



Cross-Cultural Adaptation and Psychometric Properties of Arabic Early Childhood Oral Health Impact Scale (ECOHIS) In Benghazi, Libya

By

Lamis Abdelrahim Ballo

Supervisor:

Dr. Arheiam Arheiam

**This Thesis Submitted in Partial Fulfillment of the Master
Degree in Dental Public Health**

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University of Benghazi

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Department of Dental Public Health

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This Thesis was Successfully Defended and Approved on / /2022

Supervisor

Dr. Arheiam Arheiam

Signature:

Dr. Fowziya Ali (Internal examiner)

Signature:

Dr. Azzam A. sultan (External examiner)

Signature:

(Dean of Faculty)

(Director of Graduate studies and training)

Dedication

In the name of Allah the most Gracious the most Merciful. First and foremost I would like to praise Allah for his blessing and for his guidance, mercy and support. The only is Allah whom gave me the power, chance and the persistence to accomplish my dissertation after the challenges and hard work.

On the very outset of this dissertation I would like to extend my sincere and heartfelt obligation towards all the personages who have helped me in this endeavour, without their active help, guidance, cooperation and encouragement I would not heading towards my goal.

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Table of Contents

Copyrights.....	II
Approval Sheet	III
Dedication.....	IV
Acknowledgment.....	V
Table of Contents.....	VI
List of tables	IX
List of Figures.....	X
List of Abbreviations	XI
Abstract.....	XII
1 Chapter 1 Introduction.....	1
2 Chapter 2 Literature review	6
2.1 Oral health related quality of life (OHRQoL)	7
2.1.1 Measures of Oral Health Related Quality of Life	11
2.1.2 Measures of Oral Health Related Quality of Life in Children.....	14
2.1.3 The Early Childhood Oral Health Impact Scale (ECOHIS)	15
2.2 Cross cultural adaptation and psychometric properties of OHRQoL measures.....	20
2.2.1 Reliability.....	22
2.2.2 Validity.....	23
2.3 The psychometric properties and responsiveness of ECOHIS	24

3	Chapter three Aim and objectives of the study	27
3.1	Aim:.....	28
3.2	Objectives:.....	28
4	Chapter 4 Materials and Methods	29
4.1	Section one: Cross-cultural adaptation and Psychometric properties of AECOHis	30
4.1.1	Study design.....	31
4.1.2	Study population	31
4.1.3	Sample size calculation	32
4.1.4	Sampling method.....	32
4.1.5	Data collection.....	33
4.2	Section 2: longitudinal (Responsiveness) study	34
4.3	Ethical consideration study.....	37
5	Chapter 5 Results	39
5.1	Section 1: Results of secondary data analysis	40
5.1.1	Demographic characteristic of study participants	40
5.1.2	Prevalence of OHRQoL in terms of Child and Parental domains of the study participants.	42
5.1.3	The Arabic-ECOHis reliability analysis.	44
5.2	Section 2: Results of longitudinal study (Responsiveness) sample.	49
5.2.1	Demographic characteristic of A-ECOHis responsiveness sample participants.....	49

5.2.2	Responsiveness of A-ECOHIS to perceived change in OHRQoL following dental treatment	50
5.2.3	Responsiveness of A-ECOHIS to global transition judgment in OHRQoL following dental treatment	51
6	Chapter 6 Discussion	52
7	Chapter 7 Conclusion and Recommendations	60
7.1	Conclusion	61
7.2	Recommendations	62
	References	63
	Appendices	69
	Abstract in Arabic	

List of tables

Table 2.1 Language Versions of ECOHIS.....	5
Table 5.1 Demographic characteristics of the sample of 6 years aged children and their parents	42
Table 5.2: Prevalence of OHRQoL in terms of Child and Parental domains of the study Participants.....	44
Table 5.3 The Arabic-ECOHIS reliability analysis: inter-item correlation coefficients of the 13 items.....	45
Table 5.4 Reliability analysis: corrected item-total correlation of the 13 items of the Arabic- ECOHIS, Cronbach's alpha coefficient.....	46
Table 5.5 Convergent validity test for the Arabic-ECOHIS associations between Arabic ECOHIS and subjective outcome variables (n = 205).....	48
Table 5.6 Discriminant validity of Arabic-ECOHIS through comparison of mean Arabic ECOI scores and respective sub-scales by caries status.....	49

List of Figures

Figure 2.1 Dimensions comprising oral health-related quality of life (OHRQoL).	12
Figure 5.1 Mean ECOHIS total scores in the whole sample, pre- and post-treatment.....	51
Figure 5.2 Distribution of change scores for those who remained with no change, improved a little and improved a lot (n = 89).....	52

List of Abbreviations

QOL	Quality of life
HRQoL	Health Related Quality of Life
OHRQoL	Oral Health Related Quality of Life
WHO	World Health Organization
dmft	Decayed, missed and filled teeth
ECOHIS	Early Childhood Oral Health Impact Scale
A-ECOHIS	Arabic version of the Early Childhood Oral Health Impact Scale
CIS	Child impact section
FIC	Family impact section

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Abstract

Aims and Objectives

The study's primary aim is to assess psychometric properties and evaluate responsiveness of the Arabic version of the Early Childhood Oral Health Impact Scale (A-ECOHis) in Benghazi, Libya.

Materials and Methods:

The methods of this study consists of two parts, part one for assessment of psychometric properties of A-ECOHis by secondary data analysis of 681 Libyan children of 6 years old. The data used for this study was collected as part of oral health survey that was carried out in 2017 in Benghazi, the survey conducted for collecting primary data used a cross-sectional design and WHO diagnostic criteria to assess oral health status, treatment needs and OHRQOL of Libyan children. Part two for evaluation of responsiveness of A-ECOHis for 89, 5-6 years old Libyan children. The study implemented a pre-and-post-intervention design. Participants consisted

of a convenience sample. All data were analyzed using SPSS (version 25) software at p-value ≤ 0.05 .

Results:

A total of 681 mothers participated in the present study. The majority of mothers were housewives (57%), attained tertiary education (44.9%) and gain low income (59.3%) (< 500 LYD). In the child impact section, “pain in the teeth, mouth or jaws” was the most frequently reported item by the parents (63.9%). In the family impact section, the most frequently reported items were “been upset” (29.7%) and “felt guilty” (20.4%). The Cronbach’s alpha coefficient was 0.88. The responsive sample included 89 participants. Mean ECOHIS scores in the whole sample for the whole scale prior to and following treatment are shown in figure 5.1. Higher mean scores (10.16 ± 7.38) were reported before treatment received compared to mean scores after treatment received (4 ± 5.32).

Conclusion:

This study showed that the Arabic-ECOHIS is a valid and reliable instrument to assess the negative impacts of oral disorders/conditions on the quality of life of 5-6 year old preschool children and their families in Libya. As well, results of the longitudinal study showed that the Arabic-ECOHIS is sensitive and responsive to dental treatment of ECC.

Chapter 1 Introduction

Oral diseases are generally challenging because they may directly affect the individuals' quality of life through the interaction with their ability to live a life free from pain and disease (1-4). Consequently, in recent years, more attention has been paid to assessing the impacts of general and oral and dental health on quality of life(5). Oral health-related quality of life (OHRQoL) is significantly identified as a serious worldwide public health concern. Evidence shows that children who suffer from tooth pain had trouble focusing in school and are less likely to achieve academic successes(6). Many OHRQoL measures have been developed and used to enhance conventional clinical indicators for oral health assessment (7, 8). OHRQoL measures reflect the broader social aspects of oral health and supplement oral health assessment, which is based on traditional clinical assessment of normative needs (9). This provides a better understanding of oral health needs and better informs future health care planning (10-13). OHRQoL measures are useful in assessing oral health at patient's level as it gives information on community health needs and priorities, and allows evaluation of the oral care outcome (14, 15). At population level, quality of life measures help to describe and monitor illness in the population, to plan, monitor and evaluate services, needs assessment and prioritization, and encourage greater participation of the lay people in health care (16).

In present health assessment exceedingly should include the measurement of physical, social and psychological functions as well as the quality of life (QOL)(17). The principal components of OHRQoL are function, pain and psychological components and social aspects (1). The use of OHRQoL assessments in oral health studies, researches and surveys is to evaluate the outcome of oral care. Buck and Neton (18) recommend researchers when assessing oral health outcomes and oral health need to include the psychological impact of oral health.

To use HRQOL measure in a new culture, the researcher will have to develop a new measure; or to modify an existing measure that has been previously validated in another language which is known as ‘cross-cultural adaptation’(19). To develop a new measure is time consuming, while the direct translation from its original version is unlikely to be successful because of the different language and culture between the two populations. Therefore, every time an OHRQoL measure is used in a different context or cultural group, it needs to be cross-culturally adapted and tested for its psychometric properties (19-21). This procedure aims to ensure the suitability of the OHRQoL measure to the new context as well as its equivalence to the original measure. Herdman and his colleagues (21) proposed a framework of six aspects of equivalence (semantic, conceptual,

item, operational, measurement and functional), to be considered when cross-culturally adapting quality of life questionnaires.

Over the past decades, oral health-related quality of life assessment tools have been designed and tested on various populations, especially adults and the elderly (22). However, in the last years, there had been a considerable focus on children and adolescents (23). This is a major advancement, as children under six years of age are affected by dental caries, traumatic dental injuries, malocclusion, enamel defects and dental wear (15). Moreover, children are an important focus of dental public health research and practice(24). However, there are as yet a limited number of measures for assessing oral health-related quality of life (OHRQoL) in children (23).

The Early Childhood Oral Health Impact Scale (ECOHIS) is a proxy measure of children's OHRQoL designed to assess the negative impact of oral disorders on the quality of life of preschool children. ECOHIS has been translated and cross culturally adapted into different language and cultures. An Arabic version of ECOHIS has been developed in Saudi Arabia. However, since the initial development by Farsi and his colleagues in 2017, there has been very little published research on the cross-cultural adapted to different Arabic culture (25). As recommended by Alghadeer 2010 (26),

that if you have to use the OHRQoL measure in a different country and culture with the same language you have to culturally adapt the measure before using it.

According to author knowledge there was no previous recorded research assessed psychometric properties and responsiveness of Arabic ECOHIS among Libyan children. Addressing this gap, provides the Libyan researchers with a validated tool to enhance knowledge about the burden of oral diseases and the inequalities in oral health among children in Libya and will inform the rebuilding of health care system and policy actions in Libya. Collecting information on oral health status and treatment needs of 6-year olds will provide baseline data for future monitoring of oral diseases and the evaluation of oral health programs in Libya which is essential for planning services and determining success or progress towards controlling dental diseases. In addition, the use of socio-dental indicators is deemed cost-effective tool which could be an appropriate strategy for assessing oral health needs in such conflict-affected country with deficient resources.

Chapter two Literature review

Chapter Two is the narrative review of the literature on concepts of health; health related quality of life (HRQoL) and OHRQoL. It then considers measures of OHRQoL. Finally, the aim and objectives of the research are presented.

Oral health related quality of life (OHRQoL)

The concept of oral health related quality of life (OHRQoL) has emerged in the past few decades, and yet it has a significant participation in the clinical dentistry and dental research. In order to understand the concept of OHRQoL, it is useful to define oral health and discusses health within both biomedical and bio-psychosocial models.

According to The World Health Organization (WHO) (1946), health is defined as “a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity”(27). This definition fits well with the biomedical model of health which considers health as the absence of disease which is defined by assessment’s objective and patients are only passive recipients of treatment (28). However, this model has been criticized for describing only patient level and ignoring important psychological and environmental factors. This led to the emergence of the bio-psychosocial model of health that incorporates the aforementioned

missing dimensions of health (29). The bio-psycho-social thus changes the objective of achieving health by addressing the wider determinants of health, rather than concentrating specifically on treating disease. The bio-psycho-social model suggests working at both individual and environmental levels to achieve the status of health. It has been suggested that the concept of health should extend to cover individual's ability to cope with social, physical and emotional challenges (Huber *et al.*, (30).

The Ottawa Charter for Health Promotion (31) claims that a healthy individual is the one who is able to identify aspirations, meet needs and change or cope with the environment. Hence, there is a need to examine the subjective experiences of patients (32). This is a key idea to the concept of 'Health Related Quality of Life' (HRQoL) which reflects an individual's subjective appraisal and response to health or illness. The World Health Organization (33) defined quality of life as "the individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". HRQoL is a multidimensional construct of physical health, psychological state, social relationships, personal beliefs and their environment.

The concept of HRQoL has been adopted by oral health professionals where philosophies about health have expanded from the biomedical model of merely assessing the decayed or the remaining teeth to include the assessment of the effects of oral conditions on various aspects of everyday life (16).

Oral health-related quality of life (OHRQoL) is the part of a person's quality of life that is affected by person's oral health. It is a multidimensional, subjective and patient-centred measure of functional and psycho-social aspects of oral health (34). A popular definition of OHRQoL is “ *the impact of oral disease and disorders on aspects of everyday life that a patient or person values, that are of sufficient magnitude, in terms of frequency, severity or duration to affect their experience and perception of their life overall* ”(2).

A new definition of oral health recently approved by the World Dental Federation (2017) states that ‘oral health is multifaceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow, and convey a range of emotions through facial expressions with confidence and without pain, discomfort, and disease of the craniofacial complex’(35). Oral health is complex and multidimensional and does not simply constitute the presence or absence of disease(36). It has a profound impact on an individual’s

general health and well-being. Oral health-related quality of life (OHRQoL) is an integral part of the individual's overall health and is estimated according to how oral tissues and teeth affect physical, psychological and social well-being, as well as function(35, 37).

A multidimensional OHRQoL model was developed based on HRQoL models suggested by Patrick and Erickson (38).The model comprises the absence of impairment, disease and symptoms, the appropriate physical functioning related to chewing, swallowing and absence of discomfort and pain, the emotional functioning related to smiling, the social functioning associated with normal roles, the perception of excellent oral health; satisfaction with oral health, and the absence of social or cultural disadvantage due to oral health status (39). The dimensions which constitute the frame of OHRQoL and are included in OHRQoL instruments are illustrated in Figure 2.1. Each dimension is combined with specific examples of associated items (8).



Figure 2.1 Dimensions comprising oral health-related quality of life (OHRQoL). *Excludes non-patient groups. Adopted from (8).

Measures of Oral Health Related Quality of Life

The development of socio-dental indicators was first advocated by Cohen and Jago (40) to improve the lack of data relating to the psychosocial impact of oral health problems on individuals. Buck and Neton (18) recommended that the psychological impact of oral health should be

included in the assessment of oral health outcomes and oral health. Oral health-related quality of life (OHRQoL) has been widely used as a measure of the impact of oral diseases and disorders on individuals and society.

Locker 1998 (41) defined OHRQoL as “*an individual’s assessment of how the following affect his or her well-being: functional factors, social factors, psychological factors and experience of pain in relation to oro-facial concerns*”. OHRQoL involves subjective assessment of oral health, emotional and functional well-being and self-esteem; also known as ‘socio-dental indicators’ (8). Traditionally, clinical indicators, also known as ‘Normative needs’ are used for oral health assessment and services planning, which has its well-known limitations; such as overestimation of health needs and workforce, and more importantly, overlooking the impact of oral health on daily life (13). The development of Oral health-related quality of life (OHRQoL) measures and socio-dental indicators enable the investigators to explore broader social aspects of oral health and to overcome the downsides of traditional clinical assessment (9). These developments also marked the paradigm shift in defining oral health needs and outcomes from a narrow biomedical to a wider bio-psychosocial approach (42). This allows for a better understanding of disease and health determinants and applies in oral health services’ planning and evaluation and allocation of resources (10-13).

Unlike normative clinical indicators, quality of-life measures aim to capture broad consequences of poor oral health from the perspective of affected adults, children and families (43, 44). However, it should be noted that the use of OHRQoL measures is complementary to clinical tests to capture a broader image of health, and should not be used as the only tests of oral health. The use of socio-dental indicators is a new definition of oral health introduced by the General Assembly of the Dental Federation, which defines oral health as a multifaceted concept and recognizes psychosocial role as a key aspect of oral health (35).

Most of the developed OHRQoL indicators measure either the effect or the impact of oral health on the quality of life, or sometimes they measure both the effect and the impact of oral health (45). The effect of oral health on the quality of life refers to the physical, psychological and social effect, while the impact of oral health on the quality of life refers to daily activities, ability to chew, talking to people and overall quality of life. However, the majority of the OHRQoL indices measure the effect of oral disorders on the individual's social role and their ability to work, attend school or assume parental or household duties (41, 46). The use of OHRQoL measures to assess the effect and impact of oral health is better than solely use the clinical measures of disease (47, 48).

To date, many tools have been developed to assess OHRQoL, primarily for adults such as: Social Impacts of Dental Disease (SIDD)(49), General / Geriatric Oral Health Assessment Index (GOHAI)(50), Dental Impact Profile (DIP)(51), Oral Health Impact Profile (OHIP)(45), Subjective Oral Health Status Indicators (SOHSI)(52), Dental Impact on Daily Living (DIDL)(53), The Oral Health Quality of Life Inventory(OHQOLI) (54), Oral Impacts on Daily Performance (OIDP)(55) , UK Oral Health-Related Quality of Life Measure (OH-QoL-UK)(56) and the Prosthetic Quality of Life (PQL) (57). All of them have been tested for reliability, internal consistency and validity. Besides, most of them were developed following the theoretical framework provided by the Model of Oral Health of Locker (1). Many of these adult OHRQoL measures have been adapted and tested for validity and reliability to be used in school aged children(58, 59) such as Child Oral Impacts on Daily Performance index (Child-OIDP) (60), Child Oral Health Impact Profile (COHIP) (61).

Measures of Oral Health Related Quality of Life in Children

Many instruments were developed during the past decades, to measure the impact of oral health on the child's quality of life. As mentioned in the previous section, most of OHRQoL measures in children were developed from adult's tools. At first, the OHRQoL measures for children depended

on their parents / guardians as proxy reporters (62). However, discrepancies between children and parents' responses were observed and, therefore, recent children-based OHRQoL measures were presented. The development of these measures was based on standardised approaches, which guarantee validity and reliability of questionnaires. The children OHRQoL instruments that were developed include: OHRQoL in Children (COHRQoL) (63), Child Oral Impacts on Daily Performance (Child-OIDP) (60), Child Oral Health Impact Profile (COHIP)(61), Early Childhood Oral Health Impact Scale (ECOHIS) (23) and the Scale of Oral Health Outcomes for Five-Year-Old Children (SOHO-5) (64). To select an appropriate OHRQoL measure for children, certain criteria should be met. The tool should be acceptable to the population, clear, easy to use and consist of generic definitions. The measures of OHRQoL should also demonstrate satisfactory psychometric characteristics and provide a standard for the general population and to the target age group of children (65, 66).

The Early Childhood Oral Health Impact Scale (ECOHIS)

Children in preschool period may suffer from a number of oral health problems like dental caries, disturbance in eruption and dental trauma (67). Children in this age (6 years old of age and younger) cannot recall or memorize information about their daily life events more than 24 hours (68).

Parents or guardians who take care of their preschool child and his health can experience job absence and spend money and time to provide dental care and treatment for him (39). Therefore, Early Childhood Oral Health Impact Scale was developed by Pahel and his colleague (23) to assess OHRQoL for this age group.

ECOHIS was developed and tested in the United States of America following the criteria and guidelines offered by Guyatt and his colleague (69) and Juniper (70). The process of ECOHIS development includes the development of the items followed by testing the instrument through pretesting, validity and reliability tests. ECOHIS was developed to assess the impact of oral health on the quality of life of children aged between 3 and 5 years and their parents. It consists of 13 items within two main parts: the child impact section consists of four items and the family impact section consists of nine items. The child section has four sub-domains; they are: child symptoms, child function, child psychology and self-image and social interaction, while the family section has two sub-domains: parental distress and family function. Responses are on a five-point scale (0 = never to 5 = don't know). ECOHIS scores are obtained by summing responses for all 13 questions. The child impact section range of score is 0 to 36 and the score range for family impact section is from 0 to 16. The total score ranges

between 0 and 52, and the higher ECOHIS score means poor OHRQoL and /or a great impact of oral health on quality of life.

The findings of the study on the development of the original English ECOHIS showed that oral health problems and their treatment had a significant impact on the quality of life of children and their families. The mothers were the most often representative of the children. The ECOHIS scores in both the child and the parent sections indicated a significant association between the presence of oral disease in the child and poor quality of life. The ECOHIS had a good performance in the evaluation of OHRQoL among preschool children and their families (23).

The original English version of ECOHIS has been translated into other languages and has been validated by several studies in different countries over the last twelve years. They are Brazilian, French, Dutch, Chinese, Farsi, Turkish, Kiswahili and Luganda, Spanish, Lithuanian, Malay, Malayalam, Arabic, Chilean, Nigerian Pidgin and German language versions.

Table 2.1 below summarises the published studies of cross-cultural validation of ECOHIS.

Table 2.1 Language Versions of ECOHIS

Language version	Country	Year	Author/s
French	Canada	2008	(67)
Brazilian	Brazil	2008	(71)
Chinese	China	2009	(72)
Farsi	Iran	2010	(73)
Turkish	Turkey	2011	(74)
Spanish	USA	2012	(75)
Kiswahili and Luganda	Tanzania and Uganda	2012	(76)
Lithuanian	Lithuania	2012	(77)
Malay	Malaysia	2015	(78)
Malayalam	India	2015	(79)
Arabic	Saudi Arabia	2017	(25)
Chilean	Chile	2018	(80)
Nigerian Pidgin	Nigeria	2018	(81)
German	Austria	2019	(82)

More recently a study published after data collection of our survey, its aim was translation and cultural validation of ECOHIS to Moroccan Arabic language. It was difficult to use the Arabic version of ECOHIS in Morocco because the vocabulary of Moroccan dialect is derived from the French, Spanish and Berber directly. For this demand it was a need to translate and cross cultural validate the ECOHIS to the Moroccan Arabic language. According to the study results the Moroccan Arabic language version is a useful instrument for assessment of OHRQoL among preschool children in Morocco (83).

ECOHIS and SOHO-5 are the two common instruments measure OHRQoL among preschool children. The difference between the two measures is that ECOHIS information on OHRQoL is obtained only through parental reports, and SOHO-5 has been expanded to measure OHRQoL in children through both self-reporting and parental reports (64). In a systematic review of the impact of SES on OHRQoL, ECOHIS was the preferred OHRQoL measure in most pre-school children's studies (84). This was supported by evidence from a recent systematic reviews that ECOHIS is the best measures(80) and the most commonly used instrument for OHRQoL in preschool children (85). In this regard and before collecting the data for this survey, it was found that among these two preschool children OHRQoL

instruments, only the ECOHIS is available in Arabic version. However, SOHO-5 has been validated and translated to Arabic language recently in Saudi Arabia (86).

Arabic version of ECOHIS was assessed among caregivers of preschool children aged 6 years old and younger. The most reported items in the child section among participants were "pain" (35%), "irritability or frustration" (24%) and difficulty eating (24%), and the most reported item in the family section was "being upset" (31%). A-ECOHIS scores were higher in children with greater caries experience in both sections. Participants who recruited in both community and clinic based samples were from different Arabic nationalities (25). Therefore, they conclude that A-ECOHIS is a valid and reliable tool to measure the OHRQoL in Arabic speaking caregivers of children of two to six years old.

Cross cultural adaptation and psychometric properties of OHRQoL measures

Culture is an important factor that can influence a person's activities, thinking and behavior. As countries differ regarding public health strategies, attitudes, socioeconomic conditions and other factors, varied expression of

their culture can be seen across populations (87), and , hence, measures of Health Related Quality of life (HRQoL) should go through a cross-cultural adaptation process before being used in a different country. Therefore, even among Arabic speaking countries it is usual to develop country-specific versions of instruments measuring HRQoL (88, 89). Even when the translation is performed with great precision, cultural factors may not be accurately conveyed. In order to study the health care needs of people with diverse cultural backgrounds, research instruments must be reliable and valid in each culture studied (90).

A well validated OHRQoL instrument is considered to have the ability to assess the patient's self-reported perceptions. The scientific literature contains a consensus that for an instrument to be valid, reliable and responsive, it should include at least an assessment of physical, functional and mental status and social interaction (91).

The measurement properties are divided over three domains: reliability, validity, and responsiveness (92).

Reliability

Reliability is defined as the extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: e.g. using different sets of items from the same questionnaire (internal consistency); over time (test-retest); by different persons on the same occasion (inter-rater); or by the same persons on different occasions (intra-rater) (92, 93). Reliability contains the following measurement properties:

- Internal consistency: The interrelatedness among the items in a questionnaire, expressed by Cronbach's α or Kuder-Richardson Formula 20 (KR-20) (92, 93). Internal consistency is a measure of the extent to which items in a questionnaire sub-scale are correlated (homogeneous), thus measuring the same concept.

- Reliability: The proportion of the total variance in the measurements which is due to 'true' differences between patients (92). This aspect is reflected by the Intraclass Correlation Coefficient (ICC) or Cohen's Kappa (92, 94).

Validity

Validity is the extent to which a questionnaire measures the construct it is supposed to measure and contains the following measurement properties (92): Content validity: The degree to which the content of a questionnaire is an adequate reflection of the construct to be measured (92). Important aspects are whether all items are relevant for the construct, aim, and target population and if no important items are missing (comprehensiveness) (95).

Construct validity is divided into three aspects:

- Cross-cultural validity: The degree to which the performance of the items on a translated or culturally adapted instrument are an adequate reflection of the performance of the items of the original version of the instrument (92). This is assessed by means of multi-group factor analysis or differential item functioning using data from a population that completed the questionnaire in the original language, as well as data from a population that completed the questionnaire in the new language.

- Structural validity: The degree to which the scores of an instrument are an adequate reflection of the dimensionality of the construct to be measured (92). Factor analysis should be performed to confirm the number of subscales present in a questionnaire (95).

- Hypothesis testing: The degree to which a particular measure relates to other measures in a way one would expect if it is validly measuring the supposed construct, i.e. in accordance with predefined hypotheses about the correlation or differences between the measures (92).

2.2.3 Responsiveness

Responsiveness is the ability of an instrument to detect change over time in the construct to be measured (96). Responsiveness is considered an aspect of validity, in a longitudinal context (97). Therefore, the same standards apply as for validity: the correlation between change scores of two measures should be in accordance with predefined hypotheses (97). Another approach is to consider the measurement instrument as a diagnostic test to distinguish improved and non-improved patients. The responsiveness of the instrument is then expressed as the area under the receiver operator characteristic curve (AUC) (97).

The psychometric properties and responsiveness of ECOHIS

The translation and the testing of psychometric properties are important steps to ensuring the quality of a cross-cultural adaptation of an OHRQoL measure (97). Considering the differences between social, cultural

and economic aspects, the availability of cross culturally valid, multi-lingual versions of instruments is important to obtaining reliable, comparable data (98, 99). The ECOHIS has performed well and has shown good reliability and validity. The scale has been translated into several languages and has been tested and validated on diverse populations with promising results (72, 74, 78, 79, 81, 82). The psychometric properties of Arabic ECOHIS have been tested in Saudi Arabia and performed very well (25).

Assessing the responsiveness of the ECOHIS is a key psychometric property if it is to be used as an outcome measure in trials to assess the effectiveness of interventions (88). Previous cross-sectional studies using the ECOHIS have shown that dental caries impacts on OHRQoL of preschool children and their families (85, 100). One of these studies were conducted in Libya in 2017, where the prevalence of untreated dental caries is high (71.7%) at 6 years old (101). Therefore, it is considered important to assess the effectiveness of clinical interventions to treat dental caries, including the evaluation of patient-reported outcomes. To test OHRQoL measures as outcomes in clinical trials, the measure must be, however, proved to be responsive (102).

A finding from previous study found that the Arabic version of the ECOHIS was sensitive to dental treatment for children aged 6 years or

younger with ECC under General Anesthesia. The measure also appeared to be responsive to the dental treatment for dental caries with respect to caregivers' global transition judgment with the outcome. As the majority of parents (93.9%) reported improvement in their children oral health after treatment. Improvements in children's oral health after treatment also were reflected in the differences between the mean pre- and post-treatment total A-ECOHIS scores. They declined from 19.9 to 4.3 ($P < 0.0001$) (103).

To sum up, the A-ECOHIS has been developed in the Saudi Arabia and validated in Morocco. These two countries although speak Arabic language, they are culturally different from Libya. Therefore, validating the A-ECOHIS in Libyan culture and testing its responsiveness to treatment would be a valuable asset for dental research and clinical services in the Libyan health care setting.

Chapter: Aim and objectives of the study

Aim:

The current study aims to assess psychometric properties and evaluate responsiveness of the Arabic version of the Early Childhood Oral Health Impact Scale (A-ECOHIS) in Benghazi, Libya.

Objectives:

- To adapt Arabic ECOHIS (A-ECOHIS) which developed in Saudi Arabia among six years old children in Libya.
- To assess psychometric properties of the Arabic ECOHIS (A-ECOHIS) among six years old children in Libya.
- To assess the responsiveness of the Arabic ECOHIS (A-ECOHIS) to dental treatment of dental caries among five to six years old children in Libya.

Chapter 4 Materials and Methods

This chapter describes the methodology used to achieve the objectives of the study. **The study used mixed study design.** It is divided to two sections, **section one** describes the methods of psychometric properties of ECOHIS and **section two** describes the methods of responsiveness of Arabic ECOHIS. **The** methods and materials used within the research along with details of the statistical methods and the data analysis strategy for the study will be described.

Section one: Cross-cultural adaptation and Psychometric properties of A-ECOHIS

The A-ECOHIS developed in Saudi Arabia was piloted before the original primary study in Benghazi, Libya, to assess its conceptual, item and operational equivalence to the original English version in the Libyan culture. A convenience sample of 30 child-parent dyads were selected from dental patients seeking dental care in paediatric clinic has been asked to complete the A-ECOHIS. One-to-one qualitative interviews had been conducted to investigate how the participants understood the meaning, clarity of wording, and relevance to oral health of different items of the A-ECOHIS and their views regarding the response options. Based on participants' feedback, a

final Arabic A-ECOHIS created. After the cross-cultural adaptation, the instrument is ready for being tested for its measurement properties among its target population (20).

Study design

This study design based on secondary data analysis. The data used for this study was collected as part of oral health survey that was carried out in the time period from October 2017 to March 2018 in Benghazi by the Department of Preventive and Community Dentistry, University of Benghazi, Libya. The survey conducted for collecting primary data used a cross-sectional design and WHO diagnostic criteria to assess oral health status, treatment needs and OHRQOL of Libyan children; with the specific objectives to investigate dental caries prevalence and experience, and oral health related quality of life among 6-year olds children in Benghazi Libya.

Study population

The study population consist of six years old children and their parents, attending primary health care unit for mandatory vaccination campaign for school entrance in Benghazi.

Sample size calculation

A minimal sample size of 676 children was required to estimate percentage of children who had caries experience ($dmft > 0$) with 99% confidence level and 0.05% error margin. For reliability and validity studies, a sample size of more than 400 participants had been identified to be enough (104).

Sampling method

The full list of public primary health care centres (PPHCC) in Benghazi was obtained from Ministry of Health in the city. In total, there were only 20 primary health care centres were working from original 31 centres, and the other 11 centres were closed due to Benghazi conflict. The mandatory vaccination campaign every year is only provided and organised by public primary health care centres. All preschool children of 6 years old in Benghazi must attend the vaccination campaign before enrolment in schools. The total population estimated was distributed equally overall the research sites. Every day, only 120 children were attending vaccination campaign in all the primary health care centres. Thus, to recruit 676 participants from 20 health centres (676 divided by 20), almost 34 participants were needed from each recruitment site.

To obtain the eligible population of the study, the following inclusion and exclusion criteria were applied:

a) Inclusion criteria:

- Children of 6 years of age according to the last birthday.
- Children who were free from systematic disease based on school medical report.
- Libyan nationality.

b) Exclusion criteria:

- Parents who did not give consent.
- Uncooperative children.
- Not resident in Benghazi (displaced families).

The sampling technique used in this study was simple random sampling. The 34 participants were randomly selected from 120 children attending a mandatory vaccination campaign for every day.

Data collection

Clinical data on dental experience was collected using WHO diagnostic criteria of **dmfs** index. The randomly selected participants had oral examination to assess the prevalence of caries in primary teeth. All oral examination was conducted in the dental clinic of the primary health care centre and the child seated on the dental chair. The dental examination was carried out visually by doing basic dental examination using disposable mouth mirror, following an examination format adapted and modified by WHO (Annex 4 WHO oral health assessment form for children (by tooth

surface), 2013,) (Appendix 1). A self-administered questionnaire was given to the parents addressing socio-demographic information, oral health behaviours and feeding behavioural history questions (Appendix 2).

An Arabic version of Early Childhood Oral Health Impact Scale (A-ECOHIS) was used to assess OHRQoL (Appendix 3). It comprises 13 questions and is divided into 2 impact sections: Child & Family impact sections. The child impact section (CIS) includes nine items and comprises four domains: child symptoms, function, psychology, and self-image and social interaction. The family impact section (FIS) contains 4 items and comprises 2 domains: parental distress and family function.

Section 2: longitudinal (Responsiveness) study

The study implemented a pre-and-post-intervention design. Participants consisted of a **convenience sample** including all Arabic speaking parents of healthy preschool children, with the following inclusion criteria: Arabic-speaking parents of children aged 5-6 years old; had early childhood caries; and good health otherwise. The exclusion criteria were parents of children with special healthcare needs; and refusal to give consent for enrolment in the study. The recruitment period was from April 2021 to October 2021.

Eighty nine parents were invited to participate and were enrolled. Parents were asked to consider their child's oral health status from birth to the present when answering the questionnaire. Ten questions were added to the questionnaire eliciting sociodemographic data, including parental education, employment, and income. Parents were informed that, by completing the questionnaire, they were consenting to participate in the study. One parent in each parent-child dyad completed the questionnaire on the pre-operative dental visit, their child underwent a dental examination before and after start of treatment to assess for decayed, missing or filled teeth and produce a dmft score using to the World Health Organization 1997 criteria. At the post-operative follow-up visit 2-4 weeks after treatment received, the same parent who completed the pre-operative questionnaire was asked to complete a second questionnaire without access to his or her previous responses. The referral time for the questions was the previous 2 weeks. If the child failed to attend the follow-up appointment or the same parent was not available at that time, a telephone call was made, and the parent was encouraged to give his or her responses to the questionnaire by telephone.

The evaluation of responsiveness to change was bases on two strategies : (i) comparison of test instrument scores before and after a

treatment of known efficacy (105, 106); (ii) comparison of test instrument change scores with a global transition judgment by study subjects in a longitudinal study (105); In order to compare ECOHIS change scores with the global transition judgment by study subjects, we grouped subjects according to how they responded to the question ‘How has your child’s condition changed since before dental treatment?’ (‘no change’, ‘got better’ and ‘got worse’) and compared mean change scores among these groups.

Data management and statistical analysis

All data analyses conducted using SPSS software (IBM, Version 25). Answers were recorded with five scales to register how often to incident had occurred during the whole life of the child. The scale consists of 5 rating response options for A-ECOHIS were coded as follows: 0= never, 1 = hardly ever, 2 = occasionally, 3 = often, 4 = very often, and 5 = don’t know. The parents were also required to answer a global question, ‘How would you rate the overall oral health of your child?’ using a 5-point scale (1, excellent; 2, very good; 3, good; 4, fair; 5, poor).

Internal consistency assessed by calculating Cronbach’s alpha coefficient for the overall scale and for each subscale (Oral health,

Functional well-being and Socio-emotional well-being). Cronbach's alpha values ≥ 0.6 was considered as an acceptable level (107).

Construct validity of A-ECOHIS was evaluated by examining measures of the discriminant and convergent validity (108). These were examined against a predefined hypotheses (91), as following: lower A-ECOHIS scores will be observed among those who 1) perceived their child's oral health as poor ; 2) were not satisfied with their child's oral health; 3) indicated the need of their child for dental treatment; 4) if the child had active dental caries (had more than one decayed tooth vs caries-free). To test these hypotheses, the participants asked to answer 3 general questions on whether they were satisfied with their oral health (Satisfied VS not-satisfied), whether they perceived any need for oral health treatment (Yes VS No) and how they rated their own oral health (good/excellent VS poor). All hypotheses were tested by employing Mann-Whitney U test and paired sample t test, at $p < 0.05$.

Ethical consideration study

For the current study, permission to use the primary data from oral health survey was granted from the Faculty of Dentistry, University of

Benghazi, as they are the sponsor of the research governance. The author of this study is the main researcher in the primary study. Further, ethical approval to conduct the secondary data analysis was granted from the Research Ethics Committee at Faculty of Dentistry, University of Benghazi. Before data collection the self-administered questionnaires and the consent forms were distributed to the parents of randomly selected children. Informed consents from parents have been obtained before taking part in the study.

Chapter 5 Results

This chapter presents the research results including descriptive and multivariate analysis. It consists of two sections section 1 presents results related to assessing psychometric properties of A-ECOHIS and section 2 presents results related to evaluating responsiveness of A-ECOHIS among Libyan preschool children.

The first step in this study was to cross-culturally adapt the Arabic ECOHIS developed in Saudi Arabic to the Libya culture. The cognitive interviewing with parents (30 mothers) demonstrated that the language used was clear and understandable and the questionnaire can be completed without assistance.

Section 1: Results of secondary data analysis

Demographic characteristic of study participants

The demographic characteristics of the study sample are summarized in Table 5.1. Gender was almost equally distributed; however, males were just above half of the subjects (51%). The majority of mothers were housewives (57%), attained tertiary education (44.9%) or secondary education (34.4%), and gain low income (59.3%) (< 500 LYD). Most of the fathers were working in professional level occupations (91.9%), attained

secondary education (37.7%) or tertiary education (36.6%), and gain an intermediate income (76.6%).

Table 5.1 Demographic characteristics of the sample of 6 years aged children and their parents (N = 681)

Variables of study (N = 681)	Freq (n)	Percentage (%)
<i>Child gender</i>		
Male	347	51
Female	334	49
<i>Mother's educational level</i>		
Primary	141	20.7
High school	234	34.4
University	306	44.9
<i>Mother's occupation</i>		
Professional occupation	34	5
Intermediate occupation	259	38
Not working	388	57
<i>Mother's income</i>		
less than 500 LYD	404	59.3
500-1500 LYD	263	38.6
more than 1500 LYD	14	2.1
<i>Father's educational level</i>		
Primary	175	25.7
High school	257	37.7
University	249	36.6
<i>Father's occupation</i>		
Professional occupation	626	91.9
Manual occupation	55	8.1
<i>Father's income</i>		
less than 500	64	9.1
500-1500	541	76.6
more than 1500	101	14.3

Prevalence of OHRQoL in terms of Child and Parental domains of the study participants.

Table 5.2 displays the parents' responses to each item in the ECOHIS questionnaire. In the child impact section, "pain in the teeth, mouth or jaws" was the most frequently reported item by the parents (63.9%). The items "difficulty in eating" (36.3%), "difficulty in drinking" (31.9%), "irritation or frustration" (22.9%) and "trouble sleeping" (20.8%) were the next frequently reported in this section. In the family impact section, the most frequently reported items were "been upset" (29.7%) and "felt guilty" (20.4%).

Table 5.2: Prevalence of OHRQoL in terms of Child and Parental domains of the study participants (N = 681).

ECOHIS items	Never n (%)	Hardly ever n (%)	Occasionally n (%)	Often n (%)	Very often n (%)	Mean (sd)
<i>Child Symptoms</i>						
Oral /Dental Pain	249 (36.6)	65 (9.5)	317 (46.5)	30 (4.4)	20 (2.9)	1.27 (1.09)
<i>Child Function</i>						
Difficulty in drinking hot or cold beverages	469 (68.9)	102 (15)	72 (10.6)	29 (4.3)	9 (1.3)	0.54 (0.93)
Difficulty in eating	441 (64.8)	99 (14.5)	99 (14.5)	26 (3.8)	16 (2.3)	0.64 (1.01)
Pronunciation difficulty	572 (84)	63 (9.3)	24 (3.5)	14 (2.1)	8 (1.2)	0.27 (0.73)
Missed school or day care	567 (84)	63 (9.3)	27 (4)	3 (0.4)	4 (0.6)	0.23 (0.59)
<i>Child Psychology</i>						
Trouble sleeping	543 (79.7)	71 (10.4)	52 (7.6)	9 (1.3)	6 (0.9)	0.33 (0.75)
Irritability or frustration	537 (78.9)	70 (10.3)	55 (8.1)	11 (1.6)	8 (1.2)	0.36 (0.79)
<i>Child Self-image and social interaction</i>						
Avoid smiling or laughing	595 (87.4)	57 (8.4)	22 (3.2)	3 (0.4)	4 (0.6)	0.18 (0.56)
Avoid talking	592 (86.9)	58 (8.5)	20 (2.9)	9 (1.3)	2 (0.3)	0.19 (0.57)
<i>Parental distress</i>						
Been upset	481 (70.6)	81 (11.9)	58 (8.5)	38 (5.6)	23 (3.4)	0.59 (1.07)
Felt guilty about child's oral health	544 (79.9)	63 (9.3)	35 (5.1)	26 (3.8)	13 (1.9)	0.39 (0.89)
<i>Family function</i>						
Taken time off work	629 (92.4)	37 (5.4)	15 (2.2)	---	---	0.09 (0.36)
Financial impact	618 (90.7)	41 (6)	19 (2.8)	---	3 (0.4)	0.13(9.8)

The Arabic-ECOHIS reliability analysis.

Table 5.3 shows the inter-item correlation coefficients of the 13-item scores of the A-ECOHIS. The inter item correlation coefficients ranged from 0.145 to 0.756. The weakest correlation was between items “smiling” and “financial impact” with coefficient value of 0.145 while the strongest correlation was between items “smiling” and “talking” with coefficient value of 0.756.

Table 5.3 The Arabic-ECOHIS reliability analysis: inter-item correlation coefficients of the 13 items

	Pain	Drinking	Eating	Pronunciation	Absence	Sleeping	Irritation	Smiling	Talking	Upset	Guilty	Work	Financial
Pain	1.000												
Drinking	.480	1.000											
Eating	.542	.749	1.000										
Pronunciation	.154	.273	.279	1.000									
Absence	.158	.337	.302	.438	1.000								
Sleeping	.367	.535	.554	.357	.459	1.000							
Irritation	.285	.420	.478	.422	.465	.583	1.000						
Smiling	.183	.258	.282	.330	.399	.426	.499	1.000					
Talking	.176	.292	.287	.350	.420	.467	.451	.756	1.000				
Upset	.406	.477	.515	.318	.220	.491	.459	.388	.436	1.000			
Guilty	.340	.395	.420	.278	.308	.399	.357	.322	.402	.753	1.000		
Work	.230	.365	.309	.231	.415	.322	.258	.221	.245	.309	.411	1.000	
Financial	.224	.334	.273	.175	.196	.318	.196	.145	.163	.335	.364	.400	1.000

Table 5.4 shows the corrected item-total correlation of the 13 items of the A-ECOHIS. The corrected item total correlation values were all positive ranging from 0.39 to 0.69. Of the 13 items, 12 had corrected item total correlation values above 0.4. The lowest value was related to “financial impact” (0.39) while the highest value was related to “eating” (0.68) and “sleeping” (0.69). The Cronbach’s alpha coefficient was 0.88.

Table 5.4 Reliability analysis: corrected item-total correlation of the 13 items of the Arabic-ECOHIS, Cronbach’s alpha coefficient

	Corrected item-total Correlation	Cronbach’s alpha if item deleted
Pain	0.48	0.87
Drinking	0.66	0.85
Eating	0.68	0.85
Pronunciation	0.44	0.87
Absence	0.49	0.86
Sleeping	0.69	0.85
Irritation	0.63	0.86
Smiling	0.52	0.86
Talking	0.55	0.86
Upset	0.68	0.86
Guilty	0.62	0.86
Work	0.46	0.87
Financial	0.39	0.87
Cronbach’s alpha coefficient	0.88	

5.1.3 The Arabic-ECOHIS convergent and discriminant validity.

Table 5 shows the results of the convergent validity tests of the A-ECOHIS. There was a trend of increasing A-ECOHIS scores from parents who perceived their child's oral health status as "excellent" to those who perceived their child's oral health status as "poor" ($p < 0.001$). Similar trend was observed on parents who were "very satisfied" to those who were "very unsatisfied" with their child's teeth/mouth ($p < 0.001$). Parents who perceived their child as needing dental treatment had significantly higher A-ECOHIS scores than those who perceived their child as not needing dental treatment. Those who were unsure had lowest A-ECOHIS scores compared with the other two groups of parents. The trend was statistically significantly ($p < 0.001$).

Table 5.5 Convergent validity test for the Arabic-ECOHIS associations between Arabic ECOHIS and subjective outcome variables (n = 205)

Variable	N	Mean	(SD)	ECOHIS scores CI	P value
Perceived child's oral health status					
Excellent	51	13.5	1.85	(12.9, 14.0)	≤0.001
Good	96	15.3	4.95	(14.3, 16.3)	
Moderate	32	18.7	9.14	(15.4, 22.0)	
Poor	26	20.2	8.30	(16.8, 23.5)	
Perceived satisfaction on child's oral health					
Very satisfied	67	14.5	4.71	(13.4, 15.7)	≤0.001
Satisfied	87	14.9	4.25	(14.1, 15.9)	
Moderate	9	19.5	8.42	(13.1, 26.0)	
Not satisfied	33	17.8	7.78	(15.0, 20.5)	
Very unsatisfied	9	27.3	9.67	(19.9, 34.8)	
Perceived child's oral health need					
Yes	94	18.4	7.3	(16.8, 19.8)	≤0.001
No	84	14.1	4.1	(13.2, 14.9)	
Don't know	27	13.9	4.8	(12.0, 15.8)	

Kruskal Wallis test was used to compare means

Table 5.6 shows an evidence on discriminant validity of the A-ECOHis. For each of the child impacts section, family impacts section, and the overall score, the mean A-ECOHis scores were significantly higher in children with caries than children without caries.

Table 5.6 Discriminant validity of Arabic-ECOHis through comparison of mean Arabic ECOHis scores and respective sub-scales by caries status

A-ECOHis	Caries Mean (SD)	Caries free Mean (SD)	P value
Child impact section	5.22 (4.97)	1.21 (2.89)	≤0.001
Symptoms	4.56 (4.88)	1.76 (2.34)	≤0.001
Function	2.15 (2.65)	0.58 (1.46)	≤0.001
Psychology	0.87 (1.50)	0.26 (0.85)	≤0.001
Self-image	0.44 (1.17)	0.24 (0.74)	≤0.001
Parents impact section	1.63 (2.51)	0.20 (0.78)	≤0.001
Parental stress	1.32 (2.06)	0.16 (0.61)	≤0.001
Parents function	0.31 (0.79)	0.05 (0.34)	≤0.001
Overall ECOHis	6.84 (6.82)	1.41 (3.34)	≤0.001

Section 2: Results of longitudinal study (Responsiveness) sample.

Demographic characteristic of A-ECOHIS responsiveness sample participants

All parents invited to participate in the study gave their consent and completed both pre- and post-treatment A-ECOHIS questionnaire, and no questionnaires were excluded from data analysis due to missing data. The majority (77%) of the participating children was of 6 years of age, with slightly more than half being girls (52%). About half of the fathers and a third of the mothers were educated to more than high school level. The mean dmft score before treatment was 13.2 \pm 3.5 (range: 6–20).

Responsiveness of A-ECOHIS to perceived change in OHRQoL following dental treatment

Mean ECOHIS scores in the whole sample for the whole scale prior to and following treatment are shown in figure 5.1. Higher mean scores (10.16 ± 7.38) were reported before treatment received compared to mean scores after treatment received (4 ± 5.32).

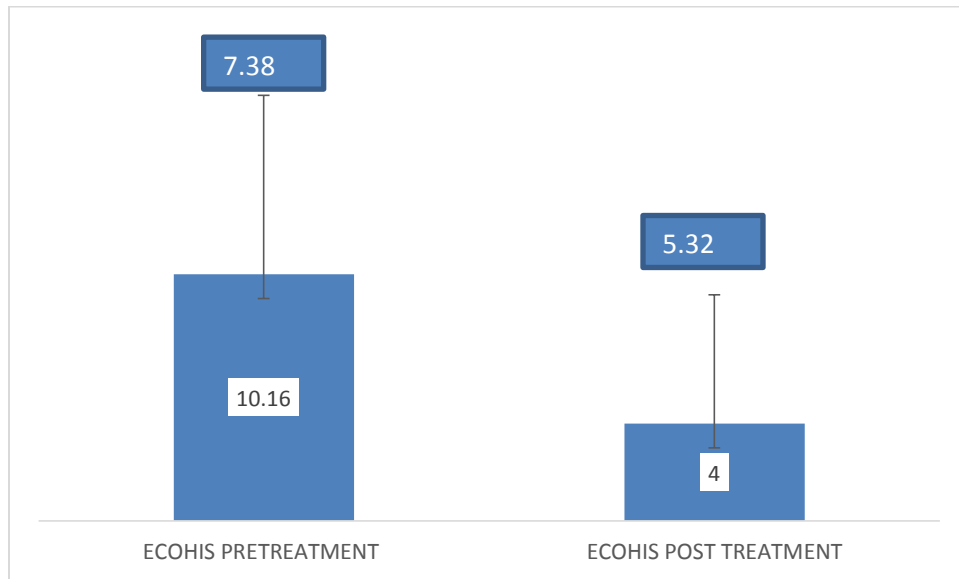


Figure 5.1 Mean ECOHIS total scores in the whole sample, pre- and post-treatment

Responsiveness of A-ECOHIS to global transition judgment in OHRQoL following dental treatment

Figure 5.2 shows the distribution of change scores by global transition judgment categories.

Mean change scores showed a gradient in the expected direction across categories of the global transition judgment, and the magnitude of change was large. Most of the parents ($n = 71$) reported change scores ≥ 10 in the ‘improved a little’ category. There were only three subjects with A-ECOHIS change score from 1 to 3, and they reported ‘no change’.

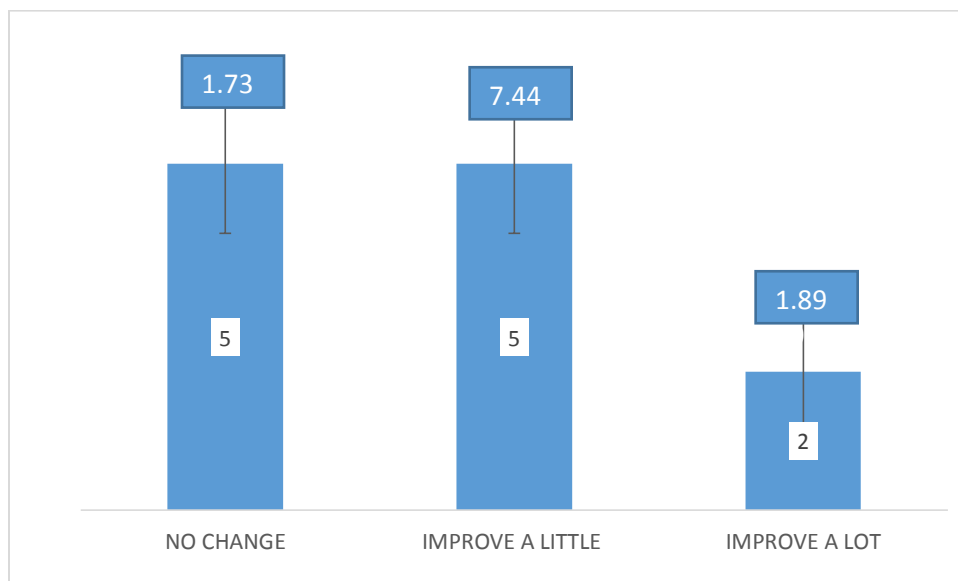


Figure 5.2 Distribution of change scores for those who remained with no change, improved a little and improved a lot ($n = 89$).

Chapter 6 Discussion

OHRQoL measures have been the target of investigation in the oral healthcare field and have proven valuable in assessing oral health needs. Most questionnaires have been drafted in English-speaking countries and adapted for use in other countries (109). The cross-cultural adaptation of an OHRQoL measure involves translation and the testing of psychometric properties, which are important steps to ensuring the quality and the validity of the instrument (80). In order to overcome this issue, researchers should adopt particular methods in the cultural adaptation of questionnaires, in particular measures of OHRQoL (26). The perceptions of QoL and the impact of health problems that differ by social, cultural and economic differences in different populations and countries. Therefore, the availability of cross-culturally valid, multi-lingual versions of OHRQoL measures is vital for both clinical and research applications of quality of life (25, 110).

With this in mind, the present study assessed the psychometric properties of the Arabic ECOHIS in Libyan culture, to determine its reliability, validity and responsiveness. The Arabic ECOHIS is a multidimensional assessment tool for measuring the negative impact of oral problems on quality of life among preschool children (0-6 years of age) that has been cross-culturally adapted to Arabic language in Saudi Arabia (25). However, this is not enough because Arabic cultures are different though

have many things in common (111). Direct translation of a questionnaire does not ensure that it is valid as the original questionnaire may include items which are misunderstood in the new population (21). In addition, simple translation of health-related questionnaires may result in misinterpretation or lack of conceptual equivalence which means the ways in which different populations conceptualize health and quality of life and the values they place on different domains of health and QoL (112) Therefore, the cross-cultural adaptation in the present study started from the step of cognitive interviewing of the Arabic ECOHIS. This step demonstrated that no modification was needed and that the questionnaire can be self-administered to the parents.

The psychometric testing showed that the Arabic ECOHIS has been proven to be valid and reliable for use by parents of 6-year-old pre-school children in Libya to assess children's oral impacts on quality of life and their family. Interestingly the 3 most common impacts reported by parents in the child impacts section were similar to those found in the earlier studies of different cultures and settings such as French and china as well as Saudi Arabia (25, 67, 72). These responses were "pain in the teeth, mouth or jaws", "difficulty in eating some foods" and "child being irritable or frustrated". This indicates that the Arabic-ECOHIS is comparable to other

ECOHIS versions to detect prevalent oral impacts among preschool children across different cultures and settings. However, in the Turkish (74) and Lithuanian (77) studies, difficulty in eating and irritability, respectively, were most commonly reported. Similar to some studies (74, 77, 109), including Saudi Arabia (25) caregivers feeling upset was the most frequently reported item in the family section in this study. However, the financial impact and taking time off work were not common. This could be explained by the fact that the study sample was recruited from the public and private schools setting and many participants were free from dental diseases. Previous studies recruited participants from clinic and hence caregivers reported a financial impact, due to other expenses incurred, such as transportation costs or missing work.

In the internal consistency reliability test analysis in study 1, almost all of the inter-item correlations of the 13 item scores were positive and coefficients ranged from 0.145 to 0.756. None of the values were above the coefficient value of 0.8 indicating that no items were deemed redundant. The corrected item-total correlations were all positive and 12 of the 13 correlations were above 0.2 indicating that most of the 13 items correlated well with the total score and the scale overall (113). Furthermore, the Cronbach's alpha value was 0.88 indicating that the scale has good internal

consistency, higher than the recommended value of 0.70 (114). Other studies on ECOHIS validation also reported high Cronbach's alpha values, with items mostly correlated with one another in a positive manner.(109). In original study of development of English ECOHIS and the study of psychometric properties of both the Farsi (73) and Turkish (74) version of ECOHIS, the item-total correlation values were higher than the recommended 0.20. Cronbach's alpha of was satisfactory (0.93, 0.92, and 0.84 for the ECOHIS, child section, and family section respectively) as it follows the standards for acceptable reliability of Cronbach's alpha (23). Cronbach's alpha was lower in the French (67), Chinese (72), and Brazilian (71) versions of ECOHIS.

Regarding convergent validity, previous studies of French, Brazilian and Turkish version of the ECOHIS scale showed a moderate correlation with the global rating of oral health. Those findings reporting that parents who thought their children had worse oral health were more likely to give their children higher ECOHIS scores(67). In the present study, construct, convergent and discriminant vitality test analyses showed that the Arabic-ECOHIS had excellent validity in the 3 tests, respectively. In the convergent validity test, the A-ECOHIS showed significant association with perceived oral health status of the children. This finding was consistent with findings

from other studies where parents who perceived their child's oral health status as poor had significantly higher ECOHIS scores (23, 67, 73, 109). This finding also supports suggestions that parents can provide valid reports on preschool children's OHRQoL when these conditions are observable (23, 115). In the construct validity test, the A-ECOHIS showed significant associations with children's levels of perceived oral health satisfaction, perceived oral health need. These findings empirically supported the construct validity of the scale.

Evidence for discriminant validity of the ECOHIS is provided by the finding of higher ECOHIS (indicating worse OHRQOL) scores on both sections among those with more than 4 decayed teeth compared with those who were caries free or had 1-3 decayed teeth. In both Brazilian and Turkish study (71) (74) , which reported that children with dental caries experience, those with more severe dental disease obtained higher ECOHIS scores than those without dental caries and those with less severe dental disease.

The responsiveness of different versions of ECOHIS has been assessed in many cultures. In most of these studies there was a substantial reduction in ECOHIS scores (the subscales and most of the domains) after dental treatment under GA, which is indicative of improvement in oral health-related quality of life (88, 116). As well most parents did perceive

that their child's condition was better following the treatment. These findings indicate that ECOHIS is sensitive to the intervention of comprehensive dental treatment for ECC under GA (103, 117). In the current study, there were significant reductions in the A-ECOHIS following dental treatment scores. These findings are indicative of improvement in the preschool children's subjective oral health after treatment. In terms of the magnitude of change, for categories of the global transition judgment from "no change" "a little improved" to "much improved" was observed for the Arabic-ECOHIS, no parents reported their child's oral condition to be "a little worse," or "worst" following dental treatment, which suggested that parents observed a noticeable improvement in their child's oral condition after treatment. This finding was similar to findings from related studies elsewhere (88, 117). Therefore, the A-ECOHIS can be used for assessing clinical intervention in both research and health care settings.

This study has a few limitations which should be highlighted. Only 5–6 year old children were included in the main psychometric analysis although the scale was developed for 1–5 year old children(23). However, the ECOHIS is completed by parents and caregivers and children's age is of little importance in this type of studies. In fact, variation in age group between this study and other similar studies was mainly due to logistic

reasons. In Libya, 1–3 year old children is difficult to reach as the majority stay at home. The use of the A-ECOHIS was based on parent's perceptions of their child's oral conditions and their impacts on the child and family. Therefore, different perceptions of their child's oral health may be the result of variation in social background of parents and may not reflect the actual impact of oral health on child. This limitation is only solved by having a child-based QOL tool. Finally, in the responsiveness sample the treatment was in traditional way, and not under general anesthesia which may hinder comparison to other previous studies in different cultures. However, even the traditional treatment of tooth decay showed changes in the perception of oral health impact.

Chapter 7 Conclusion and Recommendations

This chapter highlights the major conclusions and summarises recommendations for policy and research.

Conclusion

The Arabic ECOHIS was found to be valid and reliable to use in among Libyan children. It showed responsive to changes in the clinical status and therefore, it can be used to assess the improvement of clinical status and effectiveness of clinical intervention in dental care setting.

Psychometric testing of the measure demonstrated good construct validity, discriminant validity, as well as internal consistency. A-ECOHIS is therefore appropriate to use for assessing oral health-related quality of life in pre-school children with Libya.

Recommendations

- The Arabic version of the ECOHIS may be a useful tool for assessing oral health-related quality of life of pre-school children and for paediatric dentists.
- The Arabic version of the ECOHIS should be used as a cost-effective tool to assess oral health treatment needs in preschool children in epidemiological surveys
- Future research is needed to explore paediatric dentists understanding of the impact of oral health on pre-school children's life quality.
- Efforts should be made to develop child-based OHRQoL measures to avoid limitations of parental perception

References

1. Locker D. Measuring oral health: a conceptual framework. *Community Dental Health*. 1988;5:3-18.
2. Locker D, Allen F. What do measures of 'oral health-related quality of life' measure? *Community Dentistry and Oral Epidemiology*. 2007;35(6):401-11.
3. Slade G, Nuttall N, Sanders A, Steele J, Allen P, Lahti S. Impacts of oral disorders in the United Kingdom and Australia. *British Dental Journal*. 2005;198(8):489-93.
4. Benzian H, Williams D. The challenge of oral disease: a call for global action. *The oral health atlas 2nd ed* Geneva: FDI World Dental Federation. 2015.
5. Anderson R, Aaronson N, Wilkin D. Critical review of the international assessments of health-related quality of life. *Quality of Life Research*. 1993;2(6):369-95.
6. Kozol J. *Savage inequalities: Children in America's schools*: Crown; 2012.
7. Sheiham A, Tsakos G. Oral health needs assessments. *Community Oral Health*. 2007;2:59-79.
8. Sischo L, Broder H. Oral health-related quality of life: what, why, how, and future implications. *Journal of Dental Research*. 2011;90(11):1264-70.
9. Slade GD. *Measuring oral health and quality of life*: Department of Dental Ecology, School of Dentistry, University of North Carolina; 1997.
10. Jokovic A, Locker D, Tompson B, Guyatt G. Questionnaire for measuring oral health-related quality of life in eight-to ten-year-old children. *Pediatric Dentistry*. 2004;26(6):512-8.
11. Locker D. Applications of self-reported assessments of oral health outcomes. *Journal of Dental Education*. 1996;60(6):494.
12. Masood M, Masood Y, Saub R, Newton JT. Need of minimal important difference for oral health-related quality of life measures. *Journal of Public Health Dentistry*. 2014;74(1):13-20.
13. Gherunpong S, Tsakos G, Sheiham A. A sociodental approach to assessing dental needs of children: concept and models. *International Journal of Paediatric Dentistry*. 2006;16(2):81-8.
14. Locker D, Frosina C, Murray H, Wiebe D, Wiebe P. Identifying children with dental care needs: evaluation of a targeted school-based dental screening program. *Journal of Public Health Dentistry*. 2004;64(2):63-70.
15. McGrath C, Bedi R. Understanding the value of oral health to people in Britain--importance to life quality. *Community Dental Health*. 2002;19(4):211-4.
16. Robinson P. Choosing a measure of health related quality of life. *Community Dental Health*. 2016;33(2):107-15.
17. Waters E, Davis E, Mackinnon A, Boyd R, Graham HK, Kai Lo S, et al. Psychometric properties of the quality of life questionnaire for children with CP. *Developmental Medicine & Child Neurology*. 2007;49(1):49-55.
18. Buck D, Newton JT. Non-clinical outcome measures in dentistry: publishing trends 1988-98. *Community Dentistry and Oral Epidemiology: Commentary*. 2001;29(1):2-8.
19. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *Journal of Clinical Epidemiology*. 1993;46(12):1417-32.
20. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine*. 2000;25(24):3186-91.
21. Herdman M, Fox-Rushby J, Badia X. A model of equivalence in the cultural adaptation of HRQoL instruments: the universalist approach. *Quality of Life Research*. 1998;7(4):323-35.
22. Barbosa T, Gavião M. Oral health-related quality of life in children: Part III. Is there agreement between parents in rating their children's oral health-related quality of life? A systematic review. *International Journal of Dental Hygiene*. 2008;6(2):108-13.

23. Pahel BT, Rozier RG, Slade GD. Parental perceptions of children's oral health: the Early Childhood Oral Health Impact Scale (ECOHIS). *Health and quality of life outcomes*. 2007;5(1):6.
24. Jokovic A, Locker D, Stephens M, Kenny D, Tompson B, Guyatt G. Measuring parental perceptions of child oral health-related quality of life. *Journal of Public Health Dentistry*. 2003;63(2):67-72.
25. Farsi NJ, El-Housseiny AA, Farsi DJ, Farsi NM. Validation of the Arabic version of the early childhood oral health impact scale (ECOHIS). *BMC Oral Health*. 2017;17(1):1-11.
26. Alghadeer A, Newton T, Dunne S. Cross cultural adaptation of oral health-related quality of life measures. *Dental update*. 2010;37(10):706-8.
27. Organization WH. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. http://www.who.int/governance/eb/who_constitution_en.pdf. 1948.
28. Wade DT, Halligan PW. Do biomedical models of illness make for good healthcare systems? *BMJ: British Medical Journal*. 2004;329(7479):1398.
29. Engel GL. The Clinical Application of the Biopsychosocial Model. *Journal of Medicine and Philosophy*. 1981;6(2):101-24.
30. Huber M, Knottnerus JA, Green L, Horst Htvd, Jadad AR, Kromhout D, et al. How should we define health?. *BMJ*. 2011;343.
31. WHO W. Ottawa Charter for health promotion. *Health Promot*. 1986;1:iii-v.
32. Engel GL. The clinical application of the biopsychosocial model. *American Journal of Psychiatry*. 1980;137(5):535-44.
33. WHO. The World Health Organization quality of life assessment (WHOQOL): Position paper from the World Health Organization. *Social Science & Medicine*. 1995;41(10):1403-9.
34. Preedy VR, Watson RR. *Handbook of Disease Burdens and Quality of Life Measures*. New York, NY: Springer New York; 2010. 4325- p.
35. Glick M, Williams DM, Kleinman DV, Vujicic M, Watt RG, Weyant RJ. A new definition for oral health developed by the FDI World Dental Federation opens the door to a universal definition of oral health. *Journal of Public Health Dentistry*. 2017;77(1):3-5.
36. Arrow P, Klobas E. Evaluation of the early childhood oral health impact scale in an Australian preschool child population. *Australian Dental Journal*. 2015;60(3):375-81.
37. Jabarifar SE, Eshghi AR, Shabani M, Ahmad S. Changes in children's oral health related quality of life following dental treatment under general anesthesia. *Dental Research Journal*. 2009;6(1):13.
38. Patrick DL, Erickson P. *Health status and health policy: quality of life in health care evaluation and resource allocation*. New York: Oxford University Press, 1993. 478 p.
39. Gift HC, Atchison KA. Oral health, health, and health-related quality of life. *Medical care*. 1995;NS57-NS77.
40. Cohen LK, Jago JD. Toward the formulation of sociodental indicators. *International Journal of Health Services*. 1976;6(4):681-98.
41. Locker D. Issues in measuring change in self-perceived oral health status. *Community Dentistry and Oral Epidemiology*. 1998;26(1):41-7.
42. Sischo L, Broder HL. Oral Health-related Quality of Life: What, Why, How, and Future Implications. *Journal of Dental Research*. 2011;90(11):1264-70.
43. Genderson M, Sischo L, Markowitz K, Fine D, Broder H. An overview of children's oral health-related quality of life assessment: from scale development to measuring outcomes. *Caries Research*. 2013;47(Suppl. 1):13-21.

44. McGrath C, Broder H, Wilson-Genderson M. Assessing the impact of oral health on the life quality of children: implications for research and practice. *Community Dentistry and Oral Epidemiology*. 2004;32(2):81-5.
45. Slade GD, Spencer AJ. Development and evaluation of the oral health impact profile. *Community Dental Health*. 1994;11(1):3-11.
46. Weintraub JA. Uses of oral health related quality of life measures in Public Health. *Community Dental Health*. 1998;15(1):8-12.
47. Okunseri C, Chattopadhyay A, Lugo RI, McGrath C. Pilot survey of oral health-related quality of life: a cross-sectional study of adults in Benin City, Edo State, Nigeria. *BMC Oral Health*. 2005;5(1):7.
48. Slade GD, Strauss RP, Atchison KA, Kressin NR, Locker D, Reisine ST. Conference summary: assessing oral health outcomes--measuring health status and quality of life. *Community Dental Health*. 1998;15(1):3-7.
49. Cushing A, Sheiham A, Maizels J. Developing socio-dental indicators--the social impact of dental disease. *Community Dental Health*. 1986;3(1):3-17.
50. Atchison KA, Dolan TA. Development of the geriatric oral health assessment index. *Journal of Dental Education*. 1990;54(11):680-7.
51. Strauss RP, Hunt RJ. Understanding the value of teeth to older adults: influences on the quality of life. *The Journal of the American Dental Association*. 1993;124(1):105-10.
52. Locker D. Subjective oral health status indicators. *Measuring Oral Health and Quality of Life*. 1997:105-12.
53. Leao A, Sheiham A. The development of a socio-dental measure of dental impacts on daily living. *Community Dental Health*. 1996;13(1):22-6.
54. Cornell JE, Saunders MJ, Paunovich ED, Frisch MB. Oral health quality of life inventory (OH-QoL). *Measuring Oral Health and Quality of Life*. 1997:136-49.
55. Adulyanon S, Sheiham A. Oral impacts on daily performances. *Measuring Oral Health and Quality of Life*. 1997;151:160.
56. McGrath C, Bedi R. An evaluation of a new measure of oral health related quality of life-OHQoL-UK (W)©. *Community Dental Health*. 2001;18(3):138-43.
57. Montero J, Bravo M, López-Valverde A. Development of a specific indicator of the well-being of wearers of removable dentures. *Community Dentistry and Oral Epidemiology*. 2011;39(6):515-24.
58. Yusuf H, Gherunpong S, Sheiham A, Tsakos G. Validation of an English version of the Child-OIDP index, an oral health-related quality of life measure for children. *Health and Quality of Life Outcomes*. 2006;4(1):1-7.
59. Easton JA, Landgraf JM, Casamassimo PS, Wilson S, Ganzberg S. Evaluation of a generic quality of life instrument for early childhood caries-related pain. *Community Dentistry and Oral Epidemiology*. 2008;36(5):434-40.
60. Gherunpong S, Tsakos G, Sheiham A. The prevalence and severity of oral impacts on daily performances in Thai primary school children. *Health and Quality of Life Outcomes*. 2004;2(1):57.
61. Broder HL, McGrath C, Cisneros GJ. Questionnaire development: face validity and item impact testing of the Child Oral Health Impact Profile. *Community Dentistry and Oral Epidemiology*. 2007;35:8-19.
62. Richards Jr JM, Hemstreet MP. Measures of life quality, role performance, and functional status in asthma research. *American Journal of Respiratory and Critical Care Medicine*. 2012.
63. Jokovic A, Locker D, Stephens M, Kenny D, Tompson B, Guyatt G. Validity and reliability of a questionnaire for measuring child oral-health-related quality of life. *Journal of Dental Research*. 2002;81(7):459-63.

64. Tsakos G, Blair YI, Yusuf H, Wright W, Watt RG, Macpherson LM. Developing a new self-reported scale of oral health outcomes for 5-year-old children (SOHO-5). *Health and Quality of Life Outcomes*. 2012;10(1):1.
65. Cummins J. *Language, power, and pedagogy: Bilingual children in the crossfire*. Multilingual Matters; 2000.
66. Lawrence HP, Thomson WM, Broadbent JM, Poulton R. Oral health-related quality of life in a birth cohort of 32-year olds. *Community Dentistry and Oral Epidemiology*. 2008;36(4):305-16.
67. Li S, Veronneau J, Allison PJ. Validation of a French language version of the early childhood oral health impact scale (ECOHIS). *Health and Quality of Life Outcomes*. 2008;6(1):9.
68. Rebok G, Riley A, Forrest C, Starfield B, Green B, Robertson J, et al. Elementary school-aged children's reports of their health: a cognitive interviewing study. *Quality of Life Research*. 2001;10(1):59-70.
69. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Annals of Internal Medicine*. 1993;118(8):622-9.
70. Juniper EF. How to develop and validate a new health-related quality of life instrument. *Quality of Life and Pharmacoeconomics in Clinical Trials*. 1996:49-56.
71. Tesch FC, Oliveira BHd, Leão A. Semantic equivalence of the Brazilian version of the early childhood oral health impact scale. *Cadernos de Saude Publica*. 2008;24(8):1897-909.
72. Lee GH, Mcgrath C, Yiu CK, King NM. Translation and validation of a Chinese language version of the Early Childhood Oral Health Impact Scale (ECOHIS). *International Journal of Paediatric Dentistry*. 2009;19(6):399-405.
73. Jabarifar S-E, Golkari A, Ijadi MH, Jafarzadeh M, Khadem P. Validation of a Farsi version of the early childhood oral health impact scale (F-ECOHIS). *BMC Oral Health*. 2010;10(1):4.
74. Peker K, Uysal Ö, Bermek G. Cross-cultural adaptation and preliminary validation of the Turkish version of the Early Childhood Oral Health Impact Scale among 5-6-year-old children. *Health and Quality of Life Outcomes*. 2011;9(1):118.
75. Bordoni N, Ciaravino O, Zambrano O, Villena R, Beltran-Aguilar E, Squassi A. Early childhood oral health impact scale (ECOHIS): Translation and validation in spanish language. *Acta Odontológica Latinoamericana*. 2012;25(3):270-8.
76. Masumo R, Bardsen A, Mashoto K, Åström AN. Child-and family impacts of infants' oral conditions in Tanzania and Uganda—a cross sectional study. *BMC Research Notes*. 2012;5(1):538.
77. Jankauskienė B, Narbutaitė J, Kubilius R, Gleiznys A. Adaptation and validation of the early childhood oral health impact scale in Lithuania. *Stomatologija*. 2012;14(4):108-13.
78. Hashim AN, Yusof ZY, Esa R. The Malay version of the early childhood oral health impact scale (Malay-ECOHIS)—assessing validity and reliability. *Health and Quality of Life Outcomes*. 2015;13(1):190.
79. Bhat SG, Sivaram R. Psychometric properties of the Malayalam version of ECOHIS. *Journal of Indian Society of Pedodontics and Preventive Dentistry*. 2015;33(3):234.
80. Zaror C, Atala-Acevedo C, Espinoza-Espinoza G, Muñoz-Millán P, Muñoz S, Martínez-Zapata MJ, et al. Cross-cultural adaptation and psychometric evaluation of the early childhood oral health impact scale (ECOHIS) in chilean population. *Health and Quality of Life Outcomes*. 2018;16(1):1-11.
81. Nzomiwu C, Sote E, Oredugba F. Translation and validation of the nigerian pidgin english version of the early childhood oral health impact scale (NAIJA ECOHIS). *West Africa Journal of Medicin*. 2018;35(2):102-8.
82. Bekes K, Omara M, Safar S, Stamm T. The German version of early childhood oral health impact scale (ECOHIS-G): translation, reliability, and validity. *Clinical Oral Investigations*. 2019;23(12):4449-54.


83. Bourzgui F, Saif S, Serhier Z, Diouny S, Othmani MB. Adaptation and Validation of The Moroccan Arabic Version of the Early Childhood Oral Health Impact Scale (ECOHIS). *International Journal of Dental Research*. 2017;2(3):76-9.
84. Kumar S, Kroon J, Laloo R. A systematic review of the impact of parental socio-economic status and home environment characteristics on children's oral health related quality of life. *Health and Quality of Life Outcomes*. 2014;12(1):1-15.
85. Nora AD, da Silva Rodrigues C, de Oliveira Rocha R, Soares FZM, Minatel Braga M, Lenzi TL. Is caries associated with negative impact on oral health-related quality of life of pre-school children? A systematic review and meta-analysis. *Pediatric Dentistry*. 2018;40(7):403-11.
86. Al Qabbani H. Comparison of the Arabic Versions of the Early Childhood Oral Health Impact Scale (ECOHIS) and the Scale of Oral Health Outcomes-5 (SOHO-5) in Assessment of Oral Health Related Quality of Life. *Journal Of Applied Dental and Medical Sciences*. 2018;4:4.
87. Sperber AD. Translation and validation of study instruments for cross-cultural research. *Gastroenterology*. 2004;126:S124-S8.
88. Abanto J, Albites U, Bönecker M, Martins-Paiva S, Castillo JL, Aguilar-Gálvez D. Cross-cultural adaptation and psychometric properties of the Child Perceptions Questionnaire 11-14 (CPQ11-14) for the Peruvian Spanish language. *Medicina Oral, Patología Oral Y Cirugía Bucal*. 2013;18(6):E832.
89. Bravo-Cavicchioli D, Jiménez Del Río P. Adaptation and validation of the Spanish version of Child Perception Questionnaire CPQ-Spn11-14 in a Chilean community population. *Revista Española de Salud Pública*. 2015;89(6):585-95.
90. Maneesriwongul W, Dixon JK. Instrument translation process: a methods review. *Journal of Advanced Nursing*. 2004;48(2):175-86.
91. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *Journal of Clinical Epidemiology*. 2007;60(1):34-42.
92. Haywood KL, Garratt AM, Fitzpatrick R. Quality of life in older people: a structured review of generic self-assessed health instruments. *Quality of Life Research*. 2005;14(7):1651-68.
93. Haywood K, Garratt A, Dawes P. Patient-assessed health in ankylosing spondylitis: a structured review. *Rheumatology*. 2005;44(5):577-86.
94. Bombardier C, Tugwell P. Methodological considerations in functional assessment. *The Journal of Rheumatology Supplement*. 1987;14:6-10.
95. Andresen EM. Criteria for assessing the tools of disability outcomes research. *Archives of Physical Medicine and Rehabilitation*. 2000;81:S15-S20.
96. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *Journal of Clinical Epidemiology*. 2010;63(7):737-45.
97. Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, et al. The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. *BMC Medical Research Methodology*. 2010;10(1):1-8.
98. Mbada CE, Oguntoyinbo OE, Fasuyi FO, Idowu OA, Odole AC, Ayanniyi O, et al. Cross-cultural adaptation and psychometric evaluation of the Yoruba version of Oswestry disability index. *PloS One*. 2020;15(1):e0221138.
99. Hassen HM, Behera MR, Jena PK, Satpathy SKK. Validity and Reliability of the Amharic Version of the HLS-EU-Q47 Survey Questionnaire among Urban School Adolescents and University students in Dire Dawa, Ethiopia. 2020.
100. Nair S, Kakodkar P, Shetiya SH, Rajpurohit L, Kale S. Impact of different levels of caries experience on the quality of life of preschool children and their families in Pimpri, Pune: A cross-sectional study. *Journal of Indian Association of Public Health Dentistry*. 2018;16(3):193.

101. Ballo L, Arheiam A, Marhazlinda J. Determinants of caries experience and the impact on the OHRQOL of 6-year-old Libyan children: a cross-sectional survey. *BMC Oral Health*. 2021;21(1):1-9.
102. Calvert M, Kyte D, Mercieca-Bebber R, Slade A, Chan A-W, King MT, et al. Guidelines for inclusion of patient-reported outcomes in clinical trial protocols: the SPIRIT-PRO extension. *Jama*. 2018;319(5):483-94.
103. Farsi DJ, Farsi NJ, El-Housseiny AA, Damanhoury WH, Farsi NM. Responsiveness of the Arabic version of the ECOHIS to dental rehabilitation under general anaesthesia. *International Journal of Paediatric Dentistry*. 2018;28(1):52-61.
104. Charter RA. Sample size requirements for precise estimates of reliability, generalizability, and validity coefficients. *Journal of Clinical and Experimental Neuropsychology*. 1999;21(4):559-66.
105. Locker D, Jokovic A, Clarke M. Assessing the responsiveness of measures of oral health-related quality of life. *Community Dentistry and Oral Epidemiology*. 2004;32(1):10-8.
106. Liang MH. Longitudinal construct validity: establishment of clinical meaning in patient evaluative instruments. *Medical Care*. 2000;38(9):II-84-II-90.
107. Locker D, Slade G. Oral health and the quality of life among older adults: the oral health impact profile. *Journal (Canadian Dental Association)*. 1993;59(10):830-3, 7.
108. Broder HL, Wilson-Genderson M, Sischo L. Reliability and validity testing for the child oral health impact profile-reduced (COHIP-SF 19). *Journal of Public Health Dentistry*. 2012;72(4):302-12.
109. Scarpelli AC, Paiva SM, Pordeus IA, Varni JW, Viegas CM, Allison PJ. The Pediatric Quality of Life Inventory™(PedsQL™) family impact module: reliability and validity of the Brazilian version. *Health and Quality of Life Outcomes*. 2008;6(1):1-8.
110. Allison P. Health-related quality of life comparisons in French and English-speaking populations. *Community Dental Health*. 2001;18(4):214-8.
111. Haller M. Europe and the Arab-Islamic World. A Sociological Perspective on the Socio-cultural Differences and Mutual (Mis) Perceptions between Two Neighbouring Cultural Areas 1. *Innovation: The European Journal of Social Science Research*. 2003;16(3):227-52.
112. Herdman M, Fox-Rushby J, Badia X. A model of equivalence in the cultural adaptation of HRQoL instruments: the universalist approach. *Quality of Life Research*. 1998;7(4):323-35.
113. Field A. *Discovering statistics using SPSS*: Sage Publications; 2009.
114. Kline P. *Handbook of psychological testing*: Routledge; 2013.
115. Filstrup SL, Briskie D, da Fonseca M, Lawrence L, Wandera A, Inglehart MR. Early childhood caries and quality of life: child and parent perspectives. *Pediatric Dentistry*. 2003;25(5):431-40.
116. Almaz ME, Sönmez IŞ, Oba AA, Alp S. Assessing changes in oral health-related quality of life following dental rehabilitation under general anesthesia. *Journal of Clinical Pediatric Dentistry*. 2014;38(3):263-8.
117. Lee GH, McGrath C, Yiu CK, King NM. Sensitivity and responsiveness of the Chinese ECOHIS to dental treatment under general anaesthesia. *Community Dentistry and Oral Epidemiology*. 2011;39(4):372-7.

Appendices

Appendix 1

Annex 4 WHO oral health assessment form for children (by tooth surface), 2013.



World Health Organization
Oral Health Assessment Form for Children, 2013

Annex 4

Leave blank (1)	Year (4)	Month (5)	Day (10)	Identification No. (11)	Orig/Dupl (14)	Examiner (15)	(16)	(17)
General information:								
Sex 1=M, 2=F				Date of birth			Age in years	
(Name)				(18)	(19)	(24)	(25)	(26)
Ethnic group (27)		(28)	Other group (29)		(30)	Years in school (31)		(32)
Occupation		(33)						
Community (geographical location)				(34)	(35)	Location Urban (1) Periurban (2) Rural (3)		
Other data				(37)	(38)	Other data		
Other data				(41)	(42)	Extra-oral examination		
				(43)	(44)			

Dentition status by tooth surface														
	17	16	55	54	53	52	51	61	62	63	64	65		
Occ													(45-52)	
Mes													(53-66)	
Buc													(67-80)	
Dis													(81-94)	
Oral													(95-108)	
	47	46	85	84	83	82	81	71	72	73	74	75		
Occ													(109-116)	
Mes													(117-130)	
Buc													(131-144)	
Dis													(145-158)	
Oral													(159-172)	

Primary teeth	Permanent teeth
Status	
A	0 = Sound
B	1 = Caries
C	2 = Filled w/caries
D	3 = Filled, no caries
E	4 = Missing due to caries
F	5 = Missing for another reason
G	6 = Fissure sealant
—	7 = Fix dental prosthesis/crown, abutment, veneer
—	8 = Unerupted
—	9 = Not recorded

Appendix 2

Questionnaire of demographic characteristic and feeding and oral health behaviour.

أحد الوالدين (مطلق)-أحد الوالدين (متوفي)-الوالدين معازوج الام او زوجة الأب -كلا الوالدين متوفي	الحالة الاجتماعية للوالدين		اسم الطفل
الوالدين -الأجداد - الوالدين والأجداد معا - الأقارب - دار الرعاية	الطفل يسكن مع:	ذكر - انثى	الجنس
شقة - منزل - فيلا	نوع السكن		رقم الوطني
أساسي - متوسط - عالي	المستوى التعليمي للام		رقم تليفون ولي الأمر
أقل من 500-من 500 إلى 1500 - أكثر من 1500	متوسط الدخل الشهري		وظيفة الأم
أساسي - متوسط - عالي	المستوى التعليمي للاب		سنة الميلاد
أقل من 500-من 500 إلى 1500 - أكثر من 1500	متوسط الدخل الشهري للاب		وظيفة الاب
	ترتيب الطفل بين اخوته		عدد الأبناء

رضاعة طبيعية - رضاعة صناعية - الأثنين معا	رضاعة الطفل
دائما - أحيانا - أبدا	هل كان الطفل ينام اثناء الرضاعة
	عمر بداية الرضاعة الطبيعية
	عمر بداية الرضاعة الصناعية
	عمر فطام الطفل من الرضاعة نهائيا
نعم _ لا	هل كانت من عادة الأم النفخ في طعام الطفل الساخن قبل أكله
نعم _ لا إذا كانت الإجابة نعم هل كانت تغمس في عسل او مادة تحلية قبل إعطائها له؟	هل أخذ الطفل اللهاية (المصاص المهدنة)
نعم _ لا	

- في اي عمر بدأ الطفل تنظيف الأسنان: سنة واحدة - 2 سنة - 3 سنة - 4 سنة - 5 سنة - أبدا
- عدد مرات تنظيف الأسنان في اليوم : مرتان في اليوم - مرة واحدة - أحيانا او أبدا
- هل تساعد الطفل في تنظيف أسنانه : نعم - لا
- نوع فرشاة أسنان الطفل : كهربائية - يدوية
- هل ذهبت بالطفل لزيارة طبيب الأسنان من قبل: نعم - لا
- اذا كانت الاجابة نعم . ما سبب الزيارة : كشف دوري - عندما شعر الطفل بالألم - أبدا - السنة الفائتة - قبل السنة الفائتة
- هل تم إعطاؤك نصائح على صحة فم وأسنان الطفل : نعم - لا
- هل يحتوي فم أم الطفل على تسوس أو قامت بحشو أو خلع إحدى أسنانها : أكثر من سن - سن واحدة - لا يوجد
- هل يعاني أحد اخوة الطفل من تسوس الأسنان: نعم - لا
- نوع مياه الشرب : ماء الحنفية (الشيشمة) - ماء التحلية - ماء البئر

Appendix 3

Arabic version of Early Childhood Oral Health Impact Scale (A-ECOHIS).


إن مشكلات الفم والأسنان وعلاجها قد تؤثر على جودة الحياة اليومية للطفل وأسرته.

الرجاء اختيار الرقم الذي يعبر عن تجربة الطفل أو تجربتك، مع الأخذ في الاعتبار حياة الطفل كاملة منذ ولادته حتى الآن أثناء الإجابة على كل سؤال . إذا كان السؤال لا ينطبق عليك فاختار "إطلاقاً"

لا اعلم	كثيرا جدا	كثيرا	احيانا	نادرا	اطلاقاً	
5	4	3	2	1	0	
						1 ما مدى تكرار حدوث ألم بأسنان أو فم أو فكي طفلك؟
						ما مدى تكرار حدوث التالي لطفلك نتيجة مشكلات الفم والأسنان؟
						2 صعوبة في شرب المشروبات الباردة أو الساخنة
						3 صعوبة في تناول بعض الأطعمة
						4 صعوبة في نطق أي كلمات
						5 تغيب عن الحضانة أو الروضة أو المدرسة
						6 مشاكل في النوم
						7 أصبح محبطاً أو سريع الانفعال
						8 تجنب الابتسام أو الضحك في وجود أطفال آخرين
						9 تجنب التحدث مع أطفال آخرين
						ما مدى تكرار حدوث التالي لك أو لأحد أفراد العائلة كنتيجة لمشكلات فم وأسنان طفلك؟
						10 الشعور بالانزعاج
						11 الشعور بالذنب
						12 أخذ إجازة أو إذن من العمل
						13 تأثير مادي على العائلة

Appendix 4

Permission to carry out and analyse the survey's data.

University of Benghazi Faculty of Dentistry www.dent.uob.edu.ly		جامعة بنغازي كلية طب وجراحة الفم والأسنان
Index: <u>NC.12-18</u> الرقم الإشاري :	Date: <u>28/5/2018</u> الموافق :	التاريخ :
DECLARATION		
To whom it may concern,		
<p>We the Faculty of Dentistry, Benghazi University, inform that DR.LAMIS ABDELRAHIM BALLO is the main author for the project (Benghazi Children Oral Health Survey, 2017), and she absolutely has the right over all the data of survey.</p> <p>Accordingly she is permitted freely to use it for any purpose such as; for postgraduate studies or publications.</p>		
 Dr. Ala Darrat BDS, MS. Dean  Faculty of Dentistry University of Benghazi Faculty of Dentistry Dean		
☎: +(218-61) 909 3771 ☎: +(218-61) 9096045/ 9096046 P.O.Box: 9504 Abdul Monem Riad		

مقياس تأثير صحة الفم على الطفولة المبكرة: تكيف عبر الثقافات و الخصائص

السيكومترية في بنغازي , ليبيا.

قدمت من قبل:

لميس عبد الرحيم فتح الله باللو

تحت اشراف:

د.ارحيم احميدة العوامي

الملخص

أهداف البحث

الهدف الأساسي للدراسة هو تقييم الخصائص السيكومترية وتقييم استجابة النسخة العربية من مقياس تأثير صحة الفم في مرحلة الطفولة المبكرة في بنغازي ، ليبيا.

طرق البحث

تكون طرق هذه الدراسة من جزأين ، الجزء الأول لتقييم الخصائص السيكومترية ل مقياس تأثير صحة الفم في مرحلة الطفولة المبكرة النسخة العربية من خلال تحليل البيانات الثانوية لـ 681 طفل ليبي تبلغ أعمارهم 6 سنوات. تم جمع البيانات المستخدمة في هذه الدراسة كجزء من مسح صحة الفم الذي تم إجراؤه في عام 2017 - 2018 في بنغازي ، واستخدم المسح الذي تم إجراؤه لجمع البيانات الأولية تصميمًا مقطعيًا ومعايير تشخيصية

لمنظمة الصحة العالمية لتقييم حالة صحة الفم واحتياجات العلاج من الأطفال الليبيين.
الجزء الثاني لتقييم استجابة مقياس تأثير صحة الفم في مرحلة الطفولة المبكرة باللغة العربية للأطفال الليبيين الذين تتراوح أعمارهم بين 5 و 6 سنوات. نفذت الدراسة تصميم قبل وبعد التدخل. يتألف المشاركون من عينة ملائمة .

تم تحليل جميع البيانات باستخدام برنامج SPSS .

نتائج البحث

شاركت مجموعه 681 من الأمهات في هذه الدراسة. كانت غالبية الأمهات ربات بيوت (57%) ، وحصلن على التعليم العالي (44.9%) ويكسبن دخلاً منخفضاً (59.3%) (أقل من 500 دينار ليبي). في قسم تأثير الطفل ، كان "ألم الأسنان أو الفم أو الفكين" هو العنصر الأكثر شيوعاً الذي تم الإبلاغ عنه من قبل الوالدين (63.9%). في قسم التأثير على الأسرة ، كانت العناصر الأكثر شيوعاً "منزعج" (29.7%) و "الشعور بالذنب" (20.4%). كان معامل كرونباخ ألفا 0.88. تضمنت العينة المستجيبة 89 مشاركاً. يوضح الشكل 5.1 متوسط درجات في العينة بأكملها للمقياس الكامل قبل العلاج وبعده. تم الإبلاغ عن درجات أعلى (7.38 ± 10.16) قبل تلقي العلاج مقارنة بمتوسط الدرجات بعد تلقي العلاج (4 ± 5.32).

استنتاجات البحث

أظهرت هذه الدراسة أن مقياس تأثير صحة الفم في مرحلة الطفولة المبكرة باللغة العربية هو أداة صحيحة وموثوقة لتقييم الآثار السلبية لاضطرابات / حالات الفم على نوعية حياة الأطفال في سن ما قبل المدرسة من سن 5 إلى 6 سنوات وأسرهم في ليبيا. كذلك ، أظهرت نتائج الدراسة المطولة أن مقياس تأثير صحة الفم في مرحلة الطفولة المبكرة باللغة العربية حساس ومستجيب لعلاج تسوس الأسنان في السن المبكر.



مقياس تأثير صحة الفم على الطفولة المبكرة: تكييف عبر الثقافات و الخصائص السيكومترية في بنغازي, ليبيا

قدمت من قبل:

لميس عبد الرحيم فتح الله باللو

تحت اشراف:

د. ارحيم احميدة العوامي

قدمت هذه الرسالة استكمالاً لمتطلبات الحصول على درجة الماجستير في

طب الفم الوقائي

جامعة بنغازي

فبراير 2022