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ORAL HEALTH AND THE ASSOCIATED ORAL DISEASES OF DISABLED CHILDREN AND THE PREVENTIVE METHODS

Master's Thesis

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ORAL HEALTH AND THE ASSOCIATED ORAL DISEASES OF DISABLED CHILDREN AND THE PREVENTIVE METHODS

Master's Thesis

The thesis was done	
by student	Com annica a
(signature)	Supervisor(signature)
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20 (day/month)	20 (day/month)

EVALUATION TABLE OF THE MASTER'S THESIS OF THE TYPE OF SYSTEMIC REVIEW OF SCIENTIFIC LITERATURE

Evaluation:	
D	
Reviewer: (scientific degree, name, and surname)	••••
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No.	MT parts	MT parts MT evaluation aspects		Compliance with MT requirements and evaluation		
			Yes	Partially	No	
1	Summary	Is summary informative and in compliance with the thesis content and requirements?	0.3	0.1	0	
2	(0.5 point)	Are keywords in compliance with the thesis essence?	.0.2	0.1	0	
3	Introduc-	Are the novelty, relevance and significance of the work justified in the introduction of the thesis?	0.4	0.2	0	
4	tion, aim and tasks (1	Are the problem, hypothesis, aim and tasks formed clearly and properly?	0.4	0.2	0	
5	point)	Are the aim and tasks interrelated?	.0.2	0.1	0	
6		Is the protocol of systemic review present?	0.6	0.3	0	
7		Were the eligibility criteria of articles for the selected protocol determined (e.g., year, language, publication condition, etc.)	0.4	0.2	0	
8		Are all the information sources (databases with dates of coverage, contact with study authors to identify additional studies) described and is the last search day indicated?	0.2	0.1	0	
9	the studies,	Is the electronic search strategy described in such a way that it could be repeated (year of search, the last search day; keywords and their combinations; number of found and selected articles according to the combinations of keywords)?	0.4	0.1	0	
10	methods and strategy	Is the selection process of studies (screening, eligibility, included in systemic review or, if applicable, included in the meta-analysis) described?	0.4	0.2	0	
11	-	Is the data extraction method from the articles (types of investigations, participants, interventions, analysed factors, indexes) described?	0.4	0.2	0	
12		Are all the variables (for which data were sought and any assumptions and simplifications made) listed and defined?	0.4	0.2	0	
13		Are the methods, which were used to evaluate the risk of bias of individual studies and how this information is to be used in data synthesis, described?	0.2	0.1	0	

14		Were the principal summary measures (risk ratio, difference in means) stated?	0.4	0.2	0
15		Is the number of studies screened: included upon assessment for eligibility and excluded upon giving the reasons in each stage of exclusion presented?	0.6	0.3	0
16	tion and	Are the characteristics of studies presented in the included articles, according to which the data were extracted (e.g., study size, follow-up period, type of respondents) presented?	0.6	0.3	0
17	data (2.2 points)	Are the evaluations of beneficial or harmful outcomes for each study presented? (a) simple summary data for each intervention group; b) effect estimates and confidence intervals)	0.4	0.2	0
18		Are the extracted and systemized data from studies presented in the tables according to individual tasks?	0.6	0.3	0
19		Are the main findings summarized and is their relevance indicated?	0.4	0.2	0
20		Are the limitations of the performed systemic review discussed?	0.4	0.2	0
21		Does author present the interpretation of the results?	0.4	0.2	0
22		Do the conclusions reflect the topic, aim and tasks of the Master's thesis?	0.2	0.1	0
23	Conclusions (0.5 points)	Are the conclusions based on the analysed material?	.0.2	0.1	0
24	(v.s points)	Are the conclusions clear and laconic?	0.1	0.1	0
25		Is the references list formed according to the requirements?	0.4	0.2	0
26	References	Are the links of the references to the text correct? Are the literature sources cited correctly and precisely?	0.2	0.1	0
27	(1 point)	Is the scientific level of references suitable for Master's thesis?	0.2	0.1	0
28		Do the cited sources not older than 10 years old form at least 70% of sources, and the not older than 5 years – at least 40%?	0.2	0.1	0
	Addi	tional sections, which may increase the collec	ted number	of points	•
29	Annexes	Do the presented annexes help to understand the analysed topic?	+0.2	+0.1	0
30	Practical recommendations	Are the practical recommendations suggested and are they related to the received results?	+0.4	+0.2	0

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	General 1	requirements, non-compliance with wh	ich red	luce the num	ber of points	
33		Is the thesis volume sufficient (excluding annexes)?		15-20 pages (-2 points)	<15 pages (points)	(-5
34		Is the thesis volume increased artificially?	-2 points	-1 point		
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36		Is the thesis written in correct language, scientifically, logically and laconically?		-0.5 point	-1 points	
37		Are there any grammatical, style or computer literacy-related mistakes?	-2 points	-1 points		
38	General	Is text consistent, integral, and are the volumes of its structural parts balanced?		-0.2 point	-0.5 point	S
39	require- ments	Amount of plagiarism in the thesis.		>20% (not	evaluated)	
40	ments	Is the content (names of sections and sub- sections and enumeration of pages) in compliance with the thesis structure and aims?	180	-0.2 point	-0.5 point	S
41		Are the names of the thesis parts in compliance with the text? Are the titles of sections and sub-sections distinguished logically and correctly?		-0.2 point	-0.5 point	S
42		Are there explanations of the key terms and abbreviations (if needed)?		-0.2 point	-0.5 point	s
43		Is the quality of the thesis typography (quality of printing, visual aids, binding) good?		-0.2 point	-0.5 point	S
*In	total (maxir	num 10 points):	p.			

^{*}Remark: the amount of collected points may exceed 10 points.

Reviewer's comments:						

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ABBREVIATIONS

CP: Cerebral Palsy

ASD: Autism spectrum disorder

SHCN: Special health care needs

WHO: World Health Organization

DMFT: Decayed, missing, and filling index (for permanent teeth)

dft: decay, filled index (for primary teeth)

DT: Dental Trauma

PI: Plaque Index

GI: Gingival Index

MGI: Modified gingival index

TBVP: Toothbrushing visual pedagogy

CHX: Chlorohexidine

VPA: Valproate

ORAL HEALTH AND THE ASSOCIATED ORAL DISEASES OF DISABLED CHILDREN AND THE PREVENTIVE METHODS

SUMMARY

Aim: To study the oral health and the associated oral diseases of children with three disabilities,

Cerebral Palsy, Autism, and Epilepsy, and their convenient prevention methods.

Tasks: To determine the prevalent oral diseases in autistic, epileptic, and cerebral palsy children

and determine the type of listed disabilities susceptible to chosen oral diseases.

To ascertain the efficiency of oral health prevention methods of disabled children.

Materials and methods: PubMed/Medline and ScienceDirect databases were searched

electronically to retrieve results. The applied articles included studies in the English language and

children aged 1 - 18. Distinct evaluation methods were used to identify the oral disease's

occurrence, and particular prevention methods were used to assess their efficiency.

Results: The primary search resulted in 1,529 articles; after the duplication, and the application of

inclusion and exclusion criteria, only 7 articles were eligible for our study.

All included children with Cerebral Palsy, Autism, or Epilepsy resulted in a high occurrence of

caries or a low oral hygiene state. Epileptic children were most susceptible to caries and

malocclusion occurrence, autistic children were more vulnerable to tooth-wear, and cerebral palsy

children were more susceptible to dental trauma.

Preventive methods applied to disabled people are effective and lead to better oral health status.

Conclusion: All children diagnosed with a disability are prone to experience oral diseases, and it is

dependent on the characteristics of the disorders. Children with any type of disability must possess

further oral hygiene instructions, care, and treatment needs assessment.

Keywords: Cerebral Palsy, Autism, Epilepsy, Children, Oral disorders, Dentistry

INTRODUCTION

Children's oral health plays a significant role in their general health and overall well-being. As it is well known, the manner for ideal oral health for a child requires early age preventive pedodontics visits, motivation for oral care, and monitoring the child's diet [1]. Some children are diagnosed with special health care needs (SHCN), which were defined as people who have the possibility of acquiring a chronic physical, developmental, behavioral, or emotional condition and demand additional provision and care, further than what is needed by children in general [1][2]. These children are more prone to develop caries and other oral disorders due to several predisposing factors, such as congenital or developmental teeth anomalies, budgetary, knowledge, home oral care, and motor difficulties [1][4].

The estimated prevalence of SHCN children is 15.1% (11.2 million children) [2,3]. In this study, the conducted main disabilities are children diagnosed with Cerebral Palsy (CP), Autism spectrum disorder (ASD), and Epilepsy.

Cerebral Palsy is a disability initiated by brain impairment; it is a central nervous system (CNS) disability of mobility, the position of the limbs, and their coordination that reflects an immature brain insult [3]; they include as well the learning disability, sensory deficiency, and seizures [5]. CP is untreatable; nevertheless, tutoring, remedies, and advanced technologies can aid people to adapt to everyday life living [3]. CP children are more prone to oral disease than healthy children [5].

ASD is categorized as a complex biological lifetime heterogenous, psychiatric, neurodevelopmental, and most severe children disorder [7]; begins in the developmental period (before the age of three), and causes difficulties in several distinct ways in which a person develops [7]. The prevalence of ASD worldwide is 1 in 270 people [8].

Children with ASD are diverse with their symptoms characteristics; some selected patients can present different severity or manifest other comorbid disorders, such as seizures, anxiety, intellectual disabilities, cognitive inflexibility, and attention deficit hyperactivity disorder [10]. The listed characteristics assure that oral care practice is difficult to provide at home or by pedodontics, which can worsen the oral environment of autistic children [10].

Epilepsy is found to be a disorder and not a disease due to accompanying various diseases and conditions. It's defined as a brain disorder considered by a persistent predilection to cause epileptic seizures [11]. Epilepsy's prevalence is 0.5% - 0.9% in the overall population [15], and the oral

health of the patients is affected by the taken medications; therefore, they suffer from bad oral hygiene and oral diseases [13].

All the above-listed features and characteristics of the three different disabilities set some challenging limitations to the dentist; Hence, the dental care provider should acquire sufficient skills and knowledge to successfully provide the child with the appropriate, effective treatment [5]. Specialized people about disabilities should introduce prevention methods to parents or caregivers of a disabled child because it can aid for better well-being for both the child and the caregiver. World Health Organization displayed the significance of oral health as a critical indicator of overall health, well-being, and quality of health. Oral health includes a wide variety of diseases, and defects, that can disturb one's life to the extent of mortality, for instance, oral cancers that are among the top 15 most common cancers worldwide, causing 180 000 fatalities per year; besides, oral diseases share risk factors that can initiate non-communicable conditions [18].

There are very few researches combining different disabilities and assessing oral health by its wide range, also, few studies of disabilities with their different susceptibilities to various oral disorders. Hence in this article, we will provide different oral diseases accompanying different disabilities (CP, ASD, and epilepsy) and study their prevalence, dominations, and the prevention methods efficiency.

Aim

To study the oral health and the associated oral diseases of children with three disabilities, Cerebral Palsy, Autism, and Epilepsy; and their convenient prevention methods

Tasks

- 1. To ascertain types of oral diseases prevalent in different disabilities
- 2. To find out the type of disability that may be susceptible to specific oral diseases
- 3. To determine oral health prevention efficacy for children with specific disabilities

Hypothesis

Children with different disabilities are suspectable to poor oral status and various oral diseases.

1. SELECTION CRITERIA, METHODS, AND STRATEGY

1.1. Protocol of Systemic Review

Bioethics department provided the permission of this review; Nr. BEC-OF-88 This systemic review was prepared according to PRISMA [16] regulations

1.2. Focus Question

The focus question was developed according to PICOS study design

Table 1. PICOS characteristics

Components	Description
Population	Disabled children diagnosed with Cerebral Palsy, Autism, or Epilepsy
ropalation	Aged from 1 - 18
	Children diagnosed with Cerebral Palsy, Autism, and Epilepsy suffer from oral health
Intervention	(caries, periodontal problems, trauma, and habits)
intervention	Checking the prevalence of the listed oral diseases
	The prevention methods using a specific technique
Comparison	Comparison between the prevalence of caries, tooth wear, dental trauma, and
Comparison	malocclusion in epileptic, autistic, and cerebral palsy children
	Disabled children are suspectable of poor oral status and oral diseases more frequent
Outcomes	due to specific barriers that they suffer from
Outcomes	Specific oral diseases accompany a disability due to its characteristics or symptoms
	Prevention methods can aid in decreasing the occurrence of oral diseases
	Articles written in the English language
	Published not older than ten years (2010 – 2020)
Study Characteristics	Published studies of researches in Journals
	Randomized and Non-Randomized Control studies
	Comparative, retrospective, cohort, and cross-sectional studies
Focus	Are children with disabilities suspectable to poor oral status and oral diseases more
question	frequently, and are preventive methods for the oral care of disabled children efficient?

Inclusion criteria:

- Children with CP, Autism, and Epilepsy
- Aged from 1-18
- Articles that include human beings
- Children that include oral diseases such as caries, gingivitis, periodontitis, and dental trauma
- Articles and studies that are published not more than ten years ago (2010 2021)
- Articles written in the English language
- Randomized and Non-randomized studies

Exclusion Criteria:

- Healthy children and adolescents (not diagnosed with any disability)
- Children diagnosed with CP but suffering from a medical condition
- People older than 18 years
- Articles that include non-human beings
- Healthy children and adolescents that have a good oral status
- Healthy children and adolescents that have a bad oral environment
- Articles and studies that are published before 2010
- Articles with different languages
- Case studies, Systematic reviews

1.3.Literature search strategy

Information source: To use the suitable studies for this systematic review, and according to PRISMA [16] guidelines, electronic research was done during the time of November 2020 – January 2021, that was conducted via the Lithuanian University of Health and Sciences electronic library, using the following databases, PubMed/Medline and Science/Direct by the combination of main keywords and filters application for Science/Direct database.

Table 2 includes the dates, keywords, and number of studies.

Electronic searches used by the combination of keywords are:

"Cerebral palsy" AND "children" AND "oral disorders" AND "dentistry"

"Autism" AND "children" AND "oral disorders" AND "dentistry"

"Epilepsy" AND "children" AND "oral disorders" AND "dentistry"

Table 2. Summary of Keywords Combination

Search Date	Keywords	Results
9/11/2020 – PubMed	cerebral palsy and children and oral disorders and	92
	dentistry	
13/11/2020 – ScienceDirect	cerebral palsy and children and oral disorders and	395
	dentistry	
20/11/2020 - PubMed	autism and children and oral disorders and dentistry	186
27/11/2020 – ScienceDirect	autism and children and oral disorders and dentistry	283
03/12/2020 – PubMed	epilepsy and children and oral disorders and dentistry	48
05/12/2020 – ScienceDirect	epilepsy and children and oral disorders and dentistry	525

Also, a manual search was done to search for additional relevant articles and references

1.4. Selection of studies

Independently by two reviewers, the selection of studies was made.

Filters were applied to the ScienceDirect database due to the vast number of publications that included the medical field as a whole, not only dentistry, and several disorders that were out of the inclusion criteria.

The research was done by two stages; the first stage included screening the titles and abstracts of the publications that fit our research inclusion and exclusion criteria and excluded the duplicated, insufficient, out of our research criteria articles.

The second stage was the screening of full texts and including them in our systematic literature review, and others were excluded for several reasons, for instance, the type, subject, contents, language of the articles that were not eligible for this systematic literature review.

This review includes randomized and non-randomized control studies, retrospective studies, comparative, cohort, and cross-sectional studies. Their content included diagnosed children with one of CP, Autism, or Epilepsy, reporting the oral disorders accompanied, effective management techniques or dental treatment needs, and published in the English language between 2010 – 2021 in PubMed and ScienceDirect databases as well as journals.

The journals that were used in our review are:

International Journal of Health Science Vol. 12, Issue 1 (January - February 2018)

European Journal of Paediatric Dentistry vol. 20/3-2019

Int J Paediatr Dent. 2019;29:79-85

European Journal of Paediatric Dentistry vol. 18/1-2017

Int J Paediatr Dent. 2021;31:89–105

Pediatrics International (2010) 52, 279–283

1.5. Variables, assumptions, and simplifications

In the chosen articles, we searched for children aged between 1 -18 diagnosed with disabilities such as CP, Autism, and Epilepsy that reported oral diseases as caries, malocclusions, dental trauma, and several other diseases. Also, we were looking for prevention methods applied to disabled children aged 1- 18 and their efficacy on their oral health. We included the relevant articles for our task in this systematic review.

1.6.Risk of systemic errors of studies

The modified Downs and Black [18] assessment tool was suitable to be used and assess the risk of bias of the chosen studies [Downs&Black 1998] since they were randomized and non-randomized studies. (table 3)

Table 3. Risk of Bias

Article	Sedky	Meyer et	Kuter et	Morgan	Bagatto	Du et al.	Gurbuz
Questi	NA [19]	al. [20]	al. [21]	et al.	ni et al.	[23]	and Tan
ons*				[22]	[3]		[24]
1	1	1	1	1	1	1	1
2	1	1	1	1	1	1	1
3	1	1	1	1	0	1	1
4	1	1	1	1	1	1	1
5	1	1	1	1	1	1	1
6	1	1	1	1	1	1	1
7	1	1	1	1	1	1	1
8	0	1	0	0	0	0	0
9	0	0	1	0	0	1	0
10	1	1	1	1	0	1	1
11	1	1	0	1	1	1	0
12	0	1	0	1	1	1	0
13	1	1	1	1	1	1	1
14	1	1	0	0	0	0	0
15	0	0	0	0	0	0	1
16	1	1	1	1	1	1	1
17	0	1	0	1	0	1	0
18	1	1	1	1	1	1	1
19	1	1	0	0	0	0	0
20	1	1	1	1	1	1	1
21	1	1	0	1	1	1	1
22	1	1	0	1	0	0	1
23	1	1	0	1	0	0	0
24	0	1	0	0	0	0	0
25	1	1	0	1	1	1	0
26	0	0	1	0	0	1	0
27	0	1	0	0	1	1	0

^{*}Refer to annex 1 for 1-27 questions (the assessment tool checklist includes zone to answer each question as Yes=1 or No=0 answers or Undetermined=0).

2. SYSTEMIZATION AND ANALYSIS OF DATA

2.1. Number of Studies Screened

Identification of records took place in two databases PubMed and ScienceDirect; the screening was done according to the inclusion and exclusion criteria, where some studies were excluded by the abstract screening only, others were assessed fully for eligibility. Refer to figure 1 for the detailed study's screening.

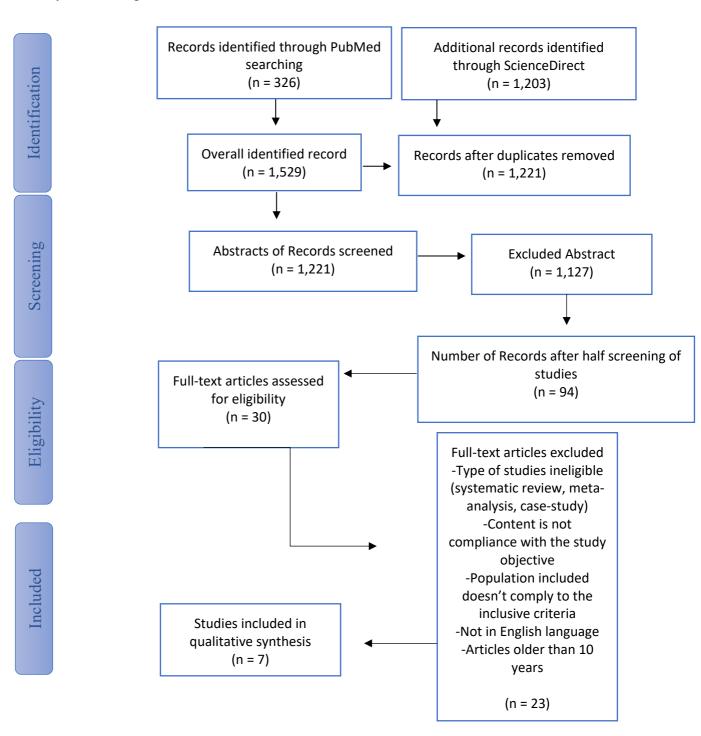


Fig 1. Prisma Flow Chart

2.2. Characteristics of Studies

The finalized selected studies are seven; two are for CP, two for ASD, and two for epilepsy; one article combined CP, Autism, and Epilepsy. These studies were published on PubMed and ScienceDirect databases, and they were of specific research types as a cross-sectional, randomized controlled trial, retrospective studies, that included population diagnosed with disabilities that are CP (125 patients), Autism (452 patients), and Epilepsy (343 patients), a total of 875 disabled children.

The studies included in the systematic review were according to the inclusion and exclusion criteria. Its content tested the effectiveness of a specific prevention method or compared oral health disorders between healthy children and disabled ones. The extracted articles contained only the oral diseases of the disabled children and their prevention methods; any other results stated in these studies that do not meet our inclusion criteria were not used, for instance, the oral diseases of healthy children or parents' education and profession.

In Table 4, the characteristics of the studies were summarized.

Table 4. Characteristics of Studies

Nr.	Author / Year of Publication	Type of Research /Population / Age	Disability type	Number of patients /gender	Criteria of Evaluation
1	Sedky NA [19] 2018	Cross-Sectional Egypt 3 – 12 years old	Cerebral Palsy	62 M (61.3%) F (38.7%)	DMFT and dft; Tooth wear; Maxillofacial Defects; Bruxism; Eruption Status; Drooling; Oral hygiene index; Gingival Index; Malocclusions
2	Kuter et al. [21] 2019	Cross-sectional study Unknown Population 5 – 16 years old	ASD	285 M (78.3%) F (21.7%)	DMFT and dmft; Plaque Index; Tooth wear; Malocclusions; Dental trauma; Drooling; Tongue thrusting; Deep palate
3	Morgan et al. [22] 2018	Retrospective cohort study Egypt 6 – 12 years old	Epilepsy	100 M (60%) F (40%)	Gingival index; DMFT and dmf; Intraoral injuries for hard and soft tissues
4	Gurbuz and Tan [24] 2010	Cross-sectional study Ataturk university 4 -15 years old	Epilepsy	211 M (120) F (91)	GI; PI; DMFT and dmft; Oral Disorders (Malocclusion, Gingival enlargement, halitosis, tooth attrition, enamel defect); Periodontal and Restorative treatment needs
5	Bagattoni et al. [3] 2017	Cross-sectional retrospective study Italy 0 – 18 years old	Cerebral palsy Epilepsy Autism	53 CP 32 Epilepsy 46 Autistic	Dental trauma occurrence of SHCN children
6	Meyer et al. [20] 2010	Randomized -Controlled Trial Brazil 8 – 16 years old	Cerebral Palsy	10	Efficacy of brushing with CHX 1% component, on: 1. GI 2. PI 3. Microorganisms of saliva
7	Du et al. [23] 2020	Randomized Controlled Trial Hong Kong 2.5 – 7 years old	ASD	122	The efficacy of TBVP on: 1- PI 2- GI (Six months trial)

2.3. Risk assessment of Systematic Errors

According to standardized measures, we evaluated our work by answering 27 questions grouped according to quality of reporting, internal and external validity, and statistical power. The score ranges were given corresponding quality levels as previously reported (Hooper, Jutai, Strong, & Russell-Minda, 2008): excellent (28-26); good (25-20); fair (19-15); and poor (≤14). According to the DOWN&BLACK assessment tool, 2 of the selected studies are at low risk (reported to be good) and 5 at high risk (reported to be fair and poor), and this will cause limitations

In Table 5, the risk of bias scores of studies is shown.

Table 5. Summary of risk of bias scores

for this systematic review.

Nr.	Articles	Excellent	Good	Fair	Poor	Score
1	Sedky [19]			+		19
2	Meyer et al. [20]		+			24
3	Kuter et al. [21]				+	14
4	Morgan et al. [22]			+		19
5	Bagattoni et al. [3]			+		15
6	Du et al. [23]		+			20
7	Gurbuz and Tan [24]			+		15

2.4. Evaluation of prevalent oral diseases of children with Cerebral Palsy

According to Sedky NA [19], they used the DMFT, and dft measurement index, for the assessment of caries were dft resulted in 2.77 ± 4.59 and DMFT 1.43 ± 3.12 , this showed the prevalence of 54.8%; for oral hygiene, OHI was used resulting in a mean of 1.60 ± 1.10 , ages were divided into mixed dentition stage(4 – 6 and 7 – 10 years old), and parameters to evaluate the oral hygiene were used (good, fair, and poor). The results showed that children aged from 4 – 6 years old had good oral hygiene with the prevalence of 52.8%, and poor oral hygiene with the prevalence of 41.7%; for children aged from 7 – 10 years old, the prevalence of good oral hygiene was 19.2%, and of poor oral hygiene 69.2% [19].

The gingival health was assessed using the modified gingival index (MGI) and resulted in a mean of 1.64 ± 1.05 , a prevalence of 57.7% of severe inflammation for children aged from 7 - 10 years old [19].

Other oral disorders prevalence such as bruxism (19.4%), tooth wear with dentin exposure >1/3 14.5%, frequent and severe drooling of saliva 22.6% [19].

Another study by Bagattoni et al. [3], who studied 53 children diagnosed with CP, and their DT experience classified according to WHO classification, showed us the 39.6% of the children had experienced it.

Refer to Table 6 for the detailed oral diseases of CP children.

Table 6. Oral diseases in CP children

CHILDREN WITH CEREBRAL PALSY									
AUTHORS	ORAL DISORDERS	RESULTS							
	CADIES	54.8% 4.18 ± 5.60		dft [DMFT	DMFT		
	CARIES			2.77 ± 4.59		1.43 ± 3.12			
		Age (years)	Good		Fair	Poor		$MEAN \pm SD$	
	ORAL HYGIENE INDEX	4 – 6	52.8%		5.6%	41.7%		1.60 - 1.10	
		7 - 10	19.2%		11.5%	69.2%		1.60 ± 1.10	
	MODIFIED GINGIVAL INDEX	Age (years)	Mild	Mild*	Moderate	Severe		$MEAN \pm SD$	
	(Inflammation)	4 – 6	11.1%	25%	13.9%	33.3%		1.64 ± 1.05	
		7 - 10	0.0%	7.7%	23.1%	23.1% 57.7%		1.04 ± 1.03	
SEDKY NA	BRUXISM			19.4%					
[19]	DENTAL EROSION	No Wear into Dentine		Dentine Exposed <1/3		Dentine Exp	posed > 1/3	Pulp Exposure	
	(tooth wear)	4.8% 6.5% 14.5% 2%						2%	
	MALOCCLUSIONS	OPEN-BITE and DEVELOPING CLASS II							
		6.5%							
	FOOD IMPACTION	8.1%							
	HISTORY OF ORAL ULCERS				4.8%				
		Moderate		Severe		F		Profuse	
	DROOLING	17.	.7%	22.6%			19.4%		
Bagattoni et al. [3]	DENTAL TRAUMA	39.6%							

^{*}Mild Inflammation of the entire gingival unit

2.5. Evaluation of prevalent oral diseases of Autistic children

According to Kuter et al., who examined the autistic children with the help of pedodontics using a mirror and a probe, they were looking for caries by the usage of DMFT and dmft; divided the children by their age 5-11 and 12-16 years old, that resulted in younger children a mean of 1.66 ± 2.07 and 12-16 years old mean of 2.07 ± 2.49 , similarly, for the plaque index, the younger group showed mean of 2.60 ± 0.48 while older group 2.60 ± 0.48 [21].

On the other hand, the deep palate was observed to result in 52.9%, besides 31.3% of children experience tooth wear, 32.1% dental crowding, and other oral manifestations such as drooling, tongue thrusting, and hypodontia, but these all showed a low percentage of occurrence according to autistic children [21].

Bagattoni et al., who studied 46 autistic children, showed a difference from Kuter's study of DT occurrence percentage was found to be 30.4% [3].

Detailed results of oral diseases are presented in table (7) below.

Table 7. Oral diseases in Autistic children

AUTISTIC CHI	AUTISTIC CHILDREN									
AUTHOR	GENDER			78.3%						
		Female			21.7%					
	Oral Disea	ses		Results						
	CARIES		Age (years)	ge (years) dmft DMFT		Plaque Index	Caries Prevalence			
			5 - 11	1.66 ± 2.07	0.52 ± 1.21	2.60 ± 0.48	50%			
			12 - 16	null	2.07 ± 2.49	3.15 ± 0.74	57.4%			
	PI VALUE		Grade 0		Grade 1	Grade 2	Grade 3			
			0.0%		25.5%	45.3%	29.2%			
Kuter et al. [21]	TO	OTH WEAR	31.1%							
	MAL	OOCULISIONS		Crowding		Open-Bite				
			32.1%			5.7%				
	DE	EEP PALATE			52.9%					
	OR	CAL HABITS		Tongue Thrusting	g Di		oling			
			16%			26.4%				
	DEN'	TAL TRAUMA	4.7%							
Bagattoni et al. [3]	DEN'	TAL TRAUMA			30.4%					

2.6. Evaluation of prevalent oral diseases of Epileptic children

According to Morgan et al., who undergone an oral examination by the usage of a mirror and an explorer to evaluate gingival health, caries, and injuries presence, the gingival condition had a mean of 1.16 ± 0.42 intraoral, dmf 4.1 ± 2.1 , and DMF 1.6 ± 1.7 for the caries occurrence, and lastly, trauma prevalence to the hard tissue (enamel) 3%, trauma with the exposure of pulp 2%, and the soft tissue (lip) trauma, 2% [22].

Another DT prevalence was done by Bagattoni et al., but DT was classified by a broader category, a system adopted by WHO, by Andreasen et al. [2007], that showed the prevalence of DT in epileptic children is 18.8% [3].

Another study was done on epileptic children where a clinical examination was conducted for the periodontal findings, by PI and GI with the parameter's usage of Grades; Grade 0 for PI, to show undetectable plaque on the gingival area, and for GI, it shows intact gingiva, with 2.4% resulting for both indexes [24].

Grade 1 in PI (34.6%) represents "film of plaque adhering to the free gingival margin," and near the tooth surface; for the GI, 36% resulted for grade 1; this will indicate mild inflammation, the gingiva won't bleed, but there will be a color alteration and slight edema. Grade 2 for PI (44.1%) will show "average accumulation of soft deposits within the gingival pocket, on the gingival margin and near tooth surface, that can be seen by the naked eye." For grade 2 of GI (42.1%), this indicates "moderate inflammation, hyperemia, edema, and bleeding on palpation" [24].

Grade 3 for PI (18.9%) indicates, "profusion of soft plaque within the gingival pocket and on the gingival margin and near the tooth surface," for GI (19.5%), it shows "severe inflammation, with noticeable hyperemia and edema, ulcerations, and prone to bleed spontaneously" [24].

For other assessments, as 96.7% caries prevalence, halitosis 79.1%, malocclusions (40.7%), tooth attrition (11.4%), and enamel defect (14.2%) [24].

Detailed prevalence of oral diseases in Epileptic children are found in table (8).

 Table 8. Oral diseases in Epileptic Children

EPILEPTIC CHILDREN								
AUTHOR	Oral Diseas	ses	Results					
	CARIES							
			$\frac{\text{dmf}}{4.1 \pm 2}$		1	DMF .6 ± 1.7		
Morgan et al.	GINGIVAL	INDEX	4.1 ± 2		± 0.42	.0 ± 1.7		
[22]		V 177	Enamel Tr	auma		2%		
	TRAUMA	Hard Tissue	Pulp Involveme	ent Trauma		3%		
		Soft Tissue		-	rauma			
Pagattani et al		2010 1 13000		2'	%			
Bagattoni et al. [3]	DENTAL TRAUMA		18.8%					
	GINGIVAL INDEX		Grade 0	Grade 1	Grade 2	Grade 3		
			2.4%	36%	42.1%	19.5%		
	PLAQUE IN	NDEX	2.4%	34.6%	44.1%	18.9%		
	GINGIVAL ENLARGEMENT BY MEDICATIONS		Valproate	Phenobarbital		Carbamazepine		
			42% 16% 0%					
Gurbuz and Tan	MALOCCLUSION		40.7%					
[24]	TRAUMATIZED ANTERIOR TEETH		27.5%					
	GINGIVAL ENLARGEMENT		29.9%					
	HALITOSIS		79.1%					
	DENTAL CARIES		96.7%					
	TOOTH ATTRITION		11.4%					
	ENAMEL DEFECT		14.2%					

2.7. Evaluation of prevention method for CP

Concerning the prevention method, and according to Meyer et al.[20], a double-blind design was made to randomly chosen children with motor deficiency (CP), were directed to use a toothpaste that contained specific ingredient such as 2% titanium dioxide, 2% aspartame, 0.04% saccharine, 8% glycerin, 12% sorbitol, 1% mint extract, and 1% CHX in natrosol gel. A saliva sample was taken before and after 7 and 14 days of toothpaste usage to analyze the PI, GI, and salivary microorganisms changes.

The analysis resulted in decreased PI from day 0 to day 14, 0.978 ± 0.353 and 0.250 ± 0.287 , respectively. According to GI, the results were 0.035 ± 0.155 on the initial day and decreased to reach 0.000 ± 0.098 at the end. Lastly, salivary microorganisms decreased in the first two intervals but increased again on the 14th day [20].

Refer to Table 9 below for more detailed results concerning the prevention method of children diagnosed with CP.

ORAL HEALTH PREVENTION METHOD FOR CP CHILDREN							
Author	Usage of toothpaste containing 1% CHX	Results					
Meyer et al. [20]	Time Interval	Plaque Index	Gingival Index	Salivary Microorganisms			
	Day 0	0.978 ± 0.353	0.035 ± 0.155	$3.9 \times 10^7 \pm 63,975,178$			
	Day 7	0.624 ± 0.328	0.31 ± 0.127	$1.23 \times 10^7 \pm 18{,}603{,}808$			
	Day 14	0.250 ± 0.287	0.000 ± 0.008	$6.87 \times 10^6 \pm 16.525.380$			

Table 9. Oral health prevention method for CP children

2.8. Evaluation of prevention method for Autistic children

According to Du et al., a visual pedagogy study was demonstrated to autistic children for the improvement of gingival inflammation, where parents were given TBVP to aid their children for oral hygiene at home; it contained pictures of step-by-step instructions and a DVD to demonstrate the brushing technique, as well as, parents were required to take a video of the brushing process. At the baseline, after 3 and 6 months of the TBVP usage, plaque and gingivitis were assessed by PI, GI, sites of plaque, and gingivitis. All the results were decreased during the time interval; for instance, the plaque sites were 84% that changed to 61% after 6 months, similarly with the other parameters examined [23].

Refer to Table (10) below for a more detailed prevention method efficacy of autistic children.

Table 10. Oral health prevention method for Autistic children

ORAL HEALTH PREVENTION METHOD FOR AUTISTIC PATIENTS							
Prevention Author	VISUAL PEDAGOGY						
	Time Interval	Plaque Index	Plaque Sites	Gingival Index	Gingivitis Sites		
Du et al. [23]	Baseline	1.00 ± 0.32	84%	0.91 ± 0.26	83%		
	3 Months	0.67 ± 0.27	62%	0.58 ± 0.26	57%		
	6 Months	0.63 ± 0.25	61%	0.60 ± 0.26	58%		

2.9. Evaluation of dental treatment needs of Epileptic children

Gurbuz and Tan studied the dental treatment needs of epileptic children by questioners provided to the parents, and this revealed that from 211 epileptic children, 161 never brushed their teeth that is 76.3% of them, while 30 (14.2%) of them brushed their teeth only one time per day, and the other 20 (9.5%) brushed intermittently; moreover 134 (63.5%) of them had never gone to a dentist [24]. According to the treatment needs, 44.1% needed prophylaxis, scaling, and oral hygiene instructions, other 53.1% required fillings [24].

Refer to Table (11) for more detailed results of treatment needs of epileptic children

Table 11. Dental treatment needs of epileptic children

EPILEPTIC ORAL CARE AND DENTAL TREATMENTS NEEDS							
Author	RESULTS	Never	1/D	Day	>1/Day		
	Frequency of Brushing	76.3%	14.2%		9.5%		
Gurbuz and Tan	Periodontal Treatment Needs	No treatment needed	OHI ^a	Prophylaxis with OHI	Periodontal therapy with prophylaxis and OHI		
and ran		2.3%	35.1%	44.1%	18.5%		
	Restorative Treatment Needs	No treatment needed	Fillings	SS b Crowns	Root Canal Treatment		
	Tradition rectal	3.3%	53.1%	32.2%	11.4%		

^a oral hygiene instructions

^b Stainless

3. DISCUSSION

This systematic review included 7 articles about the oral health, oral diseases, prevention methods, and treatment needs of children diagnosed with CP, autism, or epilepsy, using different techniques for their assessment and providing us with the results listed above.

Prevalent oral diseases for the listed disabilities

Prevalent Oral Diseases of CP children; According to Sedky, that assessed and evaluated the oral health of Egyptian children selected randomly using several criteria, showed the highest prevalence of children between the age of 7 - 10 years with poor oral hygiene (69.2%), followed by gingival inflammation (57.7%), and lastly, caries prevalence of 54.8% [19].

Another study was done in the Kingdom of Saudi Arabia by Wyne et al. [26] examined oral hygiene of CP children, dividing them into age groups, 3-6 and 7-10 years old, that resulted in 60% of younger age had fair oral hygiene, and 26.7% had poor oral hygiene. Concerning caries examination, and by the usage of dmft and DMFT indexes, which resulted in significantly higher mean caries for the older age group 11.5 ± 3.34 (p=0.017) than that of younger group 8.86 ± 4.41 , where we see that there is a difference in caries prevalence between the two studies and the two groups [26].

These two studies show us that oral hygiene index and caries are not constant for all children diagnosed with CP. Nevertheless, children with CP mainly present fair to poor oral hygiene due to their motor difficulties such as chewing and swallowing. Moreover, some unusual motions are made with the tongue and the face muscles, decreasing the "self-cleansing function" of the oral cavity. Other causative factors are the inability to solely undergo oral care, the frequently consumed food types rich in carbohydrates, and are highly viscous [27].

Results of OHI and MGI are correlated; for instance, children aged from 4-6 years old resulted in 41.7% with poor oral hygiene, and 33.3% with severe inflammation - the highest occurrence – Similarly, with the older group age, 69.2% had poor oral hygiene, and 57.7% with severe gingival inflammation [19].

Aforesaid, a high percentage of "POOR OHI" results in a high rate of "SEVERE INFLAMMATION" [19].

Concerning other outcomes, 6.5% of CP children had open-bite and developing Class II malocclusion, that is also shown in Sinha et al. study with 58% of CP children with Class II malocclusion (the most prevalent); this was explained due to the unusual alignment of tongue, lips, cheeks, together with the oral habits that CP children display [28].

Dominant Oral Diseases of Autistic Children; According to Kuter et al., who assessed the oral health of autistic children and grouped them into younger and older groups resulted in 57.4% of caries prevalence for autistic children aged 12 -16 years old, then, the deep palate incidence of 52.9%, and lastly, the PI assessment of grade 2 presiding with 45.3% [21].

According to Al-Maweri et al. [29], that studied the oral status of 42 autistic children in Yemen, resulting in a mean of DMFT 2.00 ± 2.18 , which is slightly the same result as Kuter's study, and dmf mean 5.23 ± 2.34 that was higher; however, caries prevalence in the included studies is detected to be high in autistic children. Concerning the oral hygiene status, Al-Maweri et al. found out that fair oral hygiene, or grade 2, was most prevalent, with 38.1%, and revealed that 45.4% of the included children had moderate gingival health; this can show us that autistic children suffer from their gingival health due to fair oral hygiene [29].

Deep palate prevalence of 52.1% was shown to be high in Kuter et al. study [21], on the other hand, Orellana et al. [30], that studied the oral manifestation of autistic children, found out that 10 out of 32 (33.33%) of intervened patients showed ogival palate or deep palate, and its occurrence is higher than that of healthy patients. However, both studies had an inadequate explanation of the recurrent feature occurrence; hence further studies are required to explain the deep or ogival palate occurrence in ASD patients.

Dominant Oral Diseases of Epileptic Children; Morgan et al. revealed that epileptic children with primary teeth were more prominent in experiencing caries [22].

Gurbuz and Tan [24] included 211 epileptic children and showed that children on Valproate (VPA) had experienced gingival enlargement. In contrast, those on Carbamazepine showed no side-effect on the gingiva, and this was explained that VPA causes direct bone marrow suppression that leads to the reduction of the wound healing process, provoking the infection occurrence and postoperative bleeding. Moreover, Lee et al. [31] explained the effect of VPA by the usage of mesenchymal stem cells from human being gingiva that resulted in the decrease of osteogenic differentiation and the decrease of viability stem cells of human gingiva; hence the children that are on VPA should be instructed and informed about the oral hygiene, and a frequent follow-up should be performed. Halitosis was found to be 79.1% prevalent, and its occurrence is caused by gingival inflammation or drug intake [24]. Concerning other oral findings, Grade 2 of GI (42.1%) and PI (44.1%) were the most prevalent and are correlated risks. Yeung et al. [13] showed that 60% (21/35) had the plaque seen, and this is similar to Gurbuz and Tan that resulted in 206/211 children with plaque sites. However, the most common oral disorders that accompany epileptic children are dental caries and halitosis, and they suffer from oral hygiene status because of the factors correlated with inducing the occurrence of dental caries by biofilm creation and bacterial deposition.

Type of disability that is suspectable to a specific oral disease

Specific oral diseases were chosen to be compared between the disabilities included in our study due to the lack of information about specific oral diseases. Hence, oral diseases to be compared are caries, malocclusion, dental trauma, and tooth wear for all three disabilities.

Caries; Epileptic children with primary and permanent teeth were found to be more prone to caries occurrence, and this was confirmed from two studies, Morgan et al. [22] and Gurbuz and Tan [24]; for instance, Gurbuz and Tan caries prevalence is 96.7%.

The explanation of epileptic children being at high risk and occurrence of caries is caused by neglection of dental care, and frequent intake of medications, as sodium VPA, levetiracetam, or Carbamazepine, that were reported to include sucrose in their ingredients, and epileptic children, especially young aged tend to intake the medicine in syrup form [24].

Tooth-Wear; Autistic children have the prevalence of 31.1% of tooth-wear according to Kuter et al. [21], which is higher than that of CP (29%) and epileptic (11.4%) children. Several studies were done on the oral manifestation of autistic children that resulted in "Bruxism," as the most frequent oral finding - "bruxism" terminology was used since it is the leading cause of tooth wear, attrition, or abrasion - Du et al. [32] found out that 54.2% presented tooth wear, and other studies as Orellana et al., 54.1% [30].

An autism expert, Rajalakshmi Kandaswamy, explained the causative factors of bruxism behavior in autistic people as "anxiety, stimming (repetitive actions or movements), habitual, side-effects of antidepressants, misaligned teeth or abnormal bite, and limited diet," it was added that the "underlying fundamental trigger for bruxism was "STRESS" [34].

Malocclusion; It was found that epileptic children are more prevalent for malocclusions, and it was also revealed that 46% of children on VPA showed malocclusions [24].

The malocclusion prevalence was explained by Fong et al., who reported that 41% of patients with partial seizure included a facial and body asymmetry as hemihypertrophy or atrophy. Gingival enlargement, a common oral characteristic seen in epileptic subjects, interrupts and delays the permanent teeth eruption timing and causes malocclusions in mixed dentition. Lastly, the hypertonicity by the oral muscles causes the protrusion of anterior dentitions, also the effect of orthopedic compression of the maxilla [33].

Dental Trauma; According to Bagattoni et al. [3], CP children are more prevalent for DT occurrence (39.6%), and this was explained by Cardoso et al., that the characteristics of the CP subjects are a high risk for DT, which are uncontrollable, uncoordinated body and head movements caused by muscular tone alteration as spasm and tonicity leading to tumbling and injury of teeth and soft tissues [38].

Efficacy of Prevention Techniques;

Usage of 1% CHX toothpaste for CP children; Meyer et al. [20] showed an improved oral status of CP children after using 1% CHX toothpaste.

Maiaya et al. also studied different oral hygiene tactics on CP children and examined the OHI and MGI in time intervals for six weeks; it improved oral hygiene while using the powered toothbrush, fluoridated toothpaste, and CHX spray. It was explained that CHX contains an antibacterial activity that impedes plaque, and it is recommended to be used as an adjunct [35].

It is essential to know that CHX causes some side effects on lengthened usage as staining of teeth and tongue, burning sensations, distastefulness, and loss of taste; this is caused by the precipitation of CHX and its interaction with food residues due to poor oral hygiene; hence patients should be informed about the usage timing, not longer than one week [36,37].

Despite this, the most crucial part of both studies is the assistance of parents or caregivers and their instruction; this shows how important it is to motivate and supervise your child continually for their oral care routine.

Visual Pedagogy for Autistic children; Mesibov et al. [38] stated that subjects diagnosed with ASD are capable of perceiving and processing visual information compared to other sensibilities as auditory or tactile inputs. Du et al. [23] showed the efficacy of TBVP in improving both GI and PI by mean and site's percentage. Pilebro and Backman performed a similar study that also resulted in improvements of plaque sites within an interval of time [39].

Hence, maintaining the oral health of autistic children is crucial due to unknown reactions if toothache triggered the child. Also, to avoid the unpleasant experience that the child might go through during dental treatment if the dentist lacked the necessary cations when treating autistic patients.

Epilepsy; No prevention techniques were studied on epileptic children; nevertheless, the incidence of seizures that epileptic people experience won't affect their oral health. However, the administered antiepileptic drugs mainly affect oral health and gingiva. That's why the treatments needed, according to Gurbuz and Tan [24], as periodontal treatment is prophylaxis (oral hygiene),

and for restoration needs, fillings are required. Moreover, the most needed prevention is brushing since it was shown that 76.3% never brushed their teeth; this can aid in the reduction of plaque accumulation, especially with the intake of antiepileptic drugs that causes gingival enlargement. Also, motivation for oral hygiene care by caregivers or parents is crucial. We can suggest prevention methods for epileptic children, for instance, to undergo several actions, as a team approach of a neurologist and the dentist, to decide the appropriate type of drug intake and if it causes any side effects on the oral health.

However, further studies are required for prevention techniques of epileptic children.

Limitations

This systematic review has had limitations, and they should be stated. Studies like randomized control studies were challenging to obtain, especially the updated ones. Hence, this review included a mix of interventional (retrospective studies) and observational (cross-sectional and cohort studies) studies, where the latter were included more, which affected the outcomes by lacking adequate information and the bias risk assessment. The intervened subjects were from different populations, which also affected the results. Examination strategies were distinct from one another, and diverse and unique evaluation criteria limited our results. No studies were provided for one of the criteria, which led us to use an alternative and modified our results and conclusion.

4. CONCLUSIONS

- 1- Children diagnosed with Cerebral Palsy disorder showed that poor oral hygiene is prevalent, and this is a high-risk factor leading to other oral diseases as decay or plaque; Caries is prevalent in Autistic children
 - Caries and halitosis are prevalent in Epileptic children. Moreover, specific medication intake such as Valproate is affecting the gingival health of children
- 2- Epileptic children are the most susceptible disorder for caries due to the hygiene negligence and medication intake; similarly, to malocclusions, due to facial and body asymmetry

 Autistic children are the most suspectable disorder for tooth-wear occurrence due to the accompanied anxiety
 - Cerebral Palsy children are most suspectable for dental trauma occurrence due to the unexpected body movements
- 3- In three disabilities, the most efficient prevention is the motivation for oral care provided by the caregiver', and the specific instructions and tools used for easing the oral care process

5. PRACTICAL RECOMMENDATIONS

- 1- Special health care needs with variant disabilities require extra oral care and instructions provided by dentists
- 2- During the dentistry studies, the SHCN course should be included by the university curriculum studies
- 3- Mobile clinics should be provided, especially for families in rural areas
- 4- Spreading the awareness around oral health of SHCN children, using the internet platforms
- 5- Instructions for concerned parents about the assistance and motivation required

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ANNEXES

Annex 1 Downs and Black quality assessment question [40]

Articles No.	1011 [10]
Articles No.	
Questions	Scoring (Yes =1, No =0, Undetermined = 0)
1. Is the objective/ hypothesis/ aim of the study clear?	
2. Are the main outcomes clearly described in the Introduction or	
Methods?	
3. Are the characteristics of the patients included in the study clearly	
described?	
4. Are the interventions clearly described?	
5. Are the distributions of principles confounders in each group of	
subjects to be compared clearly described? 6. Are the main findings of the study clearly described?	
7. Does the study provide estimates of the random variability in the	
data for the main outcomes?	
8. Have all important adverse events that may be a consequence of the	
intervention been reported?	
9. Have the characteristics of patients lost to follow-up been	
described?	
10. Have actual probability values been reported (e.g., 0.035 rather	
than <0.05) for the main outcomes except where the probability value is less than 0.001?	
11. Were the subjects asked to participate in the study representative of	
the entire population from which they were recruited?	
12. Were those subjects who were prepared to participate	
representative of the entire population from which they were	
recruited?	
13. Were the staff, places, and facilities where the patients were treated,	
representative of the treatment the majority of patients receive?	
14 Was an attempt made to blind study subjects to the intervention	
14. Was an attempt made to blind study subjects to the intervention they have received?	
15. Was an attempt made to blind those measuring the main outcomes	
of the intervention?	
16. If any of the results of the study were based on "data dredging,"	
was this made clear?	
17. In trial and cohort studies, do the analyses adjust for different	
lengths of follow-up of patients, or in case-control studies, is the	
time period between the intervention and outcome the same for	
cases and controls?	
18. Were the statical tests used to assess the main outcomes	
appropriate?	
19. Was compliance with the intervention/s reliable?	
20. Were the main outcome measures used accurate (valid and reliable)?	
21. Were the patients in different intervention groups (trials and cohort	
studies) or were the cases and controls (case-control studies)	
recruited from the same population?	
22. Were study subjects in different intervention groups (trials and	
cohort studies) or were the cases and controls (case-control studies)	
recruited over the same period of time?	
23. Were study randomized to intervention groups?	
24. Was the randomized intervention assignment concealed from both	
patients and health care staff until recruitment was complete and	
irrevocable? 25. Was there adequate adjustment for confounding in the analyses	
from which the main findings were drawn?	
26. Were losses of patients to follow-up taken into account?	
27. Did the study have sufficient power to detect a clinically important	
effect where the probability value for a difference being due to	
chance is less than 5%?	
SCORE	

Annex 2 Bioethics approval document



LIETUVOS SVEIKATOS MOKSLŲ UNIVERSITETAS BIOETIKOS CENTRAS

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DĖL PRITARIMO TYRIMUI

LSMU Bioetikos centras, įvertinęs Alin Amwe pateiktus dokumentus, studentės tiriamajam darbui tema "The Oral Health and the Associated Oral diseases of Disabled Children" pritaria*.

dr. Elmantas Pelčius

Pastaba: šis pritarimas neatleidžia tiriamąjį mokslinį darbą vykdančių asmenų nuo prievolės laikytis Bendrojo duomenų apsaugos reglamento nuostatų ir nuo atsakomybės gauti nacionalinio arba regioninio bioetikos komiteto leidimą, jei toks leidimas būtinas pagal LR Biomedicininių tyrimų etikos įstatyme numatytus reikalavimus.