	1	92	6 (6.5)	0.22 (0.10, 0.52)	0.57 (0.23, 1.38)	0.213	43 (-38, 77)
	2	5,174	312 (6.0)	0.20 (0.17, 0.25)	0.50 (0.36, 0.68)	<0.001	50 (32, 64)
Meningitis	0	1,654	38 (2.3)	Ref			
	1	152	0 (0.0)	0.14 (0.01, 2.25)	0.18 (0.01, 3.12)	0.240	82 (-212, 99)
	2	9,069	69 (0.8)	0.32 (0.22, 0.48)	0.41 (0.21, 0.77)	0.006	59 (23, 79)
Pancreatitis	0	1,654	13 (0.8)	Ref			
	1	152	0 (0.0)	0.40 (0.02, 6.74)	0.70 (0.03, 14.56)	0.820	30 (-1,356, 97)
	2	9,069	20 (0.2)	0.28 (0.14, 0.55)	0.46 (0.15, 1.44)	0.181	54 (-44, 85)
Hospitalisation	0	1,637	296 (18.1)	Ref			
	1	151	8 (5.3)	0.25 (0.12, 0.52)	0.46 (0.22, 0.97)	0.042	54 (3, 78)
	2	9,034	491 (5.4)	0.26 (0.22, 0.30)	0.43 (0.33, 0.56)	<0.001	57 (44, 67)

 Table 4.
 Number of cases with mumps complications or hospitalisation by MMR vaccination status and adjusted MMR vaccine effectiveness, Czech Republic, 2013-2022.

Note:

Ref - reference category (unvaccinated)

<sup>a</sup> only males, of 6,885 males

<sup>b</sup> 29 cases (16 males and 13 females) in three-dose vaccine recipients were not included in the analysis

<sup>c</sup> adjusted for age, gender, year of onset and region (NUTS 3)

Time from the second dose (in years)	Number of cases	Number of cases with complications	% of mumps cases with complications	Adjusted <sup>b</sup> odds ratio	95% CI	p value
0-4	531	1	0.2	Ref <sup>a</sup>		
5-9	2,283	26	1.1	Ref <sup>a</sup>		
10-14	3,287	151	4.6	5.26	3.45, 8.01	< 0.001
15-19	1,981	170	8.6	10.29	6.77, 15.63	<0.001
20-24	734	86	11.7	14.53	9.28, 22.75	< 0.001
25+	194	18	9.3	11.30	6.07, 21.06	<0.001
Total	9,010	452	5.0			

Table 5. Mumps complications in MMR vaccinated patients by time passed from the second dose, Czech Republic, 2013-2022.

Note:

<sup>a</sup>Ref - reference category 0-9 compounded from two categories: 0-4 and 5-9 years

<sup>b</sup>odds ratio adjusted for age at the 2nd dose

Another large retrospective cohort study analysing Korean mumps data reported that only 2% of patients had related complications (less than in our study) and the most reported complication was mumps orchitis among 42% of the males with complications, while meningitis was most frequent among females. The Korean authors concluded that in their study mumps complications were more frequent among males than in females (15) which is in line with our study results, where males accounted for 88% of all the complications.

We found that two doses of vaccine significantly reduced the risk of hospitalisation, corresponding to aVE 57% and the risk of any complication corresponding to aVE 52% in the study period 2013-2022, while in the previous CZ study the aVE was higher (71% and 68%, respectively) (12). In a large mumps outbreak in the Jerusalem district, authors estimated aVE against complications as 63% and aVE against hospitalisation as 44%, both for two doses of vaccine (23).

Our study results also demonstrated that two doses of vaccine significantly reduced the risk of orchitis and meningitis corresponding to aVE 50% and 59%, respectively. The previous CZ study showed aVE against orchitis of 72% and against meningitis aVE of 64% (12). We used the same methodology as in the previous CZ study, therefore we assume that probably other factors could play a role resulting in a lower aVE in our study, as the proportion of complications was similar in both CZ studies (e.g. the vaccination status by itself, worse quality of the source data inserted in the notification system). The rate of unknown vaccine status in the two CZ studies (current one and in the years 2007-2012) is not similar. In the current CZ study 4% of mumps cases had unknown vaccination status. In addition, another 4% of cases in the current study had an unknown number of vaccine doses. In a previous CZ study (2007-2012) vaccination status of mumps cases was: 0 doses (17% of cases), 1 dose (<1% of cases), 2 doses (82% of cases) and 3 doses (<1% of cases).

Although mumps incidence was the highest among teenagers, the highest proportion of mumps complications and hospitalisations was reported in the 35-44 years age group. In the Spanish study, hospitalisation and complication rates increased over time in the age group 25-34 years (13).

Among the two-dose recipients, the rate of complications increased from 0 to 12% in the post-vaccination interval categories after the second dose from 0-4 years to 20-24 years, then decreased slightly to 9% at 25+ years. These results of the effect of a time interval after the second dose of the vaccine on the risk of mumps complications are in line with the previous CZ study, when the rate of complications was higher and increased up to 16% (12).

The childhood immunisation programme against MMR in CZ has changed since January 2018, and not enough data for the evaluation of the new schedule was available. As of 31 December 2020, more than 95% of those born in 2017 received at least one dose of the MMR vaccine in different regions. It is important to improve VC with two doses of MMR vaccine, especially in regions with lower VC. The administrative control of vaccination in CZ was cancelled from 1 January 2022 and its results should be replaced by VC estimates obtaining data from health insurance companies (8, 24).

As part of ongoing surveillance, it is necessary to maintain high data quality when entering it in the notification system.

Reporting bias may have been present in our study, especially for the vaccination status variable, which could not be verified as the national vaccination register was launched only in January 2023. In addition, the legislation valid until the end of 2017 did not explicitly state the upper interval at which the first or second dose of MMR vaccine could be administered, therefore it was not possible to distinguish between people vaccinated on or off the immunisation schedule. Therefore, in the analytical study, a person was assessed as vaccinated regardless of the interval between the first and second dose of the immunisation schedule. Since this is a trivalent vaccine, some patients may have been vaccinated for reasons other than MMR vaccination in childhood according to the national schedule (e.g. outbreak of measles in the population, for travel reasons).

Mumps cases are reported through a passive surveillance system, therefore under-reporting cannot be ruled out. Information on hospitalisation is usually recorded at the time of testing and hospitalisations may also have been underreported.

#### **5 CONCLUSIONS**

Our findings demonstrated that two doses of vaccine substantially and statistically significantly reduced the risk of any complications and the need for hospitalisation compared with unvaccinated patients. A protective effect of two-dose vaccination against mumps complications in general and against orchitis and meningitis in particular, and against hospitalisation for mumps was confirmed. Teenagers were the most affected age group in terms of incidence, but the highest complications and hospitalisations rates were reported in 35-44 years old. This study showed that the majority of mumps patients did not require hospitalisation. The most frequent complications were orchitis, meningitis, pancreatitis and encephalitis. Among the two-dose recipients, the proportion of complications increased gradually with the time interval after the second dose.

In the future, it will be desirable to evaluate aVE based on a new vaccination register or vaccination data from health insurance companies. To assess the burden of the disease, a seroepidemiological study seems suitable as the last nationwide serological survey of mumps antibodies was performed in 2013. Further monitoring and research are required to evaluate the new MMR vaccination schedule in order to assess if it has been more effective. We recommend continuing routine childhood mumps vaccination and maintaining high MMR coverage in CZ.

#### ACKNOWLEDGEMENTS

We would like to acknowledge all stakeholders participating in the Czech surveillance system, and specifically Helena Šebestová from the NIPH for acquisition of raw data from the system.

#### CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

#### FUNDING

This project was supported by the Ministry of Health, Czech Republic - conceptual development of research organisation ("The National Institute of Public Health -NIPH, 75010330").

#### ETHICAL APPROVAL

Ethical approval was not required as in the Czech Republic public health agencies are able to access and use personal identifiable information for communicable disease investigations in the public interest.

#### AVAILABILITY OF DATA AND MATERIALS

The data presented in this study can be obtained upon request from the corresponding author.

#### AUTHORS CONTRIBUTIONS

All authors listed have contributed to this manuscript and all have read and approved the final version of this manuscript.

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October 2023

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The Slovenian Journal of Public Health has been published since 1962 by the National Institute of Public Health in Slovenia. Since 2003, the journal has been a peer-reviewed scientific journal with English abstracts, and since 2014, an international scientific public health journal in English only. The journal's mission is to promote new achievements in the broad field of public health in Slovenia and Central and South-East Europe. The Slovenian Journal of Public Health publishes internationally oriented articles and encourages an interdisciplinary approach to public health. The journal is a source for exchanging new public health concepts and solutions among researchers. The journal mainly publishes original scientific articles, and on occasion also systematic reviews, methodological articles, and invited editorials. It is published four times a year, with up to 35 articles each year, and has an average annual rejection rate of around 80%. The journal is indexed in major international databases, such as PubMed, Web of Science, and Scopus, and has had an impact factor since 2011, ranging from 0.16 to 1.6. As an openaccess journal it is available online on De Gruyter, Sciendo https://sciendo.com/journal/SJPH. The manuscripts are peer-reviewed by three international reviewers, and the process is double-blinded, fair and constructive.

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de Villiers TJ. The role of menopausal hormone therapy in the management of osteoporosis. Climacteric. 2015;18 Suppl 2:19-21. doi: 10.3109/13697137.2015.1099806.

#### Knjiga

Wilkinson IB, Raine T, Wiles K, Goodhart A, Hall C, O'Neill H, et al. Oxford handbook of clinical medicine. 10th ed. Oxford: Oxford University Press; 2017. 123 p.

Kaplan SJ. Post-hospital home health care: the elderly's access and utilization [dissertation]. St. Louis (MO): Washington University; 1995.

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Cancer Research UK. Current research into breast cancer [Internet]. 2020 [cited 2022 Dec 14]. Available from: https://www. cancerresearchuk.org/our-research/our-research-by-cancer-type/ourresearch-into-breast-cancer/current-breast-cancer-research

McNeil DG. Vaccines against HIV, malaria and tuberculosis unlikely, study says. New York Times. 2018 Sep 7. [cited 2018 Nov 14]. Available from: https://www.nytimes.com/2018/09/07/health/vaccines-hivmalaria-tuberculosis.html

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#### FUNDING

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