

Everyone's Smart University College of Management
Master of risk management in cooperation with Jaguar University

Impact of COVID19 on Health-Related Quality of Life Using the EQ-5D-5L in Saudi Arabia

تأثير فيروس كورونا على جودة الحياة في السعودية

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Date Of Receipt: 11/04/2022	Protocol Number:
1. Title Of Proposal: Impact of COVID19 on Health-Related Quality of Life Using the EQ-5D-5L in Saudi Arabia	
2. Project Description	
(2.A) Source of Data : ○ Chart Review ○ Questionnaire ○ Observational ○ Clinical Exam Lab Exam Others	
(2.B) Type of Project : ○ Qualitative Research ○ Quantitative Research ○ Others	
(2.C) Study Design : ○ Observational ○ Case-Report ○ Case-Series Cross-Sectional ○ Case-Control ○ Retrospective Cohort ○ Prospective Cohort ○ Experimental (e.g. Clinical Trial) ○ Quasi Experimental Others	
3.Starting Date: 7 November 2022	
4.Duration: 2 Months	

4. Introduction

4.1. Background

Coronavirus disease 2019 (COVID-19) is an infectious acute respiratory disease caused by a novel coronavirus, affecting all ages and gender.¹ COVID-19) was first reported in 2019, and has since spread throughout the world causing more than 628,035,553 confirmed cases, including 6,572,800 deaths globally, as of November 2, 2022.^{1,2} Kingdom of Saudi Arabia confirmed the first positive COVID-19 case on March 2, 2020 [2]. As of November 2, 2022, Saudi Arabia have been 822,718 confirmed cases of COVID-19 with 9,409 deaths.³ General Authority for Statistics has been reported the Saudi Arabia's economy decreased by 7% in the second quarter following coronavirus pandemic. The non-government sector and the government sector recorded a negative growth rate of 10.1% and 3.5%, respectively.⁴

Quality of live indicators (QoL) are strong predictors of a patient's general ability to preserve long-term well-being and productivity. Quality of live defines as a multidimensional concept that refers to an "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, and standards" and is affected by a person's physical health and psychological state.⁷⁻¹³

Health related quality of life (HRQOL) is a generic measure, which combines both the quality (health status) and quantity (life years) of health. Health-related quality of life (HRQOL) refers to the impact of illness and management of diseases on patients' overall life satisfaction.⁷⁻¹³

health-related quality of life (HRQoL) is important for measuring the burden of diseases and assisting physicians and policy makers to improve patient care and policy decisions.

There are many instruments have been implemented to measure the HRQoL such as time trade-off, standard gamble, or rating scales, Health Utility Index (HUI), EuroQol 5-Dimension, 5-Level questionnaire (EQ-5D-5L), EuroQol 5-Dimension, 3-Level questionnaire (EQ-5D-3L) , and the Short Form 6D (SF-6D)^{8,9}

The EuroQol 5-Dimension, 5-Level questionnaire (EQ-5D-5L) is a generic and preference-based tool to assess HRQOL based on the patient's perspective of their health. It evaluates the HRQOL status by five dimensions with five levels each and a visual analogue scale. Based on the population under study and value sets, an index value (utility value) is valuated using standard valuation technology.⁷

The EQ-5D is a valid and reliable measure in many disease areas and is the most commonly used tool for assessing cost-utility analyses in order to appraise healthcare interventions.^{10–16} Utility scores are used to quantify the severity of a patient's condition and the burden of disease state, allowing

for comparisons across a wide range of disease states, individuals, and different management. Utility scores range from 0 to 1 on a scale with high utility (1) indicating a full health outcome, low utility demonstrating a worse health outcome, and zero representing death.

Therefore, it is necessary to know the level of HRQoL of COVID 19 patients and identify factors that result in decreased or impaired HRQoL as this will help policy makers to prioritize funding and implement interventions to improve QoL.

4.2. Literature Review

The majority of research into Covid-19 has focused on epidemiology education, control and prevention disease, Economy, prevalence, transmission, treatment, epidemiology, mortality and morbidity associated with the virus. However, less consideration has been given to its impact on health-related quality of life (HRQoL) of patients with Covid-19.^{4,5}

Literature reviewed was conducted of studies around the world looking at population-based QoL surveys involving adults. The literature reviewed included studies which used the EuroQol 5-Dimension, 5-Level questionnaire (EQ-5D-5L) tools to assess the quality of life in different populations of different countries and different follow-up periods.

PubMed, and Google Scholar were systematically searched for related published articles, and the key words were used: "COVID 19" AND "Quality of

life" OR " health related quality of life" AND " "COVID 19" OR "COVID 19" AND " EQ-5D-5L".

November 3, 2022, In total, 5,856 studies were identified through the search strategy, and 12 studies were selected to assess the quality of life and persistent symptoms in post- recovery COVID-19 patients.

All reviewed studies were observational, and conducted in united kingdom (Haplin et al.,2021), Spain Spain (Taboada M, et al.,2021) , France (Valent et al.,2020), China (Huang C,2021), China (Ping W,et al, 2020), Spain (Moreno-Pérez et al., 2021), USA (Lubetkin El, et al,2021), India (Barani S, etal, 2021), Vietnam (Vu MQ, 2020), Morocco (Azizi A., et al, 2022) , Iran (Arab-Zozani M,2020). Belgian (Meys, R., et al, 2020).¹¹⁻²²

The aimed of these studies was to assess the QoL among patients with COVID 19. The mean EQ-5D-5L index values ranging from 0.61 to 0.949.

The studies found: the highest EQ-5D-5L index mean value was reported in the China (0. 0.949) , followed by Morocco (0.86) , UK (0.714), Norway (0.690) , Belgium (0.620) and lowest in Iran (0.612). The studies showed that the main demographic and clinical factors that significantly increase the risk of pain/ discomfort and anxiety/ depression in general population were older age, urban area, gender, lower income, epidemic effects , tobacco use, worried about get COVID-19, presence of chronic diseases especially type 1 diabetes, kidney disease and cardiovascular disease. The quality-of-life infected patients who required intensive care unit (ICU) admission have been

shown to have a significantly lower quality of life compared with patients in general ward admission.⁷⁻²²

The main limitation is the most common of the studies had followed up COVID-19 patients who were hospitalized or elderly populations. Hence, more studies on quality-of-life need to be conducted in both younger and outpatient settings.^{5,6}

4.3. Research problem

Despite the fact that Coronavirus disease 2019 (COVID-19) is a highly infectious disease and public health hazard in the world with clinical and economic impact.¹⁻⁴ Currently, there are limited information available regarding how COVID-19 affect the quality of life (QoL) of outpatients throughout the world. The most of studies focused on QoL of patients who were hospitalized and elderly.^{5,6}

In Saudi Arabia, no Data is available on the impact of COVID-19 on health-related QoL in Saudis patients.

4.4. The importance of the research

1. This is first study will be conducted in Saudi Arabi to describe HRQoL of Saudis patients who will be infected by the Coronavirus disease 2019 (COVID-19) using EuroQoL 5-Dimension, 5-Level questionnaire (EQ-5D-5L) tools and visual analogue scale (EQ-VAS).

2. This is first study will be conducted in the world to describe HRQoL of outpatients with COVID19 using (EQ-5D-5L) tools and scale (EQ-VAS) scale during illness and after recovery.
3. This is first study will be conducted in the world to investigate the relationship between HRQoL of outpatients with COVID19 and using herbal medicine, blood group, history of vaccination (Influenzas vaccine, BCG vaccine, and other), special food (honey and others), and obesity
4. This study will provide more evidence for health decision-makers to set up adequate protocols for the management of possible future pandemics.

Health-related quality of life (HRQoL) is one of the most important outcome measures for patients, so that this study is necessary to know the level of HRQoL of patients with COVID 19 and identify factors that result in decreased / impaired / improved HRQoL.

4.5. Objective

The objective of this study will evaluate the impact of COVID 19 and related socio-demographics, blood group, history of vaccine , socioeconomic, clinical factors, demographic, life style, herbal medicine, social life, health-related behaviors, chronic diseases, special food, obesity on the HRQoL

using the EQ-5D-5L instrument in Saudis patients during and after recovery from COVID 19.

4.6. Research Hypotheses

The research question is “the effects of COVID-19 on Saudis HRQoL varied according to demographic factors, blood group, history of vaccine , socioeconomic, clinical factors, life style, herbal medicine, social life, health-related behaviors, chronic diseases, special food, and obesity”.

Based on the previously reviewed literature, the following hypotheses will proposed for this study:

1. Null Hypotheses (H0): There is no relationship between HRQoL of COVID 19 Saudis patients and demographic factors, blood group, history of vaccine , socioeconomic, clinical factors, life style, herbal medicine, social life, health-related behaviors, chronic diseases, special food, obesity.
2. Alternative hypothesis (H1): The HRQoL of Saudis patients with COVID 19 will negatively correlate with demographic factors, blood group, history of vaccine , socioeconomic, clinical factors, life style, herbal medicine, social life, health-related behaviors, chronic diseases, special food, and obesity.

5. Materials and Methods

5.1. Study Area/Setting

The study will be conducted in King Abdulaziz medical city (KAMC) - Riyadh
KAMC is a 1505- bed university affiliated major tertiary care center in Riyadh, Saudi Arabia.

5.2. Study Design:

A cross-sectional questionnaire-based study will be perform from November 8 November, 2022 for two months among a general population sample from KAMC

5.3. Study Subjects:

The participants will aged 18 to 59 years and who will be infected by the coronavirus confirmed with an quantitative real time polymerase chain reaction ($qPCR$) within 30 days.
Participants younger than 18 or older than 59 years will be excluded, also who will be admitted to hospital will be excluded.

5.4. Sample Size:

Consecutive non-probability Sample size is a statistical concept that involves determining the number of patients.

The study will be conducted in kamc with an approximate population of 5,000,000, a representative sample of the adult population will be 384 patients or more at 95% confidence level and margin error within $\pm 5\%$

5.5. Sampling Technique:

Sampling Technique: We will use consecutive sampling technique.

5.6. Data Collection methods:

The patients with COVID 19 will be enrolled in to study, then the questionnaires will be demonstrated for the patients in Arabic language and the statement of confidentiality issues will explained on the cover page.

The questionnaire composed of three parts:

Part I:

1. Socio - demographic characteristics: age, gender, medical history, current use of herbal, education status, marital status, employment status and individual monthly income.
2. Clinical characteristics: symptoms, duration of disease,
3. Past medical history: chronic diseases, vaccination, smoking status

Part II Health state description:

health state description and evaluation: consists of five health status questions, relating to mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Respondents will be asked to choose one of the

statements which describe their perceived current health status using five levels of severity with 5 possible answers for each item, corresponding to 1:“no problems”, 2:“ having some or moderate problems” or 3:“being unable to do/having extreme problems”.

Part III: visual analogue scale (EQ-VAS).

The second part is the evaluation part, the respondents evaluate their overall health status using the visual analogue scale (EQ-VAS), the EQVAS, which records patients’ overall assessment of their health on a scale from 100 (best imaginable health) to 0 (worse imaginable health) The EQ-VAS.

The EQ-5D-5L level sum score (LSS) is an equally weighted score calculated by summarizing the score on each of the five dimensions of EQ-5D-5L. The EQ-5D-5L level sum score ranges from 5 (best; if all domains have level 1) to 25 (worst; all domains have level 5). The EQ-5D-5L index will calculated by using the recently published specific value and ranges from below 0 (worse than death) to 1 (best health).

5.7. Data Management and Analysis Plan

Analyses will perform using SPSS statistical software (version 22; IBM, Armonk, NY, USA). Descriptive statistics such as frequency, percentage, mean $\pm$ SD, or median (range) will be used for socio-demographic, illness variables, and problems at each level for each dimension of the EQ-5D-5L.

Bivariate analysis using Pearson's χ^2 test will be used for categorical variables.

For all statistical tests, $P=0.05$ will be considered statistically significant.

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7. Ethical Considerations

Oral informed consent will be obtained from patients . Patients' confidentiality and privacy of information will be secured by the principle investigator. The questionnaires will be demonstrated for the patients in Arabic language and the statement of confidentiality issues will be explained on the cover page.

8. Workplan:



جامعة الجميع الذكية
EVERYONE'S SMART UNIVERSITY

9. Funding Agency

تهدف الاستبيان لمعرفة قدرة المريض على الحركة والاعتماد على نفسه ومدى تأثير
العارض الصحي على وضعه الصحي العام فترة الإصابة بكورونا :
يتم التعامل مع المعاومات بكافة السرية

العمر: _____

الجنس:

☐ انثى ☐ ذكر -

التعليم:

☐ فوق الجامعي

☐ جامعي

☐ ثانوي

☐ متوسط

☐ يقرأ ويكتب

☐ لا يحسن القراءة

الوظيفة:

☐ طالب

☐ غير موظف

☐ موظف

اذ كانت موظف اذكر مسمى الوظيفة: _____

الحالة الاجتماعية

☐ متزوج

☐ اعزب

☐ مطلق

☐ ارمل

التدخين

☐ لم ادخن

☐ ادخن حاليا

☐ مدخن سابق

☐ ارافق مدخن

هل سبق لك وان اخذت التطعيم با الانفلونزا الموسمية هذا العام

☐ اخذت التطعيم

☐ لم اخذ التطعيم الموسمية

فصيلة الدم:

A+ ☐

A- ☐

B+ ☐

B- ☐

AB+ ☐

AB- ☐

O+ ☐

O- ☐

هل تعاني من مرض مزمن:

☐ لا

☐ نعم

الامراض التي تعاني منها:

☐ امراض القلب

☐ السكر (سكري الكبار)

☐ السكري (سكري الصغار)

☐ الضغط

- ☐ الربو
- ☐ الكلي
- ☐ امراض الكبد
- ☐ نقص فتامين د
- ☐ امراض المناعة
- ☐ غيرها

عدد الامراض المزمنة الي تعاني

- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ لا اعاني من امراض

هل قمت باخذ عشبية بسبب اعراض الصحي:

☐ لا

☐ نعم: _____

عدد ساعات النوم اليومي

☐ اقل من 4 ساعات

☐ من 4-5 ساعات

☐ من 6-7 ساعات

☐ اكثر من 8 ساعات

عدد مرات اصابتك بنفس العارض الصحي خلال عام:

☐ 1

☐ 2

☐ 3

☐ أكثر

أخذت التطعيمة الدرن او السل

☐ نعم

☐ لا

تقييم الوضع الصحي:

1) ضع علامة (✓) في المربع الخاص بعبارة واحدة في كل مجموعة من المجموعات التالية، لتشير

إلى أفضل عبارة تصف حالتك الصحية بعد اصابتك بالتهاب الجهاز التنفسي.

☐ إمكانية الحركة

☐ ليس لدي أي مشاكل

☐ لدي مشاكل طفيفة

☐ لدي مشاكل معتدلة

☐ لدي مشاكل حادة

☐ أنا غير قادر على المشي

☐ العناية بالنفس

☐ ليس لدي أي مشاكل

☐ لدي مشاكل طفيفة

- لدي مشاكل معتدلة
- لدي مشاكل حادة
- أنا غير قادر على غسل أو لباس نفسي
- النشاط المعتاد (العمل ، الدراسة ، الأعمال المنزلية ، الأسرة)
- ليس لدي أي مشاكل
- لدي مشاكل طفيفة
- لدي مشاكل معتدلة
- لدي مشكلة خطيرة
- أنا غير قادر على القيام بأنشطتي المعتادة
- الألم / الإحساس بعدم الراحة
- ليس لدي أي ألم أو إزعاج
- لدي ألم خفيف أو إزعاج
- لدي ألم معتدل أو إزعاج
- لدي ألم شديد أو عدم راحة
- أنا ألم شديد أو عدم راحة
- القلق / الاكتئاب
- أنا لست قلقًا أو مكتئبًا
- لدي قلق طفيف أو مكتئب
- لدي قلق معتدل أو مكتئب
- لدي قلق شديد أو مكتئب

○ أنا شديد القلق أو الاكتئاب

(2) قيم درجة وضعك الصحي اليوم من 0 الى 100 حيث ان افضل درجة 100 واسوء درجة

صفر (__)

أفضل حالة صحية
يمكن تخيلها

لمساعدة الأشخاص في التعبير عن حالتهم الصحية، قمنا برسم
مقياس مدرج (يشبه مقياس الحرارة) بحيث يشير الرقم 100 إلى
أفضل حالة صحية يمكن تخيلها والرقم صفر إلى أسوأ حالة
صحية يمكن تخيلها.

نود منك أن توضح على هذا المقياس مدى جودة أو سوء صحتك
الشخصية اليوم، حسب رأيك.



حالتك الصحية اليوم

أسوأ حالة صحية يمكن
تخيلها