ISSN 1916-9736 (Print) ISSN 1916-9744 (Online)

GLOBAL JOURNAL OF HEALTH SCIENCE

Vol. 14 No. 4, April 2022



CANADIAN CENTER OF SCIENCE AND EDUCATION®

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Comparison of Menstruation-Related Symptoms Before and During Menstruation of University Students in Japan, a Year after the COVID-19 Pandemic

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| Received: January 29, 2022 | Accepted: February 21, 2022 | Online Published: February 23, 2022 |
|----------------------------|-----------------------------|-------------------------------------|
| doi:10.5539/gjhs.v14n4p1 | URL: https://doi.org/10.5 | 539/gjhs.v14n4p1 |

Abstract

The coronavirus disease 2019 (COVID-19) pandemic affected the daily lifestyle of people, including many aspects affecting young women. Subsequent to the COVID-19 pandemic stress and anxiety have been reported related to menstrual disorders (Takmaz, Gundogmus, Okten, & Gunduz, 2021). The purpose of this study was to investigate the intensity and to compare menstruation-related symptoms before and during menstruation among university students in Japan. We conducted an online cross-sectional study from May to July 2021 using a menstrual distress questionnaire (MDQ) to assess symptoms experienced before and during menstruation. Our results showed that of 141 students, five students (3.5%) did not report any symptoms before menstruation and one student (0.7%) had no symptoms during menstruation. We found that the most frequently experienced symptoms before menstruation were skin blemishes or disorder, mood swings, irritability, swelling, cramps, fatigue, take naps, stay in bed, feeling sad or blue, weight gain and difficulty concentrating. The most frequently experienced symptoms during menstruation were cramps, fatigue, irritability, mood swings, take naps, stay in bed, feeling sad or blue, backache, swelling, skin blemish or disorder, and poor school/work performance. The total MDQ score was significantly higher during menstruation than before menstruation. Among the MDQ eight scales, the scores of five scales including pain, autonomic reaction, impaired concentration, behavior change, and control were significantly higher during menstruation than before menstruation. The prevalence of increased appetite and craving for sweets were higher than MDQ symptoms before menstruation. The prolonged exposure to pandemic may have more effect on psychological symptoms than on physical symptoms.

Keywords: COVID-19 pandemic, menstruation-related symptoms, menstrual distress questionnaire, young women

1. Introduction

Since the declaration of the coronavirus disease 2019 (COVID-19) pandemic by the World Health Organization (WHO) on March 11, 2020, the lifestyle of people has undergone many changes. The COVID-19 pandemic has influenced students' lifestyle as well as their physical and mental health. For university students, various changes in their academic life occurred, such as restrictions in access to campus and increased online classes. A prospective cohort study conducted before and during the COVID-19 lockdown amongst university students in Saudi Arabia showed that physical activity had decreased, sedentary time had increased, and that although their level of sleeping had decreased but sleeping time had increased (Jalal, Beth, Al-Hassan, & Alshealah, 2021). A cross-sectional survey amongst medical students in nine countries including Japan reported that 90% of respondents mentioned a transition to online education, and 96% of students increased their time spent in front of screens such as computers, cell phones, tablets, and others electronic devices (Perez-Dominguez et al., 2021). The same study also reported that about a half of the students reported negative changes in their studying, sleeping and eating habits, and they frequently experienced the onset and increasing mental and physical health symptoms such as backache, asthenopia, irritability, and emotional instability (Perez-Dominguez et al., 2021).

There were some reports regarding the association of the COVID-19 pandemic with menstruation and menstruation-related symptoms including premenstrual syndrome (PMS), premenstrual dysphoric disorder (PMDD) and dysmenorrhea, which affected the daily and academic life of young women, such as being absent from school (Armour et al., 2019; Tadakawa, Takeda, Monma, Koga, & Yaegashi, 2016) or by the negative effects on their concentration (Armour et al., 2019). It was reported that for women in Turkey, duration of menstruation decreased compared to their experiences before the COVID-19 outbreak and the severity of anxiety and stress positively correlated with the degree of menstrual and somatic symptoms (using the menstruation symptom questionnaire -MSQ) (Demir, Sal, & Comba, 2021). It was reported that 53% of women in Ireland had worse premenstrual symptoms and 30% women had new dysmenorrhea after the pandemic breakout (Phelan, Behan, & Owens, 2021). Moreover, the number of women having mental health symptoms increased, and the women with mental health symptoms were also more likely to report painful periods and worsening premenstrual symptoms (Phelan et al., 2021). It was further reported that female healthcare workers in Turkey had an association between the COVID-19 pandemic-induced anxiety, perceived stress, depressive symptoms, and increased prevalence of menstrual cycle irregularity (Takmaz, Gundogmus, Okten, & Gunduz, 2021). A longitudinal study in Brazil before and during pandemic also showed that the total premenstrual screening tool score showed no change in the presence and severity of premenstrual symptoms between the two periods, but that the "anxiety/stress" symptoms of this tool revealed that it was more severe in the students before the pandemic (Freitas, de Medeiros, & Lopes, 2021). Thus, stress and anxiety may be related to menstrual abnormality during the pandemic. Since more than a year of the COVID-19 pandemic has passed, students, however, may be getting used to coexisting with COVID-19 with less anxiety. Although menstrual cycle-related symptoms include physical, behavioral, and emotional symptoms (Clayton, 2008), to our knowledge, comparison of menstruation-related symptom in young women between before and during menstruation have not been reported.

This study therefore aimed to investigate the intensity of menstruation-related symptoms before and during menstruation and to compare menstrual symptoms before and during menstruation in Japanese university students, a year after the start of the COVID-19 pandemic.

2. Materials and Methods

2.1 Participants

We recruited young female university students who were enrolled in the health science department of a university in Japan. For the purpose of recruitment, we announced the recruitment during online classes or face-to-face classes with the 320 students. After these sessions, 169 students agreed to participate voluntarily.

2.2 Data Collection Procedure

Data collection for this study was conducted between May to July 2021. The questionnaire for survey was created by the authors, then converted into the online form by using SurveyMonkey (https://jp.surveymonkey.com/).

The researchers provided an explanation relating to the purpose of the survey and the protocol and then asked students to participate in the survey. The study was anonymous and completely voluntary. All questions were compulsory, but it was possible to quit the questionnaire at any time. Students could access the online survey by clicking on the URL or scanning the QR code provided. Students needed to check a button for informed consent before answering the survey questions; they could continue the survey once they had provided informed consent, or if not they could end their participation. The study was approved by the Ethics Committee of Tokushima University Hospital (approval number: 3932).

2.3 Measurements

2.3.1 Demographic Characteristics

For this study, we developed a questionnaire consisting of demographic information including age, body weight, body height, age of menarche, currently visiting gynecological doctors and taking hormone therapy, present menstrual conditions (menstrual cycle length, regularity, duration of menstrual bleeding and perceived amount of menstrual bleeding). Body Mass Index (BMI) was calculated as the body weight(kg)/body height (m²).

2.3.2 Menstruation-Related Measurements

This part of the questionnaire consisted of questions on information about the intensity of menstruation-related symptoms. The intensities of menstruation-related symptoms were assessed using the menstrual distress questionnaire (MDQ). The MDQ which has been a standard method widely used for measuring menstruation-related symptoms (Moos, 1968) contains 46 symptom items grouped into eight scales. Among the eight scales, three somatic scales are for pain, water retention, and autonomic reactions, another three scales are for

mood and behavioral changes, specifically negative affect, impaired concentration and behavior change. The last two scales are for arousal and control (Moos, 2010). Students were asked to rate their perceived intensity of each item during three menstrual phases including before menstruation (4 days before mensuration), during menstruation and the remainder of the cycle. For each item, the participants could rate their experiences on a five-point scale from 0 to 4, where 0 was no experience of symptom, 1 was present and mild, 2 was present and moderate, 3 was present and strong and 4 was present and severe. The Cronbach's alpha coefficient in this study was 0.84 and 0.86 for total MDQ score before and during menstruation, respectively. We also investigated three eating habit symptoms, comprising an increase in appetite, craving for sweets and snacks, which we found specific change before and during menstruation (Matsuura, Inoue, Kidani, & Yasui, 2020). Each symptom was also rated on a five-point scale.

2.4 Statistics Analysis

We performed the statistical analysis using SPSS version 28.0 for Windows (IBM Corp., Armonk, NY, USA). Categorical variables were presented as whole numbers with percentages or means with standard deviations. The MDQ score was calculated by total score and score for each of the eight scales, presented as median (25th percentile, 75th percentile). The three eating habit symptoms were also presented in the same way. We used the Wilcoxon signed rank test to compare the intensity of MDQ total score, each of the eight scales' score and three eating habit symptoms' score before and during menstruation. All p-values < 0.05 were regarded as statistically significant.

3. Results

We recruited from 320 female students for the survey, of whom 169 students participated in the study. We excluded 28 students, comprising 18 students who did not complete the MDQ items and 10 students who were under hormonal therapy for their gynecological diseases. Subsequently, we used the data of 141 students for analysis.

3.1 Demographic Characteristics

The mean age of the students was 19.8 ± 3.1 years, and the mean menarche age was 12.1 ± 1.4 years. Among them, 87.9% of students reported that their menstrual cycle length ranged from 25 to 38 days. Menstrual duration for most of the students ranged from 3 to 7 days. The amount of menstrual bleeding was perceived as moderate by 75.9% of the students (Table 1).

| Characteristic | Category | n | % |
|---|--|------------|------|
| Age (years) ^a | | 19.8 (3.1) | 1 |
| Height (cm) ^a | | 157.4 (4.9 |)) |
| Weight (kg) ^a | | 51.4 (6.2) | 1 |
| Menarche age (years) ^a | | 12.1 (1.4) | 1 |
| Body mass index (kg/m ²) ^a | | 20.7 (2.1) | 1 |
| Menstrual cycle length | 24 days or less | 2 | 1.4 |
| | 25-38 days | 124 | 87.9 |
| | 39 days or more | 14 | 9.9 |
| | No menstruation for more than 3 months | 1 | 0.7 |
| Menstrual cycle regularity | Regular | 67 | 47.5 |
| | Sometimes irregular | 65 | 46.1 |
| | Irregular | 9 | 6.4 |
| Duration of menstruation | 3-7 days | 137 | 97.2 |
| | 8 days or more | 4 | 2.8 |
| Perceived amount of menstrual bleeding | Light | 12 | 8.5 |
| | Moderate | 107 | 75.9 |
| | Heavy | 22 | 15.6 |

Table 1. Demographic characteristics (n=141)

^aMean (standard deviation).

3.2 Prevalence of MDQ Symptoms

Five students (3.5%) did not report any symptoms before menstruation and one student (0.7%) similarly during menstruation. The range of the MDQ total score before menstruation was 0-109 points and the range of the score during menstruation was 0-124 points.

Regarding symptoms before menstruation, the most frequently experienced symptoms were skin blemish or disorder (68.8%), mood swings (68.1%), irritability (63.8%), swelling (62.4%), cramps (61.0%), fatigue, take naps, stay in bed, feeling sad or blue, weight gain and difficulty concentrating (Table 2).

| | | Intensity | | | | | | | | | |
|-----------------------|----------------------------|-----------|------|---------|----|--------|--------|------|--------|-----|--|
| Scales | Symptoms | Non | e | Mild | Мо | derate | Strong | | Severe | | |
| | | n | % | n % | n | % | n | % | n | % | |
| | Muscle stiffness | 120 | 85.1 | 15 10.6 | 3 | 2.1 | 2 | 1.4 | 1 | 0.7 | |
| | Headache | 88 | 62.4 | 27 19.1 | 18 | 12.8 | 3 | 2.1 | 5 | 3.5 | |
| Doin | Cramps | 55 | 39.0 | 43 30.5 | 28 | 19.9 | 14 | 9.9 | 1 | 0.7 | |
| Pain | Backache | 80 | 56.7 | 33 23.4 | 23 | 16.3 | 3 | 2.1 | 2 | 1.4 | |
| | Fatigue | 58 | 41.1 | 27 19.1 | 33 | 23.4 | 18 | 12.8 | 5 | 3.5 | |
| | General aches and pains | 102 | 72.3 | 24 17.0 | 10 | 7.1 | 5 | 3.5 | 0 | 0.0 | |
| | Weight gain | 75 | 53.2 | 31 22.0 | 17 | 12.1 | 15 | 10.6 | 3 | 2.1 | |
| Votor estantion | Skin blemish or disorder | 44 | 31.2 | 32 22.7 | 33 | 23.4 | 25 | 17.7 | 7 | 5.0 | |
| Water retention | Painful or tender breasts | 81 | 57.4 | 22 15.6 | 20 | 14.2 | 15 | 10.6 | 3 | 2.1 | |
| | Swelling (breasts abdomen) | 53 | 37.6 | 31 22.0 | 37 | 26.2 | 17 | 12.1 | 3 | 2.1 | |
| | Dizziness, faintness | 89 | 63.1 | 28 19.9 | 16 | 11.3 | 7 | 5.0 | 1 | 0.7 | |
| Autonomic reactions | Cold sweats | 130 | 92.2 | 7 5.0 | 3 | 2.1 | 1 | 0.7 | 0 | 0.0 | |
| | Nausea, vomiting | 124 | 87.9 | 7 5.0 | 7 | 5.0 | 2 | 1.4 | 1 | 0.7 | |
| | Hot flashes | 106 | 75.2 | 15 10.6 | 16 | 11.3 | 2 | 1.4 | 2 | 1.4 | |
| | Loneliness | 93 | 66.0 | 14 9.9 | 21 | 14.9 | 6 | 4.3 | 7 | 5.0 | |
| | Anxiety | 88 | 62.4 | 23 16.3 | 18 | 12.8 | 5 | 3.5 | 7 | 5.0 | |
| | Mood swings | 45 | 31.9 | 30 21.3 | 27 | 19.1 | 26 | 18.4 | 13 | 9.2 | |
| NT | Crying | 102 | 72.3 | 15 10.6 | 8 | 5.7 | 9 | 6.4 | 7 | 5.0 | |
| Negative affect | Irritability | 51 | 36.2 | 27 19.1 | 19 | 13.5 | 31 | 22.0 | 13 | 9.2 | |
| | Tension | 102 | 72.3 | 17 12.1 | 13 | 9.2 | 7 | 5.0 | 2 | 1.4 | |
| | Feeling sad or blue | 63 | 44.7 | 26 18.4 | 29 | 20.6 | 12 | 8.5 | 11 | 7.8 | |
| | Restlessness | 101 | 71.6 | 21 14.9 | 14 | 9.9 | 2 | 1.4 | 3 | 2.1 | |
| | Insomnia | 111 | 78.7 | 12 8.5 | 15 | 10.6 | 2 | 1.4 | 1 | 0.7 | |
| | Forgetfulness | 124 | 87.9 | 7 5.0 | 9 | 6.4 | 0 | 0.0 | 1 | 0.7 | |
| | Confusion | 110 | 78.0 | 16 11.3 | 10 | 7.1 | 2 | 1.4 | 3 | 2.1 | |
| manipud Conservation | Poor judgment | 111 | 78.7 | 15 10.6 | 12 | 8.5 | 2 | 1.4 | 1 | 0.7 | |
| mpaired Concentration | Difficulty concentrating | 78 | 55.3 | 28 19.9 | 23 | 16.3 | 9 | 6.4 | 3 | 2.1 | |
| | Distractible | 83 | 58.9 | 27 19.1 | 20 | 14.2 | 8 | 5.7 | 3 | 2.1 | |
| | Minor Accidents | 98 | 69.5 | 21 14.9 | 14 | 9.9 | 7 | 5.0 | 1 | 0.7 | |
| | Poor motor coordination | 96 | 68.1 | 26 18.4 | 11 | 7.8 | 5 | 3.5 | 3 | 2.1 | |

| Table 2. Prevalence of MDQ symptoms before menstruation by the level of intensity (n=141) |
|---|
|---|

| | Poor school/work performance | 81 | 57.4 | 32 | 22.7 | 12 | 8.5 | 9 | 6.4 | 7 | 5.0 |
|-----------------|------------------------------|-----|------|----|------|----|------|----|------|----|------|
| | Take naps, stay in bed | 62 | 44.0 | 19 | 13.5 | 20 | 14.2 | 23 | 16.3 | 17 | 12.1 |
| Behavior change | Stay at home | 89 | 63.1 | 16 | 11.3 | 18 | 12.8 | 11 | 7.8 | 7 | 5.0 |
| | Avoid social activities | 93 | 66.0 | 24 | 17.0 | 14 | 9.9 | 9 | 6.4 | 1 | 0.7 |
| | Decreased efficiency | 83 | 58.9 | 28 | 19.9 | 15 | 10.6 | 8 | 5.7 | 7 | 5.0 |
| | Affectionate | 88 | 62.4 | 20 | 14.2 | 21 | 14.9 | 6 | 4.3 | 6 | 4.3 |
| Arousal | Orderliness | 113 | 80.1 | 12 | 8.5 | 14 | 9.9 | 2 | 1.4 | 0 | 0.0 |
| | Excitement | 121 | 85.8 | 13 | 9.2 | 4 | 2.8 | 3 | 2.1 | 0 | 0.0 |
| | Feelings of well-being | 92 | 65.2 | 25 | 17.7 | 18 | 12.8 | 5 | 3.5 | 1 | 0.7 |
| | Bursts of energy, activity | 97 | 68.8 | 29 | 20.6 | 11 | 7.8 | 3 | 2.1 | 1 | 0.7 |
| | Feelings of suffocation | 123 | 87.2 | 8 | 5.7 | 8 | 5.7 | 2 | 1.4 | 0 | 0.0 |
| | Chest pains | 123 | 87.2 | 11 | 7.8 | 6 | 4.3 | 0 | 0.0 | 1 | 0.7 |
| Cantral | Ringing in the ears | 120 | 85.1 | 13 | 9.2 | 7 | 5.0 | 1 | 0.7 | 0 | 0.0 |
| Control | Heart pounding | 125 | 88.7 | 9 | 6.4 | 5 | 3.5 | 1 | 0.7 | 1 | 0.7 |
| | Numbness, tingling | 134 | 95.0 | 5 | 3.5 | 1 | 0.7 | 1 | 0.7 | 0 | 0.0 |
| | Blind spots, fuzzy vision | 128 | 90.8 | 9 | 6.4 | 4 | 2.8 | 0 | 0.0 | 0 | 0.0 |

Subsequently, regarding symptoms during menstruation, the most frequently experienced symptoms were cramps (93.6%), fatigue (77.3%), irritability (75.9%), mood swings (73.8%), take naps, stay in bed (72.3%), feeling sad or blue, backache, swelling (breasts, abdomen), skin blemish or disorder, and poor school/work performance (Table 3).

| | | Intensity | | | | | | | | | | |
|---------------------|----------------------------|-----------|------|----|------|----------|------|--------|------|----|------|--|
| Scales | Symptoms | Non | None | | | Moderate | | Strong | | Se | vere | |
| | | n | % | n | % | n | % | n | % | n | % | |
| | Muscle stiffness | 110 | 78.0 | 15 | 10.6 | 9 | 6.4 | 5 | 3.5 | 2 | 1.4 | |
| | Headache | 77 | 54.6 | 23 | 16.3 | 30 | 21.3 | 7 | 5.0 | 4 | 2.8 | |
| Pain | Cramps | 9 | 6.4 | 26 | 18.4 | 38 | 27.0 | 51 | 36.2 | 17 | 12.1 | |
| ram | Backache | 42 | 29.8 | 24 | 17.0 | 29 | 20.6 | 31 | 22.0 | 15 | 10.6 | |
| | Fatigue | 32 | 22.7 | 25 | 17.7 | 37 | 26.2 | 34 | 24.1 | 13 | 9.2 | |
| | General aches and pains | 74 | 52.5 | 28 | 19.9 | 27 | 19.1 | 9 | 6.4 | 3 | 2.1 | |
| - | Weight gain | 79 | 56.0 | 27 | 19.1 | 25 | 17.7 | 9 | 6.4 | 1 | 0.7 | |
| Water retention | Skin blemish or disorder | 45 | 31.9 | 39 | 27.7 | 32 | 22.7 | 19 | 13.5 | 6 | 4.3 | |
| water retention | Painful or tender breasts | 75 | 53.2 | 32 | 22.7 | 22 | 15.6 | 9 | 6.4 | 3 | 2.1 | |
| | Swelling (breasts abdomen) | 43 | 30.5 | 38 | 27.0 | 39 | 27.7 | 18 | 12.8 | 3 | 2.1 | |
| | Dizziness, faintness | 63 | 44.7 | 31 | 22.0 | 35 | 24.8 | 8 | 5.7 | 4 | 2.8 | |
| | Cold sweats | 116 | 82.3 | 11 | 7.8 | 6 | 4.3 | 7 | 5.0 | 1 | 0.7 | |
| Autonomic reactions | Nausea, vomiting | 107 | 75.9 | 15 | 10.6 | 13 | 9.2 | 3 | 2.1 | 3 | 2.1 | |
| | Hot flashes | 98 | 69.5 | 27 | 19.1 | 10 | 7.1 | 5 | 3.5 | 1 | 0.7 | |

Table 3. Prevalence of MDQ symptoms during menstruation by the level of intensity (n=141)

| | Loneliness | 87 | 61.7 | 24 17. | 0 21 | 14.9 | 7 | 5.0 | 2 | 1.4 |
|------------------------|------------------------------|-----|------|--------|------|------|----|------|----|------|
| | Anxiety | 81 | 57.4 | 32 22. | 7 20 | 14.2 | 6 | 4.3 | 2 | 1.4 |
| | Mood swings | 37 | 26.2 | 37 26. | 2 35 | 24.8 | 25 | 17.7 | 7 | 5.0 |
| Nagative offect | Crying | 103 | 73.0 | 20 14. | 2 7 | 5.0 | 9 | 6.4 | 2 | 1.4 |
| Negative affect | Irritability | 34 | 24.1 | 43 30. | 5 30 | 21.3 | 22 | 15.6 | 12 | 8.5 |
| | Tension | 90 | 63.8 | 24 17. | 0 17 | 12.1 | 6 | 4.3 | 4 | 2.8 |
| | Feeling sad or blue | 40 | 28.4 | 34 24. | 1 38 | 27.0 | 16 | 11.3 | 13 | 9.2 |
| | Restlessness | 93 | 66.0 | 30 21. | 3 11 | 7.8 | 4 | 2.8 | 3 | 2.1 |
| | Insomnia | 104 | 73.8 | 19 13. | 5 15 | 10.6 | 2 | 1.4 | 1 | 0.7 |
| | Forgetfulness | 120 | 85.1 | 10 7.1 | 10 | 7.1 | 0 | 0.0 | 1 | 0.7 |
| Impaired Concentration | Confusion | 104 | 73.8 | 19 13. | 5 17 | 12.1 | 1 | 0.7 | 0 | 0.0 |
| | Poor judgment | 101 | 71.6 | 16 11. | 3 19 | 13.5 | 5 | 3.5 | 0 | 0.0 |
| | Difficulty concentrating | 53 | 37.6 | 27 19. | 1 37 | 26.2 | 20 | 14.2 | 4 | 2.8 |
| | Distractible | 61 | 43.3 | 33 23. | 4 31 | 22.0 | 13 | 9.2 | 3 | 2.1 |
| | Minor Accidents | 87 | 61.7 | 23 16. | 3 24 | 17.0 | 5 | 3.5 | 2 | 1.4 |
| | Poor motor coordination | 67 | 47.5 | 20 14. | 2 26 | 18.4 | 19 | 13.5 | 9 | 6.4 |
| | Poor school/work performance | 45 | 31.9 | 36 25. | 5 34 | 24.1 | 12 | 8.5 | 14 | 9.9 |
| | Take naps, stay in bed | 39 | 27.7 | 26 18. | 4 30 | 21.3 | 25 | 17.7 | 21 | 14.9 |
| Behavior change | Stay at home | 66 | 46.8 | 20 14. | 2 22 | 15.6 | 20 | 14.2 | 13 | 9.2 |
| | Avoid social activities | 82 | 58.2 | 21 14. | 9 17 | 12.1 | 16 | 11.3 | 5 | 3.5 |
| | Decreased efficiency | 61 | 43.3 | 27 19. | 1 30 | 21.3 | 15 | 10.6 | 8 | 5.7 |
| | Affectionate | 89 | 63.1 | 26 18. | 4 15 | 10.6 | 6 | 4.3 | 5 | 3.5 |
| | Orderliness | 117 | 83.0 | 9 6.4 | 14 | 9.9 | 1 | 0.7 | 0 | 0.0 |
| Arousal | Excitement | 128 | 90.8 | 9 6.4 | 3 | 2.1 | 1 | 0.7 | 0 | 0.0 |
| | Feelings of well-being | 96 | 68.1 | 25 17. | 7 16 | 11.3 | 4 | 2.8 | 0 | 0.0 |
| | Bursts of energy, activity | 113 | 80.1 | 19 13. | 57 | 5.0 | 2 | 1.4 | 0 | 0.0 |
| | Feelings of suffocation | 123 | 87.2 | 6 4.3 | 7 | 5.0 | 2 | 1.4 | 3 | 2.1 |
| | Chest pains | 122 | 86.5 | 10 7.1 | 8 | 5.7 | 0 | 0.0 | 1 | 0.7 |
| Control | Ringing in the ears | 119 | 84.4 | 15 10. | 66 | 4.3 | 1 | 0.7 | 0 | 0.0 |
| Control | Heart pounding | 118 | 83.7 | 13 9.2 | 7 | 5.0 | 2 | 1.4 | 1 | 0.7 |
| | Numbness, tingling | 135 | 95.7 | 1 0.7 | 3 | 2.1 | 2 | 1.4 | 0 | 0.0 |
| | Blind spots, fuzzy vision | 10(| 00.4 | 10 7.1 | 4 | 2.8 | 1 | 0.7 | 0 | 0.0 |

3.3 Comparison of MDQ Symptoms' Intensities Before and During Menstruation

The total MDQ score was significantly higher during menstruation than before menstruation. Among eight scales, the scores of five scales including pain, autonomic reaction, impaired concentration, behavior change, and control were significantly higher during menstruation than before menstruation. In contrast, the score of arousal was significantly higher before menstruation than during menstruation (Table 4).

| Scales | No. of symptoms | Before | e menstrua | ition | During | g menstrua | tion | p -value * |
|------------------------|-----------------|--------|------------|-------|--------|------------|-------|-----------------|
| Pain | 6 | 3.0 | (1.0, | 6.0) | 7.0 | (4.0, | 11.0) | < 0.001 |
| Water retention | 4 | 3.0 | (2.0, | 7.0) | 4.0 | (1.0, | 6.0) | 0.392 |
| Autonomic reactions | 4 | 1.0 | (0.0, | 2.0) | 1.0 | (0.0, | 3.0) | < 0.001 |
| Negative affect | 8 | 5.0 | (1.0, | 11.0) | 7.0 | (2.0, | 12.0) | 0.121 |
| Impaired Concentration | 8 | 2.0 | (0.0, | 6.0) | 4.0 | (1.0, | 10.0) | < 0.001 |
| Behavior change | 5 | 2.0 | (0.0, | 6.5) | 6.0 | (1.5, | 10.0) | < 0.001 |
| Arousal | 5 | 1.0 | (0.0, | 4.0) | 1.0 | (0.0, | 3.0) | < 0.001 |
| Control | 6 | 0.0 | (0.0, | 1.0) | 0.0 | (0.0, | 1.0) | 0.004 |
| Total MDQ Score | 46 | 22.0 | (12.0, | 41.0) | 34.0 | (17.0, | 52.5) | < 0.001 |

| Table 4. Comparison of MD | O symptoms' inten | sities before and during | menstruation by | subcategory (n=141) |
|---------------------------|-------------------|--------------------------|-----------------|---------------------|
| | | | | |

Data are presented as medians (25th percentile, 75th percentile). *Wilcoxon signed rank test was used.

3.4 Symptoms of Eating Habit Before and During Menstruation

The prevalence rate of the symptoms of eating habits before menstruation was increased appetite (70.2%), craving for sweets (73.0%) and craving for snacks (51.1%). The rate during menstruation was increased appetite (56.7%), craving for sweets (71.6%) and craving for snacks (46.1%). All of the items had a higher prevalence before menstruation than during menstruation. The intensity of each symptom was significantly higher before menstruation than during menstruation (Table 5).

| Table 5. Prevalence of eating habit symptoms before and during menstruation by the level of intensity and |
|---|
| comparison of eating habit symptoms intensity before and during menstruation (n=141) |

| | | | | | In | Median | | | | | | | |
|-----------------|--------------------|-------------------------------------|------|-------------------|------------------|--------|--------|------|------|-----|------|-------------------|----------------------------------|
| Menstrual phase | Symptoms | Nor | ne | Mil | ld | Mo | derate | Stro | ong | Sev | vere | (25th percentile, | p-value [*] |
| phase | | n | % | n | % | n | % | n | % | n | % | 75th percentile) | |
| | Increased appetite | 42 | 29.8 | 21 | 14.9 | 17 | 12.1 | 40 | 28.4 | 21 | 14.9 | 2.0 (0.0, 3.0) | Before vs during Increased |
| Before | Craving for sweets | for 38 27.0 | 27.0 | 27 | 19.1 | 24 | 17.0 | 32 | 22.7 | 20 | 14.2 | 2.0 (0.0, 3.0) | appetite (p<0.001) |
| | Craving for snacks | 69 | 48.9 | 26 | 18.4 | 24 | 17.0 | 10 | 7.1 | 12 | 8.5 | 1.0 (0.0, 2.0) | Before vs during —Craving for |
| | Increased appetite | 61 43.3 20 14.2 32 22.7 22 15.6 6 4 | 4.3 | 1.0 (0.0, 2.0) | sweets (p=0.029) | | | | | | | | |
| During | sweets 40 | 40 | 28.4 | 32 | 22.7 | 30 | 21.3 | 28 | 19.9 | 11 | 7.8 | 1.0 (0.0, 3.0) | Before vs during Craving for |
| | | 76 | 53.9 | 28 | 19.9 | 24 | 17.0 | 5 | 3.5 | 8 | 5.7 | 0.0 (0.0, 2.0) | snacks (p<0.001) |

*Wilcoxon signed rank test was used to compare the median of intensity of symptoms before and during menstruation.

4. Discussion

This study was conducted from May to July 2021, more than a year into the COVID-19 pandemic, thus it may affect a little to the survey results of the menstruation-related symptoms of university students in Japan. In our study, the prevalence rates of students who had experienced at least one symptom listed on the MDQ 46 items

before and during menstruation were 96.5% and 99.3%, respectively. The prevalence rate before menstruation was similar to the results of a previous study which used the MDQ 46 items (Matsumoto, Egawa, Kimura, & Hayashi, 2019). However, the prevalence rate during menstruation was higher than the result of a meta-analysis of prevalence for young women at 71.1% (Armour et al., 2019). Most of the students in the present study had symptoms during menstruation, but the number of symptoms or intensity of symptoms varied greatly depending on the individual. Some students may be diagnosed as PMS or dysmenorrhea.

Regarding intensity of the MDQ symptoms, it has been reported that among high school students, the MDQ total score and the scores of pain, water retention, impaired concentration, behavior change, autonomic reaction, and negative effect were lower in the premenstrual phase than in the menstrual phase (Otsuka-Ono, Sato, Ikeda, & Kamibeppu, 2015). Other studies have shown similar results for university students, as the MDQ total score and the scores of pain, autonomic reaction, impaired concentration, behavior change were lower in the premenstrual phase than in the menstrual phase (Ishihara, 2019; Uemura, Sakae, & Matsumura, 2014), but scores of negative affect and water retention were not different between the two phases (Ishihara, 2019). Our results were similar to a previous study conducted before the COVID-19 pandemic, which reported that the intensity of pain, autonomic reaction, impaired concentration, behavior change and MDQ total symptoms for young women may be stronger during menstruation than before menstruation.

We found that the ten most frequently experienced symptoms before menstruation were skin blemish or disorder, mood swings, irritability, swelling, cramps, fatigue, take naps, stay in bed, feeling sad or blue, weight gain and difficulty concentrating, which were most agreed with previous study (Matsumoto et al., 2019). Skin blemish, which was the most prevalent symptom in our study, may occur when sebum secretion increases due to increased progesterone secretion after ovulation. However, the prevalence rate of the skin disorder for university students varies greatly from 36% in Iran (Ghiasi, Keramat, & Mollaahmadi, 2018) to 80% for acne in Palestine (Abu Alwafa, Badrasawi, & Haj Hamad, 2021). Moreover, 56% of adults in USA reported that their acne got worse before menstruation (Geller, Rosen, Frankel, & Goldenberg, 2014), and 44% of adult women experienced premenstrual flares of their acne but this was not affected by ethnicity (Stoll et al., 2001). Thus, the difference in prevalence seems to depend on country-specific factors.

In our study, cramps, take naps, stay in bed, feeling sad or blue and difficulty concentrating were also common symptoms in the premenstrual phase. On the other hand, the cramps, take naps, stay in bed, feeling sad or blue, difficulty concentrating were not contained in the top ten of the most frequently experienced symptoms using the MDQ in previous research (Matsumoto et al., 2019). There was a significant increase in reported mental health symptoms including low mood, poor sleep, lowliness, poor concentration since the outbreak of the pandemic and the women who had these symptoms were more likely to have painful periods and worsening premenstrual symptom (Phelan et al., 2021). Therefore, according to our research results, the symptoms of lower abdominal pain, dozing, and difficulty concentrating may occur due to the worsening mental state caused by COVID-19.

Regarding symptoms during menstruation, previous studies mainly focused on the menstruation pain or dysmenorrhea, and there are less studies focusing on other menstruation related symptoms. We clarified the prevalence and intensity of the symptoms using MDQ and three eating items. Our results are consistent with previous studies in showing that the prevalence rate of cramps was as high as 79.2% (Yamamoto, Okazaki, Sakamoto, & Funatsu, 2009) and 86.5% (Ghiasi et al., 2018). Similarly, fatigue was reported as common as 84.5% (Ghiasi et al., 2018). Other studies also have reported prevalence rates of some other symptoms such as mood swings (71.8%), depression (62.7%) (Ghiasi et al., 2018) and irritability (76.3%) (Fernández-Martínez, Onieva-Zafra, Abreu-Sánchez, Fernández-Muñóz, & Parra-Fernández, 2019). Our results seem to show higher prevalence rates of mood swings and depression than the above studies. In a study conducted after the COVID-19 pandemic, 30% had new dysmenorrhea and increased psychological symptoms such as low mood, anxiety, lowliness during pandemic (Phelan et al., 2021). Because students have had to stay at home during the pandemic and cannot often communicate with others, this may influence the negative affect items, such as mood swings and depression.

Before the COVID-19 pandemic, we showed that the rate of increased consumption of sweets and snack in young students was 68.4% and 40%, respectively, before menstruation, and 47.9% and 23%, respectively, during menstruation (Matsuura et al., 2020). In the present study, which was conducted during the pandemic, we showed that the prevalence rate of the increased appetite and craving for sweets before menstruation was higher than the MDQ 46 symptoms, and that the rate of the craving for sweets during menstruation was the fifth most prevalent symptom. A study in UAE showed that 71% of university students had a craving for sweets and 72% had increased appetite (Hashim et al., 2019). Moreover, the marked change in appetite, over-eating, or specific food craving is

one of the diagnoses of PMDD (American Psychiatric Association, 2013), and these changing eating habits are common in the premenstrual phase. In our previous study, we also found that increased appetite and intake of sweets are associated with depression, anger and sleepiness before menstruation, while intake of junk food such as snacks is associated with irritability and depression (Matsuura et al., 2020). These symptoms of eating behavior may be associated with psychological symptoms caused by COVID-19 pandemic.

The premenstrual symptoms and dysmenorrhea are reported to affect school life and academic performance (Armour et al., 2019; Tadakawa et al., 2016). Recently, it has been reported that dysmenorrhea increases the risk of hypertensive disorders of pregnancy (Nakayama et al., 2020) and increases the risk of giving birth to a low-birth-weight baby (Feng et al., 2021), while PMS increases the risk of hypertension (Bertone-Johnson, Whitcomb, Rich-Edwards, Hankinson, & Manson, 2015). Thus, dysmenorrhea and PMS may influence the future health of young women. It implies that we should advise young students to visit the medical doctors in order to receive appropriate treatments.

This study has several limitations. First, the participants were limited to a department in a university and the sample size was small, which makes generalization of these results difficult. Second, the participants may have recall bias in describing their own experiences of menstruation symptoms. Third, the causal relationships with COVID -19 pandemic and menstruation related symptoms cannot be evaluated since this was a cross-sectional survey. A longitudinal study may be needed to study the changes of menstruation-related symptoms by using MDQ in other areas or in participants with different backgrounds.

5. Conclusion

In this study, which was conducted during the time of the COVID-19 pandemic, using the MDQ we found that scores of pain, autonomic reaction, impaired concentration, behavior change, and control were significantly higher during the menstruation phase compared to the scores of pre-menstruation phase. It may suggest that the exposure to the COVID-19 pandemic may affect more psychological symptoms rather than the physical symptoms.

Acknowledgments

This work was supported by JSPS KAKENHI Grant Number JP20K10830. The authors are deeply grateful to the participants.

Competing Interests Statement

The authors declare that there are no competing conflicts of interest.

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Factors Affecting Care and Maintenance of Complete Denture Prostheses (CDP)-A Literature Review

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| Received: February 1, 2022 | Accepted: February 26, 2022 | Online Published: February 28, 2022 |
|----------------------------|-----------------------------|-------------------------------------|
| doi:10.5539/gjhs.v14n4p12 | URL: https://doi.org/10. | .5539/gjhs.v14n4p12 |

Abstract

Background: The prevalence of edentulism which is a major public health concern globally relating to extensive loss of teeth had reduced. For Edentulous Patients (EDPs), Complete Denture Prostheses (CDP) therapy is a known mode of treatment to improve the overall health and the Oral Health Related-Quality of Life (OHRQoL) with appropriate care and maintenance for its longevity.

Aim: This literature review had been conducted containing the aim to gather the proficiency and ideas related to the factors that affect the care and maintenance of CDP and how it benefits the EDPs related to good CDP care practices.

Methods: Numerous electronic databases which included Scopus, Embase, Google Scholar and Open Grey literature in English language was used to search for the articles from January 1st 2005 to October 1st 2021 on factors that influenced care and maintenance of CDP. Associated article titles were chosen which was narrowed down to abstract of interested articles and the final 20 preferred full articles were reviewed. The selected articles in this study was analyzed using thematic analysis and their themes were grouped accordingly.

Results: Five themes were thematically identified as factors affecting care and maintenance of CDP: social and cultural factors, economic and demographical factors, policy related factors, physical factors and health service related factors. All articles reviewed demonstrated that every factor is highly essential when it comes to taking appropriate care and maintenance of CDP for EDPs.

Conclusion: The current evidence suggests that social, cultural, economical, demographical, policy, physical and health service related factors all significantly constitute towards effective care and maintenance of CDP for EDPs. Furthermore, the results derived from this research is essential in the development of effective post-operative guidelines for appropriate care and maintenance of CDP.

Keywords: Edentulous patients, Care and maintenance, Complete dentures prostheses, Determinants

1. Introduction

Over the last decade, edentulism has declined globally which is mainly due to the trend in high income countries where more people are taking care of their teeth (Frencken et al., 2017; Rozier, White, & Slade, 2017; Peres et al., 2019; Kailembo, Preet, & Williams, 2017). On the other hand, it had been seen that there is an opposite trend in Low and Middle Income Countries (LMICs) whereby the rate of edentulism is increasing (Kailembo, Preet, & Williams, 2017). In Edentulous Patients (EDPs), a Complete Denture Prosthesis (CDP) is utilized to restore the oral tissues as much as possible to maintain the anatomy (Goiato et al., 2011). Nonetheless, appropriate consideration needs to be provisioned for quality oral health care particularly uses of CDPs which indicated poor oral health if not given the recommended care (Nidhi et al., 2014; Bommireddy et al., 2014; Jaiswal et al., 2015; Bommireddy et al., 2016).

There is also a lack of data on denture wearers' cleaning habits. Due to the variation of CDP care and maintenance guidelines, it is extremely difficult for denture wearers to find the most opted solution to clean the CDP (Patel,

Jablonski, R, & Morrow, 2018; Marchini, 2014; Jablonski, Patel, & Morrow, 2018). Since nowadays denture wearers tend to look for guidance on the internet we cannot blame them for being confused, with there being so many different recommendations to choose from (Jablonski, Patel, & Morrow, 2018; Veronez et al., 2014; Partida, 2014; Bishop, Dixon, & Mistry, 2021).

Without proper denture care and maintenance practices, there would be an increased risk of developing a multitude of problems and infections ranging from angular chelitis, denture stomatitis, burning mouth syndrome to highly superimposed infections (Singh et al., 2014; Kosuru Sr et al., 2017). There is a need to know on the factors that affect the care and maintenance of CDP for its longevity. There are a few previous studies on complete denture wearers (Rabbo et al., 2012; Shinkai et al., 2002; Mousa, Lynch, & Kielbassa, 2020) had been conducted where the complaints based on care and maintenance of dentures were considered. This limited information available in this area of dentistry makes room for further research to be conducted in this area which plays a vital role in the lives of both the EDPs as well as the Dental professionals (DPs) in terms understanding the factors that affect the care and maintenance of CDP sin Fiji.

This article aims to produce a narrative review of the literature on this subject and draws conclusions on the factors affecting care and maintenance of CDP for EDPs in Fiji.

2. Methods

Literature search related to the topic was executed by the use of electronic databases Scopus, Embase, Google Scholar and Open Grey literature. These databases were chosen since they had been regularly utilized in previous research. Every study design such as qualitative, quantitative and mix method studies were taken into consideration in the literature search. The search was restricted to studies from 2010 to October 1st 2021. Language restrictions were applied to the research where abstracts or papers were obtained in English. Reference lists of selected articles were checked for papers that may have been missed by chance in the database search after which the references cited in retrieved papers were also examined. However, later the search was extended to January 1st 2005 to October 1st 2021 to allow for more relevant literatures to be reviewed and to appropriately identify the gaps in the knowledge in the literature.

To retrieve relevant articles, keywords (in titles and/or abstracts) such as patient "perceptions', ("care OR maintenance"), ("barriers OR challenge"), "complete denture", ("communication OR management"), and percept*, "complete denture prostheses", "dental professional perception", ("complete" OR "denture" OR "guideline" OR "insertion" OR "advise"), "edentulous patients", ("dental professional" OR "dentist" OR "Dental officer" OR dental technician"), ("teamwork" OR recommendations") were utilized. Searches were performed using "Boolean operators" ("AND", "OR", "NOT") according to syntax rules of different databases (Rethlefsen et al., 2021) to combine keywords and generate more literatures.

3. Results

Comprehensively, 641 article titles related to the topic had emerged in the search whereby 100 articles were highly appropriate to the purpose of the review thus was shortlisted upon excluding the duplicates. A second round of check for duplicates was undertaken and upon further article removal, there was 39 articles left. The abstracts of the 39 articles were thoroughly screened. Abstracts that were not of interest, not in English and those that could not be accessed were further excluded which came down to 25 articles. The 25 articles including the article titles were sent to the primary supervisor to obtain full articles. The final 20 articles were then obtained and analyzed from the list. The significant findings and conclusions from 20 articles were extracted and grouped under themes. The selected articles reviewed in this study was analyzed using the process of thematic analysis and was further grouped according to their respective themes for discussion which were 1) Social and cultural factors, 2) Economic and demographic factors, 3) Policy related factors, 4) Physical factors and 5) Health service related factors which had been explored below respectively.

4. Discussion

4.1 Factors affecting Care and Maintenance of CDP

4.1.1 Social and Cultural Factors

Social factors greatly affect EDPs in understanding that there is a need to look after their CDP. The common known social factors include: reference groups, family, role and status (Perreau, 2014). Firstly, each patient belongs to a group. This is a direct and simple classification. The second group type is a reference group. The reference group influences the self-image of patients and their behavior. The reference group provides some points of comparison to patients about their behavior, lifestyle or habits. Usually there are many smaller reference groups,

which are formed by family, close friends, neighbors, work group or other people that patients associate with. The groups to which a consumer does not belong yet can also influence. These aspirational groups are groups where an individual aspires to belong and wants to be part of in the future (Armstrong et al., 2014; Abbas, 2014) when considering social factors that would affect delivery of effective oral healthcare services.

The type of food and drink consumption also has an effect on complete denture patients when it comes to taking into account the care and maintenance aspect of it. Ideal consideration had been given to consumption of probiotic bacteria which may be associated with improved oral health. Nonetheless, probiotics and its impact on the oral microbiota of CDP patients have not been observed (Sutula et al., 2012). A 4-week consumption of probiotic drink has no overall effect on selected oral parameters in healthy denture wearers despite temporary presence of Lactobacillus casei strain Shirota (LcS). A study was conducted by Sutula, J. et al., (2012) to scrutinize the impact on the intake of a commercial probiotic product named Yakult on microbiota of saliva, tongue and prostheses biofilm in healthy CDP wearers. The study was conducted among 8 health complete denture wearing patient who undertook a 7-week trial comprising three phases: baseline; 4-week consumption of one bottle of Yakult per day, each containing a minimum 6.5×10^9 viable cells of LcS; washout period during 4 weeks. The survival rate of microbial and arrangement of saliva, tongue and denture biofilm was evaluated by using various solid measurable media. A modified OHIP-14 questionnaire was utilized in exploring denture cleaning habits of patients and also the effect of the use of dentures for improved well-being before and after study. The study showed that LcS had colonised the denture surface and the oral cavity temporarily. No major changes were seen in the success rate of Streptococcus mutans, acidogenic microorganisms, total anaerobic species and Gram-negative obligate anaerobes along the respective phases of this study. In addition, that had been no major impact of LcS on occurrence and success rates of Candida. CDP patients had an exceptional general knowledge of CDP hygiene and it was also highlighted that the responses made to OHIP-14 questionnaires had also shown improvement upon completion of the study (Sutula et al., 2012; Gera, Cattaneo, & Cornelis, 2020).

4.1.2 Economical and Demographical Factors

Economic factors are more related towards the financial acceptance a patient has and the willingness of the patient to invest in for their CDP (Berwick, 2020). The awareness level of dental information was low among complete and removable denture patients and this was associated with a low level of education and lack of accurate information. A study was conducted by Basnyat. S. K.C. et al., between June 2018 to September 2018 to assess awareness, expectation and source of information about dental implant among complete and removable partial denture wearers and to find association between them who visited Dental Outpatient Department of Dhulikhel Hospital for dental implant. The study was conducted among 300 patients where a questionnaire consisting of 6 close-ended questions was used to assess the level of knowledge and awareness. Chi-square test was used to study the association between demographic variables and awareness among patients. The study revealed differences in age (p=0.001), education level (p=0.03) and occupation (p=0.004) in awareness of dental implant and no significant difference in gender (p=0.567), when compared between complete and removable partial denture wearers. Due to lack of awareness, lower educational status and advanced age the patients responded that they "did not know" as answer to almost all the questions (Basnyat et al., 2020). Therefore, having no idea about the treatment is not going to boost the zeal of EDPs to undergo complete denture treatment (Ahuja, 2020).

Demographic factors also play thoroughly in understanding the need for complete dentures for EDPs. The use of conventional complete dentures brings negative impacts in the OHRQoL of elderly patients, mainly in case of lower prostheses that required reparation or substitution, with a removable total denture as antagonist. As study was conducted by Perea C. et al., (2013) to look into the differences on the effect of OHRQoL among CDP patients based on socio-demographics, factors related to dental prosthetics and oral status. The research was conducted among 51 patients of age range from 50-90 years who had undergone treatment with at least one complete denture at the Department of Buccofacial Prostheses of the Complutense University in Madrid. The participants answered the OHIP-14 questionnaire and the additive scoring method was used to gather variables related to prosthetics and socio-demographic. Oral conditions of patients were assessed upon undergoing clinical examination. The data was analyzed using descriptive probes and Chi-Square tests. The study showed that the predominant participants' profile was that of a man with a mean age of 69 years wearing complete dentures in both the maxilla and the mandible. The prevalence of impact was 23.5%, showing an average score of 19±9.8. The most affected domains were functional limitation and physical pain followed by physical disability. Minor impacts were recorded for the psychological and social subscales such as psychological discomfort, psychological disability, social disability and handicap. The prosthesis' location significantly influenced the overall patient satisfaction, the lower dentures being the less comfortable. Having a complete removable denture as antagonist significantly hampered the patient satisfaction. Patients without prosthetic stomatitis and those who need repairing or changing their prostheses,

recorded significantly higher OHIP-14 total scores (Perea et al., 2013; Ahmad, Mazhar, & Muhammad, 2013).

4.1.3 Policy Related Factors

Policy factors affect immensely as Fiji to date does not have a policy guideline developed on how CDP can be taken care of and maintained. Due to the recent increase in the elderly population, there is a sheer need to consider this group for an improved QoL. One of the prime factors the affect the QoL of the elderly population is Oral health especially when developing oral health policies. Presently, there is a moderate OHRQoL in the elderly patients, who have oro-dental problems. A study was conducted by Motallebnejad M. et al., (2015) to assess the aged population and the impact of oral health on OoL in Babol, Iran. The research was conducted by the use of sampling technique known as multi-stage cluster among 300 aged patients of age 65 years and over. The Persian version of OHIP-14 questionnaire was used to assess the OHRQoL. Data collection was conducted using oral examinations and interview where details based on gender, age, occupation, education, the date of the last dental visit, use of prosthetic appliances, and dental treatment needs, including the periodontal, prosthetic, and surgical needs, were recorded. Mann-Whitney and Kruskal-Wallis tests on SPSS was used to analyze the data. The study showed that no major impact was identified in OHIP-14 scores related to gender, involving least scores based on academic education. Participant with prosthetic appliances showed lesser scores in the OHIP-14 as to the ones without prosthetic appliances. Patients who were edentulous showed higher OHIP scores than the dentate patients. No correlation between age and OHIP-14 scores were highlighted (Motallebnejad et al., 2015). Such outcomes are vital contributors to the development of effective prosthetic oral health policy for the people of Fiji (Watt et al., 2019; Al Deeb at al., 2020; Listl, 2019).

4.1.4 Physical Factors

Physical factors such as the way patients and DPs live also affects their understanding on the care and maintenance of CDP. There needs to be effective denture cleaning habits adapted by the patients. Majority complete denture patients maintain their denture hygiene in good condition yet it is vital for these patients to be given proper post-insertion guidelines regarding maintenance of denture hygiene. Major origin of cleaning prostheses had been by the use of brush and water which most patients perform regularly. A study was conducted by Jandial, S., (2017) to find out the rate of CDP hygiene in patients where 146 geriatric patients were assessed on CDP hygiene habits by the use of self-administered structure proforma to identify the CDP wearing habits, practices of CDP cleaning, storing and denture wearing habits at night. Analysis of data was performed by the use of SPSS Version 16.0 at p value <0.05. The research showed that 41% geriatric patients cleaned their dentures. Majority patients' clean dentures using brush and water (46.1%) followed by use of water only (29.8%). 45% of patients wear CDPs in the day while 36.4% had utilized it during mastication of food. Upon examining, it was concluded that CDP condition was good in 52.7% patients, while 30.1% was fair and 17.2% was poor. Furthermore, the Pearson Correlation had highlighted positive correlation on the rate of cleaning and condition of CDPs (Jandial, 2017; Mahboubi et al., 2020; Sharma et al., 2020).

4.1.5 Health Service Related Factors

The effectiveness of delivery of oral healthcare services is also considered an important factor related to the provision of efficient care and maintenance of CDP. Measuring dental clinic service quality is a major factor in improving prosthetic oral healthcare for the EDPs in Fiji. The quality provided plays an important role in patient satisfaction and perception towards their CDP. A study was conducted by Bahadori, M. et al., (2015) to identify factors affecting dental service quality from the patients' viewpoint. A cross-sectional, descriptive-analytical study was conducted among 385 patients from two work shifts using stratified sampling proportional to size and simple random sampling methods in a dental clinic in Tehran between January and June 2014. A self-administered questionnaire was designed for the study based on the Parasuraman and Zeithaml's model of service quality which consisted of two parts which are the patients' demographic characteristics and a 30-item questionnaire to measure the five dimensions of the service quality. The data was analyzed using SPSS 21.0 and Amos 18.0 through some descriptive statistics like the mean, standard deviation, as well as analytical methods, including confirmatory factor. The study showed that the correlation coefficients for all dimensions were higher than 0.5. In this model, assurance (regression weight=0.99) and tangibility (regression weight=0.86) had, respectively, the highest and lowest effects on dental service quality (Bahadori et al., 2015). Therefore, it can be understood that delivery of oral healthcare service does have an impact on these EDPs when it comes to their CDP (Zaitsu, Saito & Kawaguchi, 2018; Bukleta et al., 2019; Mastilovic et al., 2021).

5. Conclusion

The current literature highlights on the factors affecting care and maintenance of CDP to improve the longevity of CDPs and its utilization. Social and cultural factors related to care and maintenance of CDP can be attained by being in a like-minded reference group to improve lifestyle and eating patterns. Economical and demographical factors towards CDP care and maintenance can be achieved through standardizing treatment costs for complete dentures and establishing more dental prosthetic clinics to provide CDP treatment to every EDP in Fiji. Policy related factors towards CDP can be made more efficient by having periodic review of CDP care and maintenance guidelines in Fiji. Physical factors can be maximized by effective engagement of both dental professionals and the patients towards undergoing a thorough practice on denture care. Finally, Health service related factors can be improved by utilizing quality CDP fabrication materials and decentralizing Dental prosthetic clinics to cater a wider range of population for its effectiveness.

Ethical Approval

Not Applicable

Funding

This work was supported by College Human Health Research Ethics Committee (CHHREC). The sponsors had no role in conceptualizing, designing, or writing of this manuscript.

Author Contribution

MN and MM planned and designed the study. The study was supervised by MM. MN collected abstracts and both authors contributed to the abstract screening and extracting the data with the drafting and revising of the paper and gave final approval of the revision to be published, and agree to be accountable for all aspects of the work.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Utilization of Rehabilitation Services at a Public Health Facility in KwaZulu-Natal

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| Received: November 23, 2021 | Accepted: January 10, 2022 | Online Published: March 1, 2022 |
|-----------------------------|----------------------------|---------------------------------|
| doi:10.5539/gjhs.v14n4p19 | URL: https://doi.org/10.5 | 539/gjhs.v14n4p19 |

Abstract

Background: Rehabilitation services are recognized as part of an essential service within all levels of care across the health system. The aim of the study was to assess the utilization of rehabilitation services at a public health facility.

Method: A cross-sectional design was implemented. Data were collected utilizing a questionnaire. A systematic random sampling strategy was used. Descriptive statistics were summarised using frequencies and binary logistic regression model was used. A p-value less than 0.05 was deemed statistically significant.

Results: Eighty-three (26.3%) participants utilized rehabilitation services. The most common reason for utilizing rehabilitation services at the public health facility was close proximity 23 (28%) whilst 18 (22%) of the participants highlighted that they had been referred to the hospital. Fifteen participants (18%) reported that they utilized the chosen health facility due to personal preference and 12 (14%) indicated that the facility was the only one they knew. Nine (11%) participants utilized the facility due to reduced transport cost incurred and six (7%) of participants chose a facility due to the perceived reduced waiting times in comparison to other facilities. Race was strongly associated with utilization of rehabilitation services.

Conclusion: The utilization of rehabilitation services in the public health facility was low. Convenience and patient referral to the hospital were the main reasons why patients chose a facility. The health professionals involved in rehabilitation services should raise awareness about the services available in the facility.

Keywords: Health services, healthcare utilization, rehabilitation services, public health facility

1. Introduction

The World Health Organization (WHO) recognizes rehabilitation as a needed health service to ensure the realization of universal health coverage. (World Health Organisation, 2018) Rehabilitation services are utilised by people across the lifespan to optimize their engagement with daily activities (Louw, Twizeyemariya, Grimmer& Leibbrandt, 2019). There is an increasing need for rehabilitation services at all levels of health care to ensure that patients are integrated well into their home environment (Caplan, 2011).

The WHO has estimated that one billion people require rehabilitation and the demand for rehabilitation services is greater in developing countries (WHO, 2019). Rehabilitation services include physiotherapy, occupational therapy, audiology and speech therapy (Kumar, 2012). The choice of selecting rehabilitation services is largely dependent on the availability of beds, geographical location of the health facility and transport (Caplan, 2011). Factors that influence a patient's decision to utilize healthcare services and rehabilitation are dependent on cultural and social influences (Luiz J, 2004). Poverty, quality of care, availability of resources, and service delivery contributes to the utilization of health care services (Sibiya, 2013; Adam, 2014; Chia, 2014). In addition, competent human resources are crucial in promoting utilization of health services (Adam, 2014).

Rehabilitation is not an optional health service for those who live in urban areas or those that can pay for private insurance (WHO, 2019). Rehabilitation services should not be viewed as an alternative when preventive and curative interventions fail. Rehabilitation services should be accessible and affordable to all patients irrespective of their social or economic background (WHO, 2019). Furthermore, rehabilitation interventions should commence in

the early phase of in order to prevent secondary health conditions.

South Africa (SA) has reported a high burden of communicable diseases and non-communicable diseases respectively. The progression of communicable diseases may cause neurological impairments, dementia, mental illness, TB of the spine, joint disease, pain and fatigue (National Department of Health, 2016). Furthermore, these health conditions often impact on one's physical functioning and may develop impairments (National Department of Health, 2016; WHO, 2019). This means that more patients will need rehabilitation services to regain maximum function and increase their physical and environmental independence.

The demand for rehabilitation services is largely unmet due to a number of factors such as: inadequate rehabilitation services in rural settings, prolonged waiting times, shortage of assistive technologies and devices (WHO, 2019). Majority of patients in KZN seek rehabilitation care for injuries as a result of trauma, HIV-related disabilities, musculoskeletal and medical conditions. There is paucity of literature with regards to utilization of rehabilitation services in public health facilities in SA. The study purpose was to assess the utilization of rehabilitation services at a public health facility in KwaZulu-Natal (KZN).

2. Methodology

A cross-sectional survey was conducted. Patients who sought treatment at the facility's outpatient unit were recruited. In KZN, there are 61 hospitals and 178 clinics which are operated by the public health sector. The chosen facility is a regional hospital with a bed capacity of 543. The hospital is one of the major hospitals located in a suburb in the eThekwini health district. The facility offers a comprehensive package of care and has a catchment population of over 1 500 000 which makes this facility suitable to conduct the study. The facility offers both out-patient and in-patients which includes obstetrics and gynaecology, orthopedics, surgery, intensive care, pediatrics, and medical units. Rehabilitation services consists of physiotherapy, occupational therapy, audiology and speech and hearing therapy. The rehabilitation services are subsidized up to 40% of total costs and the charges are based on one's income. A systematic random sampling approach was used. The first participant was selected at random and thereafter every third person was selected to achieve the targeted the number. A standardised questionnaire was used. Variables measured in the questionnaire included demographic information, utilisation of rehabilitation services at that public health facility.

The data were coded and entered in a Microsoft Excel spreadsheet and then exported into SPSS version 27. Frequency distribution tables and graphs (bar and pie charts) were used to summarise the demographic characteristics and the distribution of the utilization of the rehabilitation services. Logistic regression was used to determine the socio-demographic characteristics associated to the utilization of rehabilitation services. The variables that were shown to be significant (p < 0.05).

The researcher obtained approval from the University of KwaZulu-Natal (BE427/18), and the KwaZulu-Natal Department of Health (KZ_2018_) Each study participant received an information sheet and provided written informed consent.

3. Results

Of the 424 questionnaires administered, 376 were adequately completed yielding the response rate of 98%. The average age of the participants was 55(SD 14.7) with majority being female (n=247; 68.4%) and aged between aged between 31 and 55 years (n=202; 57.5%). Most of the participants were employed (n=218; 58%), utilized public transport (n= 249; 76.4%) and earned between R0–R5 000 (n=125; 65%) per month. Almost half of the participants (n=176; 51.6%) resided more than 10km from the regional hospital, were Indian (n=198; 54%) and had less than a matric qualification (n=154; 45.6%). (Table 1)

Missing

Demographic characteristics Number Percentage Age (years) (18 - 30)74 21.1 202 57.5 (31-55) 58 (56 - 70)16.5 (70+)17 4.8 Missing 25 Gender Female 247 68.4 Male 114 31.6 Missing 15 Race group Black 153 41.7 White 5 1.5 Indian 198 54 Coloured 4 1.4 Other 4 1.4 Missing 12 **Educational Status** Matric 154 45.6 No matric 145 42.9 Diploma 24 7.1 Degree 15 4.4 38 Missing **Employment status** Employed 218 58 Unemployed 127 33.8 Missing 31 Participants that reside: within 10km of the hospital 165 48.4 more than 10km from the hospital 176 51.6 Missing 35 Mode of transport Private 80 21.3 Public 257 68.4 39 Missing Income levels (in ZAR) $(0-5\ 000)$ 125 61 (5001-10 000) 48 23.4 (10 001-14 000) 4 2 (14 001 and above) 28 13.7

Table 1. Sociodemographic profile of participants utilizing the facility (n=376)

Figure 1 below shows the distribution of the utilization of rehabilitation services, approximately 74% of the participants were not utilizing rehabilitation services, whereas 26% were utilizing rehabilitation services.

171

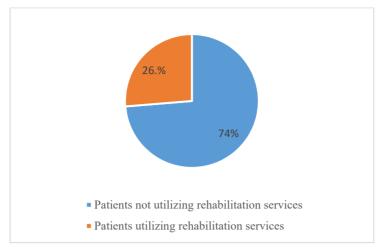


Figure 1. Distribution of Patients' utilization of rehabilitation services

Figure 2 below shows the various rehabilitation services used participants. Approximately, 49% of the participants were utilizing physiotherapy, 35% were using occupational therapy and 16% were utilizing speech and audiology services.

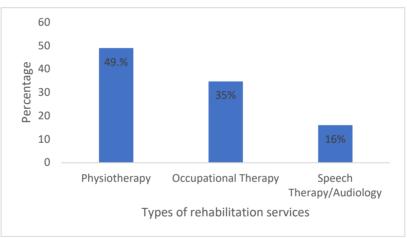


Figure 2. Types of rehabilitation services used by patients

Secondly the study sought to identify reasons that influenced the participants' decision to utilize rehabilitation services at the public health facility. Eighty-three (26.3%) of the participants indicated that they were utilizing rehabilitation services. The most common reason for utilizing rehabilitation services at the public health facility was that the facility was closest to them 23 (28%) whilst the main reason for 15 (18%) of the participants was that they had been referred to the hospital by nearby facilities. Sixteen participants (19%) reported that it was their personal preference to utilize the chosen health facility and 14 (17%) indicated that the facility was the only one they knew. Nine (11%) participants utilized the facility due to reduced transport cost incurred and six (7%) of participants chose the facility based on perceived reduced waiting times (Table 2).

Table 2. Reasons for utilizing rehabilitation services at the public health facility (n=83)

| Reasons for using public facility for rehabilitation services | Frequency | Percentage |
|---|-----------|------------|
| Only facility I know | 14 | 17 |
| Nearest facility to me | 23 | 28 |
| Reduced waiting time | 6 | 7 |
| Referred to the facility | 15 | 18 |
| Personal preference | 16 | 19 |
| Transport cost is cheaper | 9 | 11 |

Thirdly, the relationship between participants' utilization of rehabilitation services and sociodemographic characteristics was established. Race was significantly associated to the utilization of rehabilitation services. Black participants were approximately 4 times (aOR = 4.22 [95% CI: 1.42, 12.6]) more likely to utilize rehab services when compared to other racial groups accessing the hospital. More still, participants earning between R5 001 – R10 000 were 3 times (aOR = 2.97 [95% CI: 0.52, 17.06]) more likely to utilize rehabilitation services compared to those earning more than R14000. Furthermore, participants who had matric or a higher education qualification were more likely (aOR = 1.88 [95% CI: 0.72, 4.87]) to use rehabilitation services when compared to those with an education qualification less than matric. Unemployed participants were also more likely (aOR = 1.14 [95% CI: 0.67, 1.96]) to utilize rehabilitation services when compared to the employed ones. Table 3 summarises the logistic regression for the factors associated to the utilization of rehabilitation services.

| Characteristics | Odds ratio | CI | Pp - value |
|---------------------------|------------|--------------|------------|
| Gender | | | |
| Female | 0.91 | 0.65 - 2.25 | 0.83 |
| Male (ref.) | | | |
| Age | | | |
| (18-30) | 0.51 | 0.03 - 10.60 | 0.67 |
| (31-55) | 0.46 | 0.03 - 8.42 | 0.60 |
| (56-70) | 0.24 | 0.02 - 6.11 | 0.39 |
| 70+ (ref.) | | | |
| Race | | | |
| Black | 4.22 | 1.42 - 12.60 | 0.01* |
| Other races (ref.) | | | |
| Distance | | | |
| Less than 10 km | 2.05 | 0.79 - 5.33 | 0.14 |
| greater than 10 km (ref.) | | | |
| Income status | | | |
| $R0 - R5\ 000$ | 1.83 | 0.34 - 9.82 | 0.48 |
| $R5\ 001 - R10\ 000$ | 2.97 | 0.52 -17.06 | 0.22 |
| more than R 14001 (ref.) | | | |
| Mode of transport | | | |
| Public | 0.99 | 0.34 - 2.93 | 0.99 |
| Level of education | | | |
| Matric or more | 1.88 | 0.72 - 4.87 | 0.19 |
| No Matric (ref.) | | | |
| Employment status | | | |
| Unemployed | 1.14 | 0.67 - 1.96 | 0.62 |
| Employed (ref.) | | | |

Table 3. Relationship between participants utilization of rehabilitation services and sociodemographic characteristics (n=376)

*(ref): The reference for calculating odds ratio.

4. Discussion

The purpose of this study was to assess the utilization of rehabilitation services at a public health facility in KZN. The current study findings indicated that 26.3% of patients utilized rehabilitation services at the health facility. The

low utilization of rehabilitation services is a great concern considering that KZN has a high burden of non-communicable diseases, injury, TB and HIV which has an impact on the need for rehabilitation services (KZN, 2015). Previous studies reported low utilization and accessibility of rehabilitation services (Leitarts, 2014; Alshehri, 2018). The low utilization of rehabilitation services could be attributed to a lack or awareness of rehabilitation coupled with poor referral systems and to prejudices associated with rehabilitation services (Leitarts, 2014; Adam, 2014).

Most of the patients in this study reported that there were utilising physiotherapy services. Rehabilitation professionals include occupational therapists, physiotherapists, speech therapists and audiologists. Each type of rehabilitation therapy can be accessed in various healthcare settings such as inpatient, outpatient and community-based rehabilitation services. The key focus is to restore and improve function and mobility. Rehabilitation services are essential in preventing disease progression and complications. This in turn improve the quality of life and as well as improved reduce disabling effects that result from chronic illnesses and injuries. The inclusion of rehabilitation services within the health care system offer a continuum of a multidisciplinary and coordinated approach. Socio-economic factors have large influence on the utilization of health care services (Stellenberg, 2015). Social, cultural and environmental circumstances reflect choices to utilize healthcare (Chia, 2014). The current study found that geographical location and referral patterns were reported as the common reasons for using rehabilitation services at the public health facility. This concurs with the findings of a study done in Kenya which concluded that distance influences utilization of medical and health services (Prosser, 2007).

Patient's perceptions and attitudes plays a major role in the utilization of health services (Buor, 2005). The individual preferences are largely associated with perceived need, past experiences and health literacy. In addition, patient's preferences are influenced by quality of health services, staff attitudes and availability of equipment (Adam, 2014). About a third of the participants reported that they preferred to utilized the chosen health facility. Further study needs to be conducted to establish what influenced the patient's preferences to utilise rehabilitation services at the public health facility.

The financial cost incurred to travel to a health institution can pose a barrier to utilization of health services. Perceived high costs of services could lead to low utilization of health services (Grut, 2012). Some participants in this study highlighted that the utilized the rehabilitation services at the facility because they do not spend a lot on transport for travelling.

Waiting time is an essential predictor of health service utilisation, and patient's satisfaction. Waiting times in public health facilities impacts on the patient's perception of health services and indirectly influence the decision to utilise health services at that health facility (Ogaji, 2017). To achieve a positive patient experience, in an out-patient setting, research has shown that waiting time is a crucial health service factor (Ogaji, 2017). The participants of this study indicated that they chose the facility based on the perceived reduced waiting times when compared to other facilities.

Access to health services is often associated with race (Nattrass, 2001). Health disparities have been extensively documented in SA as a result of racial divisions brought about by the legacy of apartheid (Knight, 2009; Coovadia, 2009). Black patients in South Africa, make up 52% of the total number of patients who utilize public health facilities (McLaren, 2014). This study found that black patients were most likely to utilize rehabilitation services more than any other race group at the hospital.

4.1 Study Limitations

The study was conducted in a public health facility in one health district. Further study needs to be conducted to establish the utilisation of rehabilitation services in other districts within KZN province. Furthermore, this study was an exploratory descriptive study and did not seek the level of quality of care and what rehabilitation services does for these patients. A qualitative study should be conducted to explore this further.

5. Conclusion

The utilization of rehabilitation services in the public health was low. Participants utilised rehabilitation services based on their perceived waiting times, personal preference, patient referral and geographical location to the health facility. The health professionals involved in rehabilitation should raise awareness about the availability of rehabilitation services in public health facilities.

Acknowledgements

The authors acknowledge the participants of the study.

Authors' Contributions

JK- Principal author was responsible for the development of the conceptualisation, analysis and writing of the manuscript as part of the Master's degree.

T.D- was responsible for supervising the entire thesis and helped in the writing of the manuscript.

BT- was responsible for data analysis.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Screen Viewing Behaviour among Children under 2 Years in Fiji: Reasons and the Perceptions of Parents/Caregivers

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Received: January 4, 2022Accepted: February 21, 2022Online Published: March 11, 2022doi:10.5539/gjhs.v14n4p27URL: https://doi.org/10.5539/gjhs.v14n4p27

Abstract

Background: Screen-viewing among children has become a growing public health concern. There is no existing research done in Fiji on children's screen viewing behaviour, therefore, this study aimed to determine the reasons and the perceptions of parents/caregivers in affecting screen viewing behaviour among children under 2 years in Suva Fiji.

Materials and Methods: This cross-sectional mixed method study was conducted at three randomly selected Maternal Child Health (MCH) clinics among parents or accompanying guardians of children under two years old. Using proportional sampling, 361 participants who met the study criteria participated in this study. Data collection was carried out using a 20-item self-administrated questionnaire for quantitative study and a semi-structured open-ended questionnaire for the qualitative study through two Focus Group Discussions (FGDs). Descriptive analysis was used for quantitative data and thematic analysis was applied for the qualitative data to emerge themes.

Results: Most children (32.8%) watched screens several times in a week, regardless of age. The main reason for children's screen time is that it is a distraction tool (29.9%) followed closely by using it to calm child or to prevent negative behaviour (26%) and education (22%). The study found that most of the parents/ caregivers know that there are negative consequences of screen time on their children. Majority of these parents/ caregivers (66%) however think that the only effect is that related to children's eye health and are unaware of the other health consequences. About 24% think that there is no negative effect at all on children engaged in screen viewing. The study also found that more than half (56%) of the parents (or caregiver guardians) think that screen viewing below the age of 2 years actually has positive consequences on children. Of these the vast majority (76.7%) think that screen viewing makes their children smart/ helps them to learn from a very young age.

Conclusion: The findings of this study highlighted the main reasons of screen viewing among children under 2 years.

Keywords: Screen viewing, parental/caregiver perception, children below 2 years, Fiji

1. Introduction

Screen-viewing among children remains a global public health concern (Stiglic & Viner, 2019; Vanderloo, 2014). Today, discretionary screen time, often involving multiple devices such as television, smart phones and tablets, is the single main experience and environment of children (Vanderloo, 2014; Sigman, 2014). Now more than ever, children from a very young age are allowed unlimited access to a wide variety of screen devices, and the prevalence is increasing (Stiglic & Viner, 2019; Vanderloo, 2014; Sigman 2014; Segev et al., 2015). Child development experts recommend limiting children's daily screen time. This is because real-life interactions with parents and others are much better for the child's wellbeing, learning and development (Sigman, 2014; Segev et al., 2015).

Mounting evidence has shown that many children start using screen media in infancy and increase their media use through infancy (Domingues-Montanari, 2017; Duch et al., 2013; Heelan & Eisenmann, 2006; Rideout et al., 2010; Cox et al., 2010). Excessive screen-viewing has been linked to several paediatric health determinants and outcomes (Hinkley et al., 2012; Sigman, 2017; WHO, 2019), and with several risk factors that affect this behaviour (Vanderloo, 2014; Sigman, 2017; Moon et al., 2014; Mark, 2008; Xianhua-Wu, 2013). Screen time is associated with obesity mainly through the displacement of time available for physical activity and more directly through reduction in metabolic rate (Domingues-Montanari, 2017). There is also evidence that high screen time is

associated with deleterious effects on irritability, low mood and cognitive and socioemotional development, as well as speech and language development delays (Domingues-Montanari, 2017; Duch et al., 2013; van den Heuvel, 2019).

The recognition that early childhood years play a fundamental role in the development of health-related behaviours, coupled with concerns about young people's screen time, have prompted various countries to issue guidelines on screen time for children. Currently Canada and Australia recommend no screen time exposure for children under two years old and less than an hour a day for 2–5-year-olds (Canadian Paediatric Society and Australian Government Department of Health). The American Academy of Paediatrics recommends a maximum of one-hour screen time a day for children aged 2 to 5 years old. Babies below 18 months should not be given access to screens (Sigman, 2017). The World Health Organization (WHO) recommends that children younger than a year should not be exposed to any electronic screens. It also recommends that children of ages two to four have no more than one hour per day of sedentary screen time including playing computer games or watching television (WHO, 2019).

Children are allowed screen time for various reasons, from keeping them entertained to ensuring they are well behaved, using it as a reward or punishment (Xianhua-Wu, 2013; Bentley et al., 2016). Parents and caregivers can mediate children's access to and use of screen devices. In Fiji, 213,004 children age less than 5 years and of these 91,830 are from the Suva sub-division (Fiji MoHMS, 2021). The engagement in screen viewing by children of this age range is highly obvious in Suva however, there has been no study conducted locally on-screen viewing behaviour of children. This study therefore aimed to find the reasons for screen viewing and to analyse the role of parental relationship in affecting this behaviour among children under 2 years in Suva, Fiji. Findings from this study will help to fill a gap in literature at a local level and bring to attention the public health concern for young children not often talked about in Fiji or in the Pacific.

2. Materials & Methods

2.1 Study Design and Setting

A mixed method study was conducted including both qualitative and quantitative techniques of data collection and both types of data were collected at the same time and integrated. Three Maternal and Child Health (MCH) clinics were randomly selected from the eight designated MCH clinics in the Suva subdivision, Suva, Fiji. These included the Nuffield, Valelevu and Makoi MCH clinic.

2.2 Study Sample

This study included the parents, grandparents, guardians or caregivers who brought at least one child aged less than 2 years, child was living in Suva and attended the three MCH clinics during the study period. Those who were not willing or able to participate in this study were excluded.

In-order to get the actual participants for the research, a purposive sampling was used and the total population of children less than 2 years was obtained from the Expanded Programme on Immunisation (EPI) monitoring registers of the 3 MCH clinics. The EPI monitoring register keeps records of children's personal details, growth and immunisation and nutritional data, and milestones for each child. The total population of registered children under 2 years at the 3 clinics was found to be 5832. A proportional sampling method was then used to calculate the sample size using a 5% margin of error and 95% Confidence Interval (95% CI) of parents or accompanying guardian of children aged less than 2 years at the 3 selected MCH clinics in the Suva subdivision. After adding 18 as 5% non-respondent rate, the total sample size for this study was 361.

2.3 Data Collection Tools

A 20-item structured questionnaire was used to collect quantitative data. The structured questionnaire included a set of standardized questions that explored the screen viewing behaviours of children aged less than 2 years. The questionnaire had two sections. The first section included 7 demographic questions to identify characteristics such as age of child, sex of respondent parent, place of recruitment, childbirth order, number of children, ethnicity and daytime care giver arrangement while the second section focussed on screen viewing behaviour. In the second section there were various styles of questioning used including two Yes/ No questions, which asked whether the participant thought there was any negative consequence of screen time on the child and whether the participant thought there was any positive consequence of screen time on the child, 9 multiple choice questions were used mainly to measure frequency of child's screen time, number of apps downloaded for the child, child's ability with mobile devices and so forth and there was one rating scale question which sought to determine child's age at first use.

For the qualitative study, a semi-structured open-ended questionnaire was used to collect data through Focus

Group Discussion (FGD). There were 8 questions with some probing questions asked as needed to facilitate discussions. The researcher also took note of important demographics for example the date/ time of FGD, number of participants, sex of participants, venue. A non-directive style of interviewing using open-ended questions was used allowing the participants some freedom to control pacing and subject matter of the interview, while a more directive style of questioning was used to get more clarification of information that the participants will be providing.

Pilot testing was done at the Makoi and Nuffield MCH clinics with a sample of eight volunteer participants who met the inclusion criteria of the study ensuring that the questionnaire was readable and understandable by participants. It was also tested by two experts to validate content of the tool. Following the pre-test, minor changes were made to the questions and structure of the data collection tools.

The main predictor variable for this study was infant/ toddler screen time. Additional variables were studied to explore relationship with the main predictor (screen time). This included frequency of screen viewing, reasons, use of software applications, and consequences as perceived by parents/ caregivers.

2.4 Data Collection Procedure

Data collection happened between 1st March and 30th September 2019. The main researcher organised an initial meeting with the Sub-Divisional Medical Officer (SDMO) and sister-in-charge of the three MCH clinics. A week earlier than the actual data collection, prior awareness was also done with the medical officer, sister-in-charge and zone nurses of the MCH clinics to highlight the importance of this study and the support needed from the clinics. This was also an opportunity to discuss in detail plans for data collection and obtain the total number of children younger than two years on record at the clinics.

During the data collection period, the main researcher travelled to the MCH clinics to fill in the questionnaires with each participant. Participants were invited to an anonymous, one-on-one questionnaire administered by the researcher while waiting to see the health care providers at the clinics. With support of a MCH nurse on duty, an announcement about the study was done to all waiting participants in the three major languages, English, Hindi and *iTaukei*. In the announcement, information about the survey was shared and an open invitation made to potential participants to be part of the study. Recruitment of participants was done by the researcher. Participants who brought more than one eligible child to the clinic completed the questionnaire only for the youngest child. For those who volunteered to participant, a next round of one-on-one information was provided. Participants provided informed verbal and written consent prior to taking part in the study. Questionnaires were filled in by the researcher with each participant at a designated confidential space within the MCH clinic. Translations of the questionnaire was done in Hindi and *iTaukei* depending on the need of participants. In cases where both parents were present, both were included when filling the questionnaire and it was left to the parents to decide who took the lead in answering.

For qualitative data, two FGDs were held with 11 participants with 5 – 6 participants in each FGD. Existing subjects that were known to the main researcher (from the quantitative survey), recruited other subjects in their area who met the inclusion criteria to be part of FGDs. Information about the FGD were shared with all participants at least 3 days in advance via phone calls or personal visits. Their confirmation for participation was sought via follow up phone calls. As and where needed, travel arrangements for participants was done by the main researcher, which included buses and taxis. Additional support with regards to childcare and toys/ activities children can engage was organised while parents were attending to FGDs. The main researcher conducted the FGDs and a note taker was assigned to help with note taking. Each FGD was a maximum of one hour followed by a light refreshment, and held at a designated common place in the community. The entire program finished within 90 minutes so that parents could return home in time for childcare and other duties. After 2 FGDs theoretical data saturation was reached. Facilitation was a crucial element of the FGDs. Particular consideration was given to ensure even participation, careful wording of the key questions, and maintaining a neutral attitude and appearance. Sessions were summarised to reflect the opinions evenly and fairly.

All possible safeguards were used to protect participants' rights. Participants were advised of the voluntary nature of their participation and that they could withdraw from the study at any time. Information sheet was given, and written consent sought during both qualitative and quantitative data collections.

2.5 Data Management and Analysis

For the quantitative data, data was entered to the KoBo Toolbox for data cleaning and coding and then transferred to Microsoft Excel for further analysis using the Excel's Analysis Toolpac feature. Data was analysed using descriptive statistics. Chi square test was used for categorical variables to assess the relationship between risk

factors and screen viewing.

For qualitative data, the first step was to transcribe all the data. The raw data was largely unstructured or sometimes made no sense. Hence the first step converted all data into textual form. The collected data was then organised according to the research objectives or questions in a visually clear way. This was achieved using tables. The research objectives were input into the table and data was assigned according to each objective. Categories were then generated noting patterns in the data, relating to the topics described by interviewees. A manual thematic analysis was used (19) data analysing was done based on a structure predetermined by the researcher. The research question was used as a guide for grouping and analysing data. While analysis of raw data was done from FGDs to form categories or themes, the researcher had setup some codes already and defined them according to the source (e.g. literature review). However, when some coded segments of the text do not fit the categorization matrix, it was possible for new categories to be created.

2.6 Ethical Considerations

Upon receiving the necessary ethical approval from the Fiji National University's (FNU) College Health Research Ethics Committee (CHREC) and from the Fiji National Health and Research Ethics Committee (FNHREC), the researcher sought a written approval from the Sub-Divisional Medical Officer (SDMO), Fiji Ministry of Health and Medical Services (MoHMSs) to carry out the research work at the three MCH clinics in Suva. Informed consent was taken from all participants in the study.

3. Results

3.1 General Characteristics of Participants

A total of 361 participants (with the response rate of 89%) answered the questionnaire completely or were part of focus group discussions. The study participants responding were predominantly female (82%). Majority of children (69.8%) were younger than 12 months of age and was the youngest child (53.5%) when it came to childbirth order. Daytime caregiver arrangement was predominantly parents (71%), and ethnicity was predominantly *iTaukei* (74%). The total number of children at home was quite uniformly distributed (Table 1).

| Variables | Frequency (n) | Percentage (%) |
|---|---------------|----------------|
| Place of recruitment | | |
| Makoi MCH clinic | 136 | 38 |
| Nuffield MCH clinic | 124 | 34 |
| Valelevu MCH clinic | 101 | 28 |
| Child age | | |
| < 12 months | 252 | 69.8 |
| <u>≥</u> 12 -> 24 months | 109 | 30.2 |
| Participants' sex | | |
| Male | 32 | 13 |
| Female | 308 | 82 |
| Male and female | 21 | 5 |
| Childbirth order (n=355) | | |
| Youngest child | 190 | 53.5 |
| First born | 154 | 43.4 |
| Middle child | 11 | 3.1 |
| Daytime caregiver arrangement (<i>n</i> =355) | | |
| Parents | 252 | 71 |
| Grandparents | 72 | 20.3 |
| Nannies | 20 | 5.6 |
| Home-based caregiver | 11 | 3.1 |

Table 1. Demographic characteristics of study participants (n=361)

| Total number of children at home (<i>n</i> =358) | | | |
|---|-----|------|--|
| 1 | 109 | 30.4 | |
| 2 | 126 | 35.2 | |
| > 2 | 123 | 34.4 | |
| Ethnicity | | | |
| iTaukei | 267 | 74 | |
| Fijian of Indian descent | 76 | 21.1 | |
| Others | 18 | 5 | |

3.2 Frequency and Reasons of Screen Viewing

As Table 2 shows, most parents/ caregivers let their children watch television or smart phones (or other screen devices) sometimes (37.7%) and often (20.8%) when out running errands, doing chores around the house or to keep child calm in public places. Only 22.2% never leave children unsupervised with screen viewing activity.

Table 2. Frequency of screen viewing when caregiver is out running errands or doing chores

| | Frequency (n) | Percentage (%) |
|-------------|---------------|----------------|
| Sometimes | 136 | 37.7 |
| Often | 75 | 20.8 |
| Hardly ever | 21 | 5.8 |
| Never | 80 | 22.2 |

As presented in Table 3, the main reason given for children's screen time use was that it is a distraction tool (29.9%) followed closely by using it to calm child or to prevent negative behaviour (26%) and education (22.4%).

| Reasons | Frequency (n) | Percentage (%) |
|---|---------------|----------------|
| Distraction tool | 108 | 29.9 |
| To calm child/ prevent negative behaviour | 94 | 26.0 |
| Education | 81 | 22.4 |
| For baby/ toddler to rest | 19 | 5.3 |
| Family time | 18 | 5.0 |
| Other | 16 | 4.4 |
| Babysitter | 2 | 0.6 |
| Used as a reward/ punishment | 1 | 0.3 |

Table 3. Reasons for screen viewing by children

The result of qualitative study also showed that majority of participants use screen time as a reward or punishment for certain behaviours.

"I give the phone if he is good and it stops him from going outside to the neighbour's house to watch TV.....we have no TV so I give him the phone to watch...he watches ABC, songs and kids things and is learning from it...he watches while I prepare dinner....I ask him to not take the phone too close to the eyes...he is smart, learning fast from the phones, he knows how to turn it on now, [giggles] learning to sing and dance, it keeps him happy...but sometimes he runs away to watch TV outside, neighbours house, then he is there and won't want to come back quickly, they have a baby also...I prepare food then go and get him...." (Mum of 2-year-old, FGD participant)

Participants also mentioned that provision of phones or allowing the infant to screen-time is a form of entertainment:

"For me watching cartoons on the phone and TV is a good form of entertainment for my one-year-old as she has

nothing much to do ... " (Mum of one year old, FGD participant).

In many cases, caregivers allow screen time as a form of distraction, so it enables them to do other chores or even calms them down.

"My child becomes very frustrated and bangs his feet and hands when I do not give the phone to him so I have no choice but to give it, he watches until the battery goes down (giggles from mum) ...in one way it is good as it keeps him inside the house and not running away to the neighbour's house, otherwise he will not be home..." (Mum of 18-month-old, FGD participant).

Another participant stated:

"I give him the phone and TV to watch while I prepare the meals. That way he is kept busy and lets me do all my work" (Mum of 1 year old, FGD participant).

It was alos noticed by another participant that;

"When he cries, I give the phone and he stop crying [giggles], it helps to calm him down...baby watches and watches and then feels sleepy ...it helps him to sleep, especially the nursery rhymes on the phone" (Mum of 7-month-old, FGD participant)

Screen-time is also allowed by caregivers for educational purposes, to learn how to read and to expose children to early learning in life:

"We live in this modern world where kids need to know and learn early about how to keep up to the world, but limits are important" (Dad of 4-month-old boy, FGD participant)

Another participant mentioned that:

"For me I don't want my little one to watch TV or phone, but I am working and people at home show her the phone. She watches TV in the daytime together with grandparents and that keeps them occupied, like she does not watch full time but it's in the background, so she watches from time to time...." (Mum of 2-year-old girl, FGD participant)

3.3 Frequency of Applications Used

As Table 4 presents, 30.5% of the participants downloaded apps on their mobile devices for children to use, and of these, almost half (46%) downloaded more than two apps and 43% downloaded one app. 11% downloaded two apps. 69.5% of the participants did not download any apps on the mobile devices. Educational, entertainment and content delivery apps were popular across all age groups. For participants that did not download any apps, children that were engaged in screen viewing (mostly via mobile device), viewed directly from YouTube, a content delivery application. YouTube was popular among children 12 - 24 months of age. Netfix, another content delivery application was also reported by at least three participants.

| Apps downloaded | Number of Apps | Frequency (n) | Percentage (%) | |
|-----------------|----------------|---------------|----------------|---|
| Yes | | 110 | 30.5 | _ |
| | > 2 apps | 51 | 46 | |
| | only 1 app | 47 | 43 | |
| | 2 apps | 12 | 11 | |
| No | | 251 | 69.5 | |

3.4 Child Ability with Screen Device

One quarter (25.5%) of the participants stated that children always needed help in navigating a screen device, 5% needed help sometimes and 5% needed help most of the time. 5.8% of the children did not need any help navigating through the screen device. 59% of the respondents did not provide an answer mainly because their child was not engaged in screen viewing.

3.5 Consequences of screen time

Majority (60%) of the participants thought that there is some negative consequence of screen viewing, while 24% thought that there is no negative consequence of screen viewing. 16% did not provide an answer mainly because they were unsure (could not say either yes or no). The main negative consequence stated was effects to children's

vision. When asked about whether there was any positive consequence of screen viewing on children, the vast majority 56% said yes while 25% said no. 19% did not provide an answer and this was mainly because they were unsure. The main positive consequence stated was that it helps in children's learning and education.

3.5.1 Negative Consequences

As Table 5 reveals, 211 participants stated that there are negative consequences of screen viewing on children. The vast majority (66.4%) noted the negative consequence as bad effect to the eye including watery eyes, swollen eyes, and painful eyes. 5.2% of participants identified addiction as the negative effect. A few of the participants (less than 2% each) stated that screen viewing affects children's sleep, has bad influence on them, had bad impact on education, distracts them from being active, makes them idle, exposes children to violent content, and makes them aggressive.

| Negative Consequence | Frequency (n) | Percentage (%) |
|---|---------------|----------------|
| Affects eyes (including watery eyes, swollen eyes, painful eyes, more blinking) | 140 | 66.4 |
| Addiction | 11 | 5.2 |
| Child does not want to socialise | 2 | 0.9 |
| Bad influence | 1 | 0.5 |
| Negative impact on education | 1 | 0.5 |
| Less communication with parents, cuts bonding time | 2 | 0.9 |
| Child not interacting with sibling | 1 | 0.5 |
| Sleep affected | 4 | 1.9 |
| Distracts children from being active, sedentary behaviour | 2 | 0.9 |
| Exposure to violent content | 2 | 0.9 |
| Kids do not want to do anything else, makes kids idle | 3 | 1.4 |
| Radiation can cause brain cancer | 1 | 0.5 |
| Aggressive behaviour | 3 | 1.4 |
| Affects brain cells | 2 | 0.9 |
| Cause headache | 1 | 0.5 |

Table 5. Negative Consequences of screen viewing as perceived by parents/ caregiver (n=211)

Qualitative study showed that some of parents/ caregivers stated that exposure to screen devices has physical consequences including effects to eyes.

"It's not good, affects eyes. Sometimes they need food but they still watching, they don't care about food" (Mother of 2-year-old boy)

Another participant mentioned:

"Radiation is not good, harms eyes...can get addicted and they become inactive watching TV for long time...." (Mother of 7-month-old, FGD participant)

Some of participants mentioned that screen time can expose children to violent content and at the same time make them aggressive.

"Can get furious when you take the tablet away from her, like if she is eating, she will throw away everything..." (Mother of 2 children, the older one 2 years watches phone and has a tablet of her own, watches every day for about an hour at a time, the younger boy 6 months does not watch but tries to snatch the phone from elder sister. Parents watch with the 2-year-old sometimes. Note they brought tablet to the MCH clinic and the 2-year-old watched full time while they were waiting).

"*My little one is addicted. If you do not give the phone, she gets angry and jumps to the floor*...." (Mother of 2 year old, FGD participant)

It was also stated that

"If they have too much screens, they don't want to do anything else. That's not good for them makes them idle -

they just sit and watch either the phone or the TV and don't want to play with the other kids outside.... he does not want to play outside with other children but with me full time...so I give him the phone while I do my other job..." (Mother of 1 year old)

3.5.2 Positive Consequences

As Table 6 shows, majority of participants (76.7%) stated that they feel screen viewing helps in their children's education, or learning process for example learning English, alphabets, colors and numbers. 4.8% stated that it helped to keep their children calm or to stop them from crying. 3.8% stated that screen viewing helped in putting children to sleep and 2.4% stated that it helped their children to talk and develop speech. The remaining less than 2% each stated that screen viewing made learning fun for children, helped in brain development of children, is a form of entertainment for children, or helps in preventing negative behaviour.

| T-1-1- (Ditime | - f | | | (-210) |
|--------------------------------|-----------|--------------|----------------------|---------------------|
| Table 6. Positive consequences | of screen | i viewing as | perceived by parents | / caregiver (n=210) |
| 1 | | 0 | 1 21 | 0 |

| Positive Consequence | Frequency (n) | Percentage (%) |
|---|---------------|-------------------|
| Helps in education, children learn from it, become smarter, learn English, alphabets, colours and numbers. Makes learning fun | 161 | 76.7 |
| Helps in brain development of child, makes them smarter | 7 | 3.3 |
| Calms baby, stop crying | 10 | 4.8 |
| Religious songs, prayer | 2 | 1 |
| Form of entertainment for baby | 2 | 1 |
| Helps children to talk, speech | 5 | 2.4 |
| Good for distracting child while doing housework | 4 | 1.9 |
| Helps in putting them to sleep | 8 | 3.8 |
| Helps in preventing negative behaviour | 1 | 0.5 |
| Family time | 1 | 0.5 |
| Helps in moving | 1 | 0.5 |

Analysis of qualitative data shows that participants think screen time has educational benefits for their children.

"I let my son view screen so that he is smart from a very young age...." (Mother of 12 months old boy)

Another participant stated:

"I have two children, this one is new born, very small so we do not give any phone to watch ...she cannot even hold the phone but gets attracted to the advertisements on television so when we watching television in the sitting room and advertisements come up, the baby tries to turn her head to watch...she takes a glimpse but does not keep watching until another loud sound of advertisement comes up...I think it is helping her to more and recognise sounds but loud sound may be not so good for her....with the older son, we let him watch cartoons and learn ABC, he is nearing 2 years but can already start talking some words in English..." (Mother of 2 children)

Screen time identified as a firm of entertainment for children.

"I put TV on and its entertainment for all of us...it makes us happy and busy at home...We watch the serial 'Pavitra Rishta' and some others and very little film...my daughter in law and son goes to work and me and my husband look after my son's baby, he is getting naughty, before it was good when he was small it was easy yeah, just change the diaper and give milk but now he is pulling everything on the floor...crawling very fast and may be walking soon....it's good the phone calms him, we give it sometimes when he doesn't want to eat, we give the food and he start eating [giggle]... its good and bad, we should not give too much and just little..." (Grandparents of 9 month old baby)

4. Discussion

This study filled a gap in literature at the local level by determining the reasons and the perceptions of parents/ caregivers in affecting screen viewing behaviour among children under 2 years in Fiji. Discussion on the results of this study in relation to the existing research literature is presented below. Possible explanations for high screen time are discussed in the subsequent sections.

4.1 Reasons for Screen Viewing

This study found that most parents/ caregivers use screens as a means of distraction for children so they could do their housework, prevent negative behaviour (such as screaming, running around or becoming fussy), feed their child etc. The study by Hanrahan et al (2018) and Greco (2013) found that distraction techniques such as screen devices can be successful in reducing discomfort and anxiety children sometimes feel when experiencing medical procedures. Compared to other studies, this study did not find many parents using screen device as a reward and punishment. The study by Hawi & Rupert (2015) however found that a significant number of parents use screen devices as a discipline tool to reward their children's good behaviour and/or prohibit the use of screen devices to punish children's bad behaviour. For instance, children whose parents allowed the use of screen devices to reward their good behaviour were more likely to exceed the recommended screen time compared to children who were not rewarded with screen devices.

To parents/ caregivers that participated in this study, negative behaviour included any behaviour they perceived as wrong and disturbing including children being fussy, not wanting to eat, screaming, running around making noise, throwing things etc. These however are mere things when compared with the other behavioural problems children can sometimes have including lying, defiance, impulsive behaviour and aggression. Guiding children's behaviour is an important aspect of educating and caring for children. There are various healthy and child friendly treats that parents or caregivers can offer children to keep them engaged while doing their housework or while feeding children, instead of offering the screen device. These can include, coloring, playing with a balloon, healthy snack or beverage etc. Since young children's attention spans are so short, distraction is often effective (The Washington Post, 2011). There are various forms of distraction available to handle children however the fact that more and more parents are using screens to distract children is quite concerning.

This study also found that most parents/ caregivers watched screens mainly when children were sleeping, this is in contrast with existing literature (Jago et al., 2012; Kildare & Middlemiss, 2017). The study by Jago et al. (2012) noted that parental TV viewing was strongly associated with children's TV viewing time across all sex and age subgroups. Kildare & Middlemiss (2017) also demonstrated that children's non-mobile media use reflects their parents' non-mobile media use, and emerging evidence draws the same conclusion for mobile media device use (Barber et al., 2017). Parents' mobile media device use during parent-child interactions makes them both verbally and nonverbally less responsive to their children. The study by Barber et al. (2017) showed that Mothers' TV-time, the time the TV was on in the home, and mothers' attitude towards child TV-time, all significantly predicted child's TV-time.

Furthermore, this study found that majority of parents had downloaded more than two software applications (apps) for their children to use. According to the respondents, the most popular were the educational and entertainment apps including *Netfix, Biblical and religious apps, Nursery Rhymes, Cartoons, Colours, ABC and Quick Maths.*

The swift adoption of tablets and smartphones has sparked an unprecedented explosion of software games, videos and educational programs aimed at the very youngest minds, dramatically increasing the amount of time these children are spending in front of electronic media (Council on Communications and Media, 2011). Experts estimate that tens of thousands of kid apps are offered on Apple and Google Android devices, with titles such as '*BabyPlayFace'* and '*Elmo's Birthday'*. This is quite worrying for some educators and child-development experts who view the flood of baby and toddler apps with trepidation (Sigman, 2017). According to a statement by the American Academy of Pediatrics (2011), for children 2 or younger, all those screens can have a negative effect on development.

For parents that did not download any apps, children viewed videos directly from YouTube. YouTube is a popular video repository offering family entertainment channels (Buzzi, 2011). However, pornography is flooding the Internet and children can accidently access unsafe videos. Specifically, porno audio content inserted into popular cartoons is present in YouTube, with the risk of exposing children to disturbing experiences (Buzzi, 2011; Quadara, 2017).

Parents stated that children watched from YouTube not from YouTube Kids. YouTube was very popular with kids hence in 2015 the website decided to create a channel specifically geared towards younger children called YouTube Kids. YouTube Kids was developed for 7-year-olds and older to have a safer space (Buzzi, 2011). While YouTube Kids has some restrictions on emotionally upsetting and violent stunts and pranks, inappropriate materials may still be accessible. For children above 2 years, downloading apps instead of allowing children to watch from YouTube is safer in this regard.

4.2 Parents/ Caregivers Perception on Children Screen Viewing Behaviour

The study found that while most of the parents know that there are negative consequences of screen time on their children, they however do not know all the detrimental health effects of screen viewing by children as young as 2 years. Most parents/ caregivers think the only effect is that related to children's eye health (66%) and are unaware of all the other health consequences. This finding denotes the Iceberg Principle or Iceberg Theory. The Iceberg Principle (Iceberg Theory) is a theory that suggests that aggregated data can hide information that is important for the proper evaluation of a situation (Iceberg of Disease Concept, 2011). This study revealed that only a few of the negative consequences of screen viewing is apparent to most parents/ caregivers such as effect to eyes including eye strain and blurred vision; while the bulk of the consequences is not known by parents/ caregivers) including poor metabolic profile, higher risk of obesity, neck, back and shoulder pain, poor social life, psychological stress, brain damage, emotional problems, attention deficit, speech and language development delays and so on.

It is quite concerning that a substantial percentage of parents (24%) also think that there is no negative effect at all on children engaged in screen viewing. This clearly shows the lack of knowledge of parents.

Researchers suggest that children's screen time is linked to norms in the household which are determined in part by individual level variables, including parental beliefs and attitudes about how often and in what ways media devices are used in the home (Bochner & Eisenberg, 1987; Coyne et al., 2014; Calvert et al., 2002). The study by Minges et al. (2015) and He et al. (2010) showed that although parents are generally well informed about the negative impacts of high screen use and the need to restrict screen time in children, many are high screen users themselves.

In this study, a large number of parents/ caregivers felt that children did not need restrictions on screen viewing in order to prevent extended periods of viewing. For instance, some parents explained that their child did not have the attention span for extended periods of television viewing and could only view 15 - 30 minutes of television before moving onto something else. This was common among children who were just few months old. As the study reveals, parents may be unaware of all the detrimental effects of screen time for children hence it makes sense that they do not see the importance of restricting screen time. The study by Schoeppe et al. (2016) however revealed that most adults think it is appropriate to restrict children's screen time to ≤ 2 h/day but few adults themselves adhered to ≤ 2 h/day of leisure-related screen time. Several studies have shown that adult rules on screen use can effectively deter children from participating in excessive TV viewing and computer use (Barradas et al., 2007; Jago et al., 2011; Carlson et al., 2010). However, it is not just the presence of screen time rules and restrictions that is important but also the support through adult modelling of low screen use (Wartella et al., 2013; Chiu et al., 2017). The study by Hawi & Rupert (2015) found that children who tend to continue to use screen devices in the presence of their parents have significantly higher odds of averaging screen time in excess of the 2-hour cutoff.

This study found that more than half (56%) of the parents (or caregiver guardians) think that screen viewing below the age of 2 years has positive consequences on their children. Of these the vast majority (76.7%) think that screen viewing actually makes their children smart/ helps them to learn from a very young age. Consistent with the findings of this study, Ortiz et al. (2011) found that parents view current technology as important to their child's academic performance and future job success. In this study many parents confessed that screen time has made their children smart, helps them learn. Quote from a mum, 'This child is actually learning English from such a young age...' As the study found, parents use screen time for all sorts of reasons including to calm down their children, stop them from crying, distraction tool while they tidy their housework, to help them to sleep and to help develop their speech. This suggests that digital devices are used as 'digital pacifiers' to placate or distract children or as a means to manage children's behaviour. Alternative explanations include parent's desire to educate their child or have their child develop good communication skills. The study by Barber et al. (2017) also notes that mother's attitudes towards child's TV time significantly affected TV viewing behaviour. Further, the study found that the strength of this association increased as the children aged; by the age of 36 months every hour of mother's TV viewing was associated with an increase of around 25 min in child TV viewing. This suggests that mothers' TV-time may be a key target for intervention. Furthermore, the strength of the association between mother and child TV-time increased as the children aged, thus supporting the idea that early intervention would reap greater effectiveness. In the Northwestern study, although parents used media as a tool for managing daily life, most parents (70%) did not think the devices made parenting easier (Bochner & Eisenberg, 1987). The study by Hawi & Rupert (2015) found that children whose parents did not establish home policies for screen time were more likely to exceed the recommended screen time compared to those whose parents did have policies for screen time.

The study by Radesky et al. (2014) also notes that parental motivations to provide screen time before 2 years of age may stem from household or family characteristics (example single parent household or maternal depression), beliefs in educational value of media, and TV's ability to keep children occupied while parents get things done

around the house. On a behavioural level, screen addicts appeared to be constricted with regards to their impulse control and behavioural inhibition.

Some parents in this study mentioned that children showed aggressive and violent behaviours when screens were not given. This was consistent to findings from Radeskey et al. (2014) that showed that that infants rated by their mothers as fussy were exposed to more TV. In that study, infant behaviours and media use were measured at the same time, so it is unknown whether media exposure is dysregulating to infants or whether parents are using TV to try to calm their fussy infants.

This study clearly demonstrates that many parents/ caregivers feel the pressure of decisions over screen viewing worrying, as they describe, not only that their children may become 'addicted' to screens or have other negative effects but also that if they fail to provide digital opportunities, their children will be 'left behind'.

4.3 Limitations

Results of this study cannot be generalised to all children in Fiji as it was conducted specifically in the Suva sub-division. Although the sample size of this study was adequate, the diversity of the study in terms of ethnicity was not fully proportional and representative so *iTaukei* were overrepresented. The baseline demographical information did not show equal representation of sample in terms of age and ethnicity.

5. Conclusion

Majority of parents/ caregivers (60%) in Fiji know that there are negative consequences of exposure to screens on children below 2 years, yet they engage children to screen activity. Parents/ caregivers in Fiji also trust in screen viewing's positive impact on their children. Early childhood is an important time of development and is a crucial window for intervention, hence parental engagement and role modelling are critical for the development of healthy habits of children. More research is necessary on the mechanisms by which screen viewing interacts with child outcomes in Fiji and the types of interventions that can mitigate the effects of screen exposure in children's development.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Scoping Review of School-Based Obesity Interventions among Children and Adolescents in Arabic Speaking Countries

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Received: February 8, 2022Accepted: March 1, 2022Online Published: March 15, 2022doi:10.5539/gjhs.v14n4p40URL: https://doi.org/10.5539/gjhs.v14n4p40

Abstract

Background: Childhood and adolescent obesity globally presents a huge public health problem and the dramatic increase in its prevalence and associated poor health outcomes pose serious concerns among Arabic-speaking countries.

Aim: This scoping review seeks to identify the characteristics and assess the effectiveness of school-based health promotion interventions on prevention or reduction of overweight/obesity among children and adolescents. This review further describes the implementation and evaluation of nutrition and physical activity interventions and their measured health outcomes for schools in Arabic speaking countries.

Methods: We searched 10 electronic databases (PubMed MEDLINE, Scopus, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), ERIC, EMBASE, ProQuest, EBSCO Host and Global Health) from 2010 to 2020 for studies evaluating school-based health promotion interventions on obesity or overweight among children and adolescents in Arab speaking countries. Sixteen studies met the inclusion criteria for this review and narrative synthesis was conducted.

Results: The 16 articles reported on eight discretely different interventions which were largely school-based and examined physical activity and/or nutritional changes as well as changes in knowledge and attitude in regard to physical activity and nutrition.

Conclusion: Our review demonstrates an inconclusive and mixed effect of behavioural and physical activity intervention on prevention or reduction of obesity and/or overweight. While the strengths and limitations of the various interventions may have influenced the outcomes, long-term school-based interventions with rigorous methodological and theoretical frameworks are necessary to assess the true impact of these interventions on childhood and adolescent obesity in Arab speaking countries.

Keywords: School-based interventions, childhood obesity, adolescent obesity, Arabic speaking countries

1. Introduction

Obesity among children and adolescents is a challenging public health issue globally (Karnik & Kanekar, 2012). The dramatic increase in the prevalence of obesity and its associated poor health outcomes is concerning in Arabic-speaking countries located in the East Mediterranean, Arabian Peninsula, and northern parts of Africa (Al Hammadi & Reilly, 2019; World Health Organization, 2016). In this region, multifactorial influences, comprising rapid societal and environmental transformations, education, and difference in socioeconomic backgrounds has led to an increase in lifestyle-related diseases and increased rates of childhood obesity (Badran & Laher, 2011). In recent decades, the populations living in middle eastern countries have undergone a nutritional transition where traditional foods have been substituted by fast foods which are usually energy-dense and nutrient poor (Al Moraie, 2014; Alzaman & Ali, 2016; Badran & Laher, 2011). The consumption of unhealthy foods and sugary carbonated drinks, especially among children and adolescents is increasing rapidly (Aboul-Enein, Bernstein, & Neary, 2016; Al Dhaifallah, Mwanri, & Aljoudi, 2015). In addition, people from Middle Eastern Arabic countries are more

likely to adopt sedentary lifestyles when compared to other non-Arab cultures with this including increased television viewing time, playing video games and Internet use during leisure time (Musaiger, 2011). The increased socio-economic status among residents in high income Arab countries in recent decades has resulted in increased use of personal cars for transportation (Badran & Laher, 2011). Children are less likely to walk to school and play outdoors than in the past and report increased use of indoor games and television viewing (Sahoo et al., 2015). Poor dietary habits and a sedentary lifestyle among children can lead to overweight and obesity.

Obesity is associated with high morbidity and mortality rates (Kuźbicka & Rachoń, 2013). Non-communicable diseases such as cardiovascular diseases and various cancers are some of the most common health outcomes attributed to overweight and obesity (Bechard, Rothpletz-Puglia, Touger-Decker, Duggan, & Mehta, 2013; Najeh, Kandi, Rguibi, & Belahsen, 2012). As a result of obesity, children may experience increased psychological impact such as anxiety, depression, negative self-perceptions, low self-esteem, decreased physical functioning due to health-related issues such as joint pain and muscle pain and poor quality of life (Badran & Laher, 2011; Halasi et al., 2018). The parents of children with overweight and obesity may also experience emotional distress (Rankin et al., 2016).

Prevention interventions are considered important in public health efforts to reduce childhood obesity (Pandita et al., 2016). The school community provides an ideal setting for health promotion interventions (Rebecca Langford et al., 2017). School-based health promotion interventions can reach most children and adolescents at a critical age when many eating habits, attitudes, and lifestyles are being established (World Health Organization, 2014). The school setting also provides opportunities for school students to practice healthy eating through appropriate food selection in the school canteen and to participate in physical activity through physical education classes (Chen et al., 2015). The World Health Organization (WHO) Health Promoting Schools (HPS) framework (Rebecca Langford et al., 2015) is the most comprehensive and multifaceted school-based approach (Griebler, Rojatz, Simovska, & Forster, 2017). The HPS framework includes strategies across three domains including: curriculum, learning and teaching; school organisation, ethos and environment; and partnerships and services. Despite complex socio-ecological interactions, a review of HPS interventions found evidence of reduction of body mass index, increased physical activity, increased consumption of fruit and vegetables and reduction of unhealthy behaviours including drug use, cigarette smoking and bullying (R. Langford et al., 2014). Despite the global recognition of the importance of a whole school approach, there are challenges with implementation including: lack of community involvement and intra-sectorial and inter-sectorial collaboration; inadequate infrastructure, capacity and human resources; and inconsistent policy-making, regulations, and management approach (Fathi, Allahverdipour, Shaghaghi, Kousha, & Jannati, 2014).

Reducing childhood obesity requires effective lifestyle and behavioural interventions that target healthy eating and physical activity behaviours among children and adolescents as well creating supportive environments (Xu et al., 2015). Schools were identified as the ideal setting for health promotion because health and education are closely linked and children spend a significant amount of time in school (Rebecca Langford et al., 2015). Though overweight and obesity interventions in schools are challenging, the collaborative assistance of parents and teachers is likely to enhance community knowledge, encouraging health support and thus enhancing general family quality of life (Allafi, 2020; A. Bani Salameh et al., 2017; Ben Cheikh et al., 2020; Dendana et al., 2017; Habib-Mourad et al., 2014). Therefore, exploring the effectiveness of interventions is a key action that can assist with health planning and prevention of childhood overweight and obesity in the future.

This scoping review identifies the characteristics and effectiveness of school-based health promotion interventions focusing on overweight/obesity prevention or reduction among children and adolescents in Arabic speaking countries. This review examined implemented and evaluated nutrition and physical activity interventions and measured health outcomes for schools in Arabic speaking countries.

2. Methodology

2.1 Information Sources

Different databases and other registries (Google, Google Scholar, reference lists of relevant articles) were used with broad and inclusive search terms to identify eligible studies published during the last 10 years. Electronic databases used: PubMed MEDLINE, Scopus, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), ERIC, EMBASE, ProQuest, EBSCO Host and Global Health. Reference lists of relevant articles such as systematic reviews on Google and Google Scholar were manually searched. English or Arabic language restrictions were applied.

2.2 Intervention Selection

This scoping review focused on interventions with school-aged children and adolescents in Arabic speaking countries (i.e. Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Algeria, Palestinian Territories,

Comoros, Djibouti, Egypt, Iraq, Jordan, Lebanon, Libya, Mauritania, Morocco, Somalia, Sudan, Syria, Tunisia and Yemen). Studies included focus on school-aged children aged from five to 18 years and school-based interventional studies aiming to prevent or reduce overweight and obesity. All studies were published over the last 10 years in peer-reviewed articles, written in English or Arabic with full text available. Quantitative and qualitative studies were included. Systematic reviews and other secondary studies, studies published in languages other than English or Arabic and studies conducted in countries other than those identified above were excluded.

A search strategy with broad criteria was predefined to initially select articles. Based on the review questions, the terms were identified using Population; Intervention; Comparator; Outcome; Time frame (PICOT) (Abbade, Wang, Sriganesh, Mbuagbaw, & Thabane, 2016) to guide the generation of relevant keywords for searching and developing inclusion and exclusion criteria. Table 1 illustrates the PICOT framework guiding.

| PICOT-framework | Keywords |
|-----------------|--|
| | child, adol* |
| Population | Bahrain OR Kuwait OR Oman OR Qatar OR Saudi Arabia OR United Arab Emirates OR gulf countries OR Gulf Cooperation Council OR Algeria OR Palestinian Territories OR Comoros OR |
| Place | Djibouti OR Egypt OR Iraq OR Jordan OR Lebanon OR Libya OR Mauritania OR Morocco OR Somalia OR Sudan OR Syria OR Tunisia OR Yemen |
| | school |
| Intervention | AND |
| | intervention OR program OR curriculum OR health promotion OR health education |
| Comparison | - |
| Outcomes | physical activity OR exercise OR diet OR nutrition OR food choices OR obesity OR overweight OR BMI OR Body Mass Index OR body weight |

Table 1. Shows the PICOT Framework guiding the Search of Literature

2.3 Extracting and Charting of Results

Three researchers were involved with screening the search results. One researcher identified the included studies through title and abstract screening, followed by full article screening. The other two researchers checked the full articles to ensure they met the inclusion criteria. Removal of duplications and systematic searching was documented using the reference management software EndNote X9.

The multiple database search initially resulted in 1199 potentially relevant articles. After removal of duplicates, n= 416 articles were further screened. After screening by title, a further 323 articles were excluded and an additional 51 were excluded after the abstract was reviewed. The primary author tabulated all remaining articles (n=42) for full-text review. During the full-text review, further articles were excluded because they were not school-based (n=18); focused on a range of health risk factors without specific focus on prevention or early intervention in overweight and/or obesity (n=5); described methodology only (n = 3); or were not from one of the designated countries (n = 1). Additional papers excluded were abstracts from conference proceedings without full content (n =2). Figure 1 outlines the PRISMA flow diagram for the study selection processes.

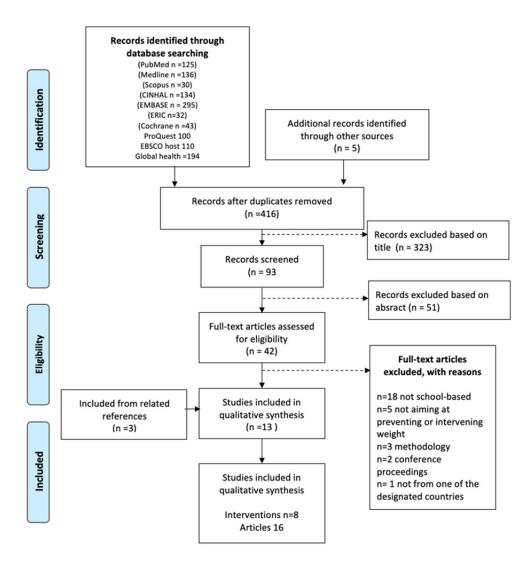


Figure 1. PRISMA flow chart

A descriptive summary of all included studies was extracted from each of the 16 articles that met the inclusion criteria. The characteristics of each study and the relevant key information of this study was reported in accordance with Gerrard's Matrix Method (Garrard, 2017). Extraction fields included authors, year of publication, country, study setting, study design, participants, location of the study conducted (in this case school-based intervention), instrument tools used and study outcomes (Peters et al., 2015). The enablers and barriers of intervention implementation were considered but, out of the 16 included articles, only two studies discussed the feasibility and challenges regarding the implementation of the instrument and/or the intervention. All data were extracted directly into a table by the primary author and checked for completeness and accuracy by all authors. The data was qualitatively examined by their number of participants, duration of intervention and outcomes related to nutrition or physical activity program elements.

In accordance with the Graphic Appraisal Tools for Epidemiology (Ezzati et al., 2018) for intervention and risk version (Jackson et al., 2006), studies were qualitatively assessed and were tabulated accordingly. The components appraised comprised: methodology (recruitment, allocation, maintenance, blinding process and objective measurement) and whether appropriate statistical analysis was employed. The quality appraisal was performed for this scoping review to identify the strength and the weaknesses of all included studies. Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) (Tricco et al., 2018) guidelines were used to inform and summarise in reporting this review. Further analysis was not possible because of the heterogeneity of the study design and differences in outcomes of interest between studies.

3. Results

3.1 Characteristics of Included Studies

Characteristics of included studies are described in detail in Table 2. Of the 16 studies, 10 included quasi-experimental study designs (Awad Elkarim Elfaki et al., 2020; Ben Cheikh et al., 2020; Dendana et al., 2017; Ghammam et al., 2017; Harrabi et al., 2010; Kebaili et al., 2014; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b; J. M. Maatoug, Harrabi, Delpierre, Gaha, & Ghannem, 2013; Zammit et al., 2016) and the remainder reported randomised controlled trials (Allafi, 2020; A. Bani Salameh et al., 2017; El Ansari, El Ashker, & Moseley, 2010; Habib-Mourad et al., 2020; Habib-Mourad et al., 2014; Kutbi, Al-Jasir, Khouja, & Aljefri, 2019). These 16 articles reported on eight discretely different interventions. Eight of the studies reported on the long-term Promote Healthy Lifestyles program intervention in a school in Sousse, Tunisia which promoted increased physical activity and healthy eating in addition to tobacco prevention (Dendana et al., 2017; Ghammam et al., 2017; Harrabi et al., 2010; Kebaili et al., 2014; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b; J. M. Maatoug et al., 2013; Zammit et al., 2016). Three of these reported on the pilot program that took place in 2007 (Harrabi et al., 2010; Kebaili et al., 2014; J. M. Maatoug et al., 2013) while four reported on the resulting program implemented 2009-2015 (Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b; Zammit et al., 2016). An additional paper by the same authors detailed a specific program for overweight and obese students implemented within the wider program in 2012-2014 (Jihen Maatoug et al., 2015a). A further two of the 16 articles reported on the pilot and later refinement of the Health-E-PALS program in Lebanon (Habib-Mourad et al., 2020; Habib-Mourad et al., 2014). The remaining six articles reported on another six separate interventions: One in Sousse Tunisia with primary school aged children (Ben Cheikh et al., 2020), two from Saudi Arabia (Awad Elkarim Elfaki et al., 2020; Kutbi et al., 2019) and one each from Egypt (El Ansari et al., 2010), Jordan (Ayman Bani Salameh et al., 2017), and Kuwait (Allafi, 2020).

Participants were mostly from middle, intermediate or secondary schools with one study involving participants from a primary school (Ben Cheikh et al., 2020). The age of participants ranged from six (Ben Cheikh et al., 2020) to 18 years (A. Bani Salameh et al., 2017). Most of the studies included both male and female participants but one study involved only males (Kutbi et al., 2019) and another only females (Awad Elkarim Elfaki et al., 2020). The majority of intervention-based studies included all students and were focused on specific age and school grade, however two interventions (Ayman Bani Salameh et al., 2017; Jihen Maatoug et al., 2015a) targeted only obese or overweight students. Most interventions selected clusters of classes from the middle and secondary schools, the maximum number of students involved ranged from 148 (Kutbi et al., 2019) to 4275 (Jihene Maatoug et al., 2015b), and the intervention duration varied from six weeks (Allafi, 2020) to a maximum of three years (Dendana et al., 2017; Ghammam et al., 2017).

3.2 Summary of Interventions

A team of researchers in Tunisia conducted the School based intervention to promote healthy life styles among school children in Sousse in 2007. This pilot study was reported on by Harrabi et al. (2010); J. M. Maatoug et al. (2013) and Kebaili et al. (2014). Harrabi et al. (2010) described their aim to evaluate the effect of a school cardiovascular disease (CVD) risk factors prevention program on the knowledge and intentions of more than 2,000 students aged between 12 -16 years (Harrabi et al., 2010). The intervention was implemented in two public schools in Ezzahra and Khzemain. The intervention consisted of class-room based education sessions focusing on tobacco use, physical activity and healthy diet and interclass sport tournaments. These were delivered by the research team, teachers and school doctors. Nutrition knowledge and intentions improved for all students and was significantly higher in the intervention group (Harrabi et al., 2010). Additionally, while there was a statistically significant increase in physical activity for both groups, it was significantly higher in the intervention group. However, there was no change in BMI for either the control or intervention group. J. M. Maatoug et al. (2013) reported in more detail a significantly higher post-test knowledge and behavioural intention in the interventional group. They further described the same study with the aim of identification of predictors of health diet and physical activity patterns finding that younger children, those of higher socioeconomic status and those who already ate well and undertook physical activity were predictive of positive behaviours and intentions (J. M. Maatoug et al., 2013). Kebaili et al. (2014) also reported the same pilot study focusing on the nutrition survey detailing the significant pre-and post-survey differences in knowledge, intention and behaviours for the intervention group.

The Tunisian researchers then undertook a longer and more comprehensive intervention with more than 4,000 children aged 11 to 16 years in Sousse undertaking baseline assessment in 2009-2010, delivering a three year intervention from 2011 to 2013 with post intervention assessment in 2013-2014 and a one year follow-up in 2015 (Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b; Zammit et al., 2016). The intervention included: training student leaders to motivate peers and help organise educational events and media

(e.g., posters, dances) for peers, parents, and teachers; interactive classroom-based lessons with teachers; and environmental change such as increased afterschool and interschool sports and encouraging community shops to stock healthier snack foods that children were rewarded for purchasing or encouraging the owners of snack stores to switch the usual sweetened snacks with healthy alternatives(Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b). A number of validated self-complete surveys measuring knowledge and self-efficacy were used to assess the level of behavioural changes associated with the effect of interventions evaluated in these Tunisian studies (Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b; Zammit et al., 2016). In addition, biometric measures were used to assess the impact of various interventions on weight and other body composition (Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b; Zammit et al., 2016). Dendana et al., (2017) and Maatoug et al. (2015b) reported that the post intervention data showed a statistically significant increase in fruit and vegetable consumption (p = 0.026) but decreased proportion of pupils who were obese which did not reach statistical significance in the intervention group. On the other hand, a statistically significant increase in proportion of pupils with obesity (p = 0.001) and those with low fruit and fruit and vegetable consumption (p = 0.001) were seen in the control group. A one year follow-up indicated some continuing positive effects but a drop-off in improvement in fruit and vegetable consumption and body weight concluding that interventions should be maintained (Ghammam et al., 2017). It was posited that the Tunisian revolution and the lack of outdoor security resulted in the lower physical activity recorded (Ghammam et al., 2017). A smaller follow-up of a group of 204 students in middle school reported by Zammit et al. (2016) concluded that the intervention had limited sustainable effects on nutrition and physical activity.

Jihen Maatoug et al. (2015a) conducted another study in 2012-2014 (alongside the larger Sousse intervention) involving more than 500 overweight and obese children to investigate the challenges and results of school based interventions to manage excess weight (Jihen Maatoug et al., 2015a). The intervention group of more than 300 overweight and obese children participated in a one year intervention consisting of an exercise program and small group sessions with a dietician focusing on healthy eating; with a psychologist focusing on self-esteem; and with a medical doctor focusing on snacking. Individual 3-monthly sessions with medical staff and individual dietary advice for obese children were provided. The children were assessed at pre-intervention, post-intervention and after 4 months. A standardized, pretested self-administered questionnaire in Arabic was used to evaluate physical activity behaviors and fruit and vegetable consumption of schoolchildren. The questionnaire was administered in schools in the presence of trained medical doctors to standardize and assist the students in filling out the questionnaires and to define terminology. The authors collected biometric measurements (i.e. height and weight) of the students. Body weight was recorded to the nearest 0.1 kg by using a portable electronic scale taken with participants wearing a light layer of clothing. Data on height were measured with the participants standing barefoot and recorded to the nearest 0.5 cm. The BMI of the intervention group reduced significantly at the 4 month follow up point. The authors discussed their perception that the students did not show a larger decrease in BMI as they were unmotivated, Tunisia contains fewer healthy food choices and more unhealthy choices, the Tunisian school environment does not promote or provide infrastructure for physical activity and that the parents valued academic achievement above weight loss.

Ben Cheikh et al. (2020) conducted a quasi-experimental study in Tunisia to study the effect of a school based nutrition promotion intervention on over 500 hundred primary school children aged 6 to 12 years (Ben Cheikh et al., 2020). The intervention involved two schools with one receiving an intervention and one acting as the control, promoting of the reduced consumption of unhealthy morning snacks. The 6 month intervention consisted of educational activities for children and parents (e.g. dietician led sessions, peer training of student leaders to motivate peers, cooking workshop, competitions, parent Facebook group and SMS messages to parents). Ben Cheikh and colleagues also implemented a set of interventions which comprised role modelling; a drawing competition, writing, poetry and chef on the theme of healthy and balanced diet; provision of healthy snacks for children such as fruits and vegetables in the school canteen and limited accessibility at least in primary school to unhealthy products, mainly trans-fat, high fat and high salted food: the school canteen, the street vendor and the small stores around school were encouraged to sell healthy snacks: school children who chose the healthy snacks were rewarded with incentive stickers, which they collected for a prize: two SMS messages per months were sent to parents which explain the importance of parents' implication in promoting a healthy diet (Ben Cheikh et al., 2020). The main outcome was measured with the use pretested self-administered questionnaires in Arabic which was administered to parents and school children in both intervention and control schools. The self-administered questionnaire for parents included the sociodemographic characteristics and eating habits of their children whereas the questionnaire for children was given in classes in the presence of trained medical doctors to assist children filling in the questionnaires. It has included snacks consumed the day before the survey and its composition. The results revealed that the consumption of morning snacks decreased significantly and that the consumption of healthy foods increased after the intervention.

Habib-Mourad et al. (2014) reported on the Health-E-PALS (Intervention to promote Healthy Eating and Physical Activity in Lebanese School children') intervention to investigate the effect of health eating and physical activity among school children aged 9 to 11 years in Lebanon. The Health-E-PALS intervention program consisted of: weekly nutrition sessions in classes run by nutritionists; family involvement via meetings, health fairs and information and recipes sent home with food samples; and promotion of health food at the school shop and in lunchboxes from home. The intervention group, compared to the control group, had significantly higher knowledge and self-efficacy and reported less purchasing of unhealthy foods. However, this pilot study also reported no significant difference in physical activity behaviours or change was observed in BMI between intervention and control groups. The lack of change in BMI is likely attributable to insufficient duration (12 weeks) between pre-test and post-test. In a two trial study conducted by the same group of investigators Habib-Mourad et al. (2020) evaluated the effectiveness of a school-based intervention delivered by a non-nutrition specialist (trained school teachers) compared to a nutritionist in over 2200 students aged 9-11 years across 60 schools in Lebanon (Habib-Mourad et al., 2020). In this study, two trials of the same school-based intervention using the same intervention package were delivered over one year, one by nutritionists to 30 schools and another by trained school teachers to another 30 schools. Dietary behaviours and physical activity were the main focus of the intervention. In both trials, the 60 selected schools were randomized to intervention or control groups; students in both groups were compared at post-test on knowledge and self-efficacy scores, as well as dietary and physical activity behaviours. In addition to behavioural interventions, Habib-Mourad and colleagues implemented environmental changes including role modelling of significant others and availability of healthy choices at home and school (Habib-Mourad et al., 2020; Habib-Mourad et al., 2014). In both studies, a food service intervention targeted the school shops, checking the lunch boxes sent by the families, role modelling of significant others and availability of healthy choices at home and school were the main environmental factors addressed in both groups as interventions. Parents contributed to the success of the Health-E-PALS intervention by ensuring the availability and accessibility of healthier food options at home, and through role modelling. Parents and teachers involved in interventions served as role models for students and positively impacted study outcomes through continued positive reinforcements via praise and tokens (Habib-Mourad et al., 2020). Anthropometric measurements including height, weight and waist circumference were taken at both time points (pre and post intervention) using standardized techniques and calibrated equipment. Self-administered questionnaires on determinants of behavioural change, eating and physical activity habits were administered to the students in both groups at baseline and post intervention. Focus group interviews were conducted in intervention schools at the end of the study. For students in both intervention and control schools, a baseline assessment (pre-test) was conducted a week prior to the start of the intervention, followed by another assessment one week after the completion of the intervention (post-test). Both assessments took place in the classroom. The questionnaire used was designed to collect data on indication of dietary physical activity, and sedentary behavioural habits. It was not designed to measure dietary intake, physical activity, or sedentary behaviours (Habib-Mourad et al., 2020). A statistically significant improvement in knowledge and self-efficacy scores was observed in intervention versus the control group. An improvement in dietary behaviours was observed with the intervention but physical activity did not increase for either group. The lack of improvement in physical activity among the students could be attributed to the limited accessibility to extracurricular activities, as a result of budget constraints, homework overload or the lack of safe and free places for spontaneous physical activity or play.

Ayman Bani Salameh et al. (2017) assessed the effectiveness a 12 weeks school-based educational preventative program for type 2 diabetes mellitus in Jordanian overweight and obese male and female adolescents aged 12-18 years in two unisex high schools (Ayman Bani Salameh et al., 2017). This study in Irbid City was a single-blinded randomised controlled trial which enrolled about 400 visibly overweight or obese adolescents in two unisex high schools and randomly allocated them into intervention and control groups. The 12-week educational program consisted of group information sessions for an average of five students and their parents. The intervention was based on the Australian Swap It Don't Stop It program with an individual 12 week guide providing diet and physical activity recommendations and shopping advice for parents. Students were reminded by teachers to fast for eight hours prior to data collection. Physiological measurements such as weight and height were measured using a standardized protocol and calibrated equipment. The authors measured weight of students with each clothed, but without shoes, on a digital scale whereas height in centimetres was measured with the participant barefoot using standard scale on the wall and a ruler on the head (stadiometer). Body mass index (BMI) was calculated using the anthropometric measures and classified according to the CDC standard charts accounting for gender, age in years and months, height in metres, and weight in kilograms (CDC, 2009). Peripheral blood glucose levels of participants were estimated with the use of glucometers. Weekly diet and exercise monitoring records were checked bi-weekly. School-based early preventative intervention effectively reduced weight and fasting blood glucose in Jordanian at-risk adolescents. There was a statistically significance difference between pre and

post-intervention weight and fasting blood glucose between the two groups. The control group gained weight and increased their fasting blood glucose level while the intervention group lost weight and decreased their fasting blood glucose level.

Awad Elkarim Elfaki et al. (2020) evaluated the effect of school-based healthy lifestyle intervention on obesity with 565 female students aged 12-15 years randomly selected from four schools in Jizan City in Saudi Arabia. The two intervention schools promoted healthy food choices and physical activity over a six month period using: a one day counselling session; health education classes; daily before-school exercise classes; educational materials for parents; and an individual intervention plan for girls who were overweight or obese. The World Health Organization (WHO) STEPS survey instrument was used to measure the effectiveness of the intervention and to assess outcomes of the study. The WHO STEPS covers three different levels of steps of risk factor assessment. The authors used only two of the three WHO STEPS surveys to evaluate the effectiveness of the intervention. STEP-1 which included a questionnaire covering the basic demographic information and behavioral risk factors (dietary patterns, physical activity) of participants and STEP-2 which covered physical measurements (anthropometric measurements) were employed. Anthropometric measurements such as height and weight were taken using standardized protocols and calibrated equipment. Weight was measured to the nearest 0.1 kg in light indoor clothing and with bare feet or stockings while height was measured without shoes and recorded to the nearest 0.5 cm using a calibrated weighing scale. This revealed that the intervention group, compared with the control group, demonstrated a significant increase in walking, moderate and vigorous physical activity and reduction in consumption of fast food and soft drinks. Additionally, there was a significant reduction in the prevalence of obesity in the intervention group and an increase in obesity in the control group.

Kutbi et al. (2019) conducted a cluster randomized controlled trial of 184 male adolescents aged 10 to 15 years to evaluate the impact of an educational program in Jeddah, Saudi Arabia on physical activity, consumption of healthy foods, and anthropometric measurements (Kutbi et al., 2019). The intervention was a two-month school-based program providing one weekly session which was either a health education session, a group counselling session, a group presentation developed by the students or a discussion of student presentations. The first month discussed healthy dietary behaviours and the second discussed physical activity comprising one weekly session which was either a 60-minute health education session, a group counselling session, a 5-10 minute presentation developed by the students or a discussion of student presentations. Anthropometric measurements (i.e. weight) of study participants were assessed using standardized protocol and calibrated equipment. A growth chart recommended by the Saudi Ministry of Health was used to plot the weight of the adolescents and then calculate BMI for adolescents according to the international definition of children's overweight and obesity developed by Cole, Bellizzi, Flegal, and Dietz (2000). The researchers measured and calibrated physical activity using the metabolic equivalent equation recommended by the compendium of physical activity 2011. By this, participant's activity was converted into metabolic equivalents in minutes per day for ease of analysis and comparison to standards. Dietary habits and sedentary behaviours were measured as recommended by healthy food pyramids and the Canadian Physical Activity and Sedentary Behavior Guidelines respectively. The intervention increased the percentage of students who: participated in sufficient physical activity; ate more fruit and vegetables; and ate less fast food. However, there were no statistically significant effects between the intervention and control groups. The authors pointed out that the adolescents were in the age of physiological growth and development with a natural increase in the weight and height and this could explain the lack significant difference anthropometric parameters seen between the intervention and control groups.

An experimental study conducted by Allafi (2020) assessed the effectiveness of a combined pedometer-feedback and rewards versus feedback alone on increasing physical activity in 225 male and female students aged 9-11 years who attended six different public schools in Kuwait City, Kuwait (Allafi, 2020). The students were randomly assigned to three different groups during school physical activity classes,:-feedback, feedback with rewards, and control group. Participants in the feedback group received information about the function of pedometer only whereas the feedback plus reward group received information about the function of the pedometer and were asked for a 3000 counts milestone to receive ten stickers. The control group participants did not receive any information about the function of the pedometer. Participants were given pedometers at the beginning of every session. All pedometers were set to zero and participants were instructed to keep wearing them during the whole session (50 minutes). Pedometer counts were taken from all participants after five physical education classes. Participant's body mass and height were measured without shoes using a Hanson electronic scale and a tape measure attached to a vertical wall, respectively. Each student's BMI was then computed. The study results were similar for male and female students and revealed that there was as significant increase in number of steps between students who were taught about the pedometer and the control group. A significantly higher number of steps were taken by the student who were also given a rewards indicating that encouraging children with rewards will increase their physical activity levels.

El Ansari et al. (2010) evaluated the effectiveness of a physical activity intervention programme which comprised an after school one hour of moderate exercise three times a week for a period of three months in a randomized study of 160 secondary male and female school pupils aged approximately 15 years in one school in Mansoura, Egypt (El Ansari et al., 2010). These sessions were additional to the usual two physical activity classes taken by both the intervention and the control groups. The researchers assigned each participating pupil with a data capturing sheet where research assistants recorded the pupil's anthropometric and physiological parameters at baseline and after three months and each of the measurements were obtained three times on the same day to ensure accuracy. Anthropometric evaluation comprised three parameters-weight and height, BMI status and body fat. Weight and height was measured using a digital weight and height scale. Height was measured to the nearest 0.1 cm while the participants stood barefooted, and body weight was measured to the nearest 0.1 kg with participants wearing light clothing and no footwear. The BMI status was estimated from weight and height using Metric BMI Formula [BMI (kg/m^2) = weight in kilograms/the squared height (m^2)]. For measurement of body fat, skin folds thickness were measured using The Harpenden Skinfold Caliper and the 3-Site formula was used to measure skin folds. Body density was calculated according to standard formulae and body fat percentage was described in line with the American College of Sports Medicine. The values for three sites of the left side of the body were obtained in millimetres. The authors reported a statistically significant increase in BMI after three months follow-up for both boys and girls in the control group. The control pupils displayed increases (worsening) across all the anthropometric and physiological parameters that were examined. However, these increases were only statistically significant for BMI in boys, and BMI and diastolic blood pressure (DBP) in girls. Despite that lack of statistical significance in many parameters, it is noteworthy that for all the parameters and for both genders, the differences for the control pupils were positive (*i.e.*, the control pupils got worse) (El Ansari et al., 2010).

Table 2. Characteristics of the included studies

| -Author, Year, Name of Cohort/Study, Citations, Country | Study Design, Patient Characteristics | Key Intervention Characteristics | Outcomes |
|---|--|--|---|
| | Age: | Duration of intervention: 3 years | |
| | Intervention: 12.39 ± 0.68 | Follow-up: 1 year | |
| | Control: 12.4 ± 0.72 | Teacher training: None reported | • Intervention group Pre vs post |
| | Sample: school- | Parent involvement: None reported | Diet (fruit and veg.): increase 15.2% (p=0.017) |
| | children enrolled in middle schools | Digital component: None reported | Recommended PA: not significant |
| Zammit et al. (2016), Tunisia | Sample size: | Behavioural intervention: tobacco prevention, physical | Control group Pre vs post |
| Zammit et al. (2010), Tumsia | Intervention (n=105) | activity and healthy eating promotion | Diet (fruit and veg.): increase 22.7% ($p=0.002$) |
| | Control $(n = 99)$ | Other: questionnaire administered in presence of a trained medical | Recommended PA: not significant |
| | Total = 205 | doctor | Control vs Intervention group |
| | Study Design: Study Design: | Environmental factors: None reported | not reported |
| | Quasi-experimental | Instruments use: | BMI not reported |
| | Behavioural intervention | - Standardized, pretested questionnaire | |
| | Follow up study | - Anthropometric measurements | |
| | Age: 11-16 years old | Duration of intervention: 3 years | • Intervention group Pre vs post |
| | Intervention: NR | Follow-up: 1 year | Weight mixed |
| | Control: NR | Teacher training: None reported | Among normal weight: $p = .024$ |
| | Sample: Grade 7 and 9 students | Parent involvement: None reported | Among overweight : p=.036 |
| | Sample size: | Digital component: None reported | Among obese : p=.515 |
| (1) (2017) | Intervention (n=2000) | Behavioural intervention: tobacco prevention, physical | Behaviour Assessment: |
| Ghammam et al. (2017), Tunisia | Control ($n = 2000$) | activity and healthy eating promotion | Diet (fruit and veg.): p= 0.026 |
| Tunisia | Total = ~4000 | Other: questionnaire administered in presence of a trained medical | Recommended PA: p= 0.010 |
| | Study Design: | doctor | Control group Pre vs post |
| | Quasi-experimental | Environmental factors: None reported | weight |
| | Behavioural intervention | Instruments use: | -Among normal weight: p=.016 (weight increase) |
| | Follow up study | - Standardized, pretested questionnaire | -Among overweight : p= .602 |
| | quasi experimental | - Anthropometric measurement | -Among obese (weight increase): p=<.001 |

| | | Behavioural intervention | | Behaviours Assessment: |
|--|------------------------|---|--|---|
| | | Follow up study | | Diet (fruit and veg.): p= 0.001 |
| | | | | Recommended PA: p= NS |
| | | | | • Control vs Intervention group |
| | | | | not reported |
| | | | Duration of intervention: 3 years | |
| | | Age: 11 – 16 years | Follow-up: 1 year | • Intervention group Pre vs post |
| | | Intervention: NR | Teacher training: None reported | Low Diet (fruit and veg.): p=0.026 |
| | | Control: NR | Parent involvement: None reported | Low PA (>10 min/day walk): NS |
| | | Sample: Grade 7 and 9 students | Digital component: None reported | BMI: NS |
| | | Sample size: | Behavioural intervention: Health promotion and training groups | Control group Pre vs post |
| Dendana et al. (2 | 2017), | Intervention (n=2074) | leaders to (physical activity and healthy diet promotion, tobacco control) | Low Diet (fruit and veg.): p= 0.001(increased low |
| Tunisia | | Control $(n = 1929)$ | Other: questionnaire self-administered | intake of fruit and veg.) |
| | Total = 4003 | Environmental factors: Encouraging the owners of snack stores to | Low PA (>10 min/day walk): NS | |
| | | Study Design: | switch the usual sweetened snacks with healthy | BMI: <i>increase</i> in obesity (p=0.001) |
| | | quasi-experimental | alternatives | • Control vs Intervention group |
| | | Behavioural and environmental | Instruments use: | Not reported |
| | | change intervention | - Standardized, pretested self-administered questionnaire | |
| | | Follow up study | - Anthropometric measurement | |
| | | | Duration of intervention: 3 years | • Intervention group Pre vs post |
| | | Age: 11 – 16 years | Follow-up: | weight |
| | | Sample: Grade 7 and 9 students | Teacher training: None reported | -Among normal weight: p= .03 |
| Jihene Maatoug et al. (2015b), Tunisia | Sample size: | Parent involvement: None reported | -Among overweight : p= .03 | |
| | Intervention (n=2074) | Digital component: None reported | -Among obese : p= .51 | |
| | Control ($n = 1929$) | Behavioural intervention: Promotion of adopting healthy nutrition | -Effect on excess weight: p=.02 (protective factor | |
| | Total (n = 4003) | and doing the recommended physical activity | against excess weight) | |
| | Study Design: | Other: questionnaire self-administered | -Behaviours Assessment: | |
| | | quasi-experimental | Environmental factors: None reported | Diet (fruit and veg.): p= 0.03 |
| | | Behavioural intervention | Instruments use: | Recommended PA: $p=0.031$ |

| | Follow up study | Standardized, pretested questionnaire | Control group Pre vs post |
|-----------------------------|--|---|--|
| | | Anthropometric measurement | weight |
| | | | Among normal weight: p= .02 |
| | | | -Among overweight: p= .58 |
| | | | -Among obese : p=<.001 |
| | | | -Effect on excess weight: NS |
| | | | -Behaviours Assessment: |
| | | | Diet (fruit and veg.): p= 0.01 |
| | | | Recommended PA: p= NS |
| | | | • Control vs Intervention group |
| | | | • Not measured |
| | | Duration of intervention: 3 months | |
| | | Follow-up: None reported | |
| | Age: 9 – 11 years Sample: Grade 4 and 5 students in 4 private and 4 public schools Sample size: Intervention (n= 193) Control (n = 181) Total (n = 387) Study Design: | Teacher involvement: Role modelling | |
| | | Parent involvement: Role modelling, accessibility and availability of healthy choices | Intervention group Pre vs post Not reported |
| | | Digital component: None reported | Control group Pre vs post |
| | | programmes and healthy food choices (<i>Promotion</i> increasing consumption of fruits and vegetables, favouring healthy over high energy dense snacks and | Not reported |
| | | | • Control vs Intervention group |
| Habib-Mourad et al. (2014), | | | Recommended PA: NS |
| Lebanon | | | Dietary habits: not conclusive |
| | | drinks, increasing the habit of having breakfast daily, in- | Knowledge score:p<0.001 |
| | sequential explanatory | creasing moderate-to-vigorous physical activity | Self-efficacy score : p<0.001 |
| | mixed method | and decreasing overall sedentary behaviour) | BMI: NS |
| | Behavioural and environmental change intervention Follow up study | Other: none reported | Qualitative results: |
| | | Environmental factors: Family programs and interventions on school shops and lunch boxes to create an environment to promote healthy choices. | Increased knowledge, skills and self-confidence preparing and enjoying healthy food. |
| | | Instruments use: | |
| | | Focused group discussions | |

| | | - Adopted questionnaire | |
|--|--|---|---|
| | | - Anthropometric measurement | |
| | | Duration of intervention: 1 year | |
| | | Follow-up: None reported | |
| | | Teacher involvement: Role modelling and teacher centred program | |
| Habib-Mourad et al. (2020), Lebanon | Age: 9 – 11 years Sample: Cluster of middle school students Sample size: Intervention (n= 699) Control (n = 701) Total (n = 1400) Study Design: Two Randomized control trials in one study Behavioural and environmental change intervention Follow up study | Parent involvement: Role modelling, accessibility and availability of healthy choices Digital component: None reported Behavioural intervention: interactive classroom learning, family programmes and healthy food choices (<i>Promotion</i> increasing consumption of fruits and vegetables, favouring healthy over high energy dense snacks and drinks, increasing the habit of having breakfast daily, increasing moderate-to-vigorous physical activity and decreasing overall sedentary behaviour) Other: Team of nutritionist involved in one arm of trial Environmental factors: Family programs and interventions on school shops and lunch boxes to create an environment to promote healthy choices. | Knowledge score Nutritionist OR= 2.97, 95%CI (2.68; 3.68) Teacher OR= NS Self-efficacy score Nutritionist = OR= 2.00, 95%CI (1.45; 2.50) Teacher = NS -Dietary habits Nutritionist: Significant Teacher: NS Physical activity Nutritionist: NS Teacher: NS |
| | | Instruments use: | |
| | | - Pretested questionnaire | |
| | | - No anthropometric measurement | |
| | Age: 12 16 years | - No anthropometric measurement Duration of intervention:3 months | • Intervention group Pre vs post |
| Sa Sa Kebaili et al. (2014), Tunisia Int Cc To | Age: 12 – 16 years Sample: Middle school students | Follow-up: None reported Teacher involvement: None reported | significant knowledge, intentions, and behaviours changes pre to post test |
| | Sample size: Intervention (n= 1247) | Parent involvement: None reported | • Control group Pre vs post |
| | Control $(n = 1091)$ | Digital component: None reported | No significant knowledge, intentions, and |
| | Total $(n = 2338)$ | Behavioural intervention: Healthy nutrition promotion | behaviours changes pre to post test |
| | Study Design: | (importance of balanced diet, breakfast, dietary pyramid) | • Control vs Intervention group |
| | Quasi-experimental | Other: None reported Environmental factors: None reported | Intervention group showed a significan improvement than in the control group a |

| | Behavioural intervention | Instruments use: | post-assessment |
|--|---|--|--|
| | Follow up study | - Validated self-administered questionnaire | |
| | | - No anthropometric measurement | |
| | | Duration of intervention:3 months | |
| Harrabi et al. (2010), Tunisia | Age: 12 – 16 years Mean (13.4± 1.1) Sample: 4 Public secondary school Sample size: Intervention (n= 1965) Control (n = 1737) Total (n = 2338) Study Design: quasi experimental Behavioural intervention Follow up study | Follow-up: None reported Teacher involvement: None reported Parent involvement: None reported Digital component: None reported Behavioural intervention: Cardiovascular disease risk factors prevention curriculum Health promotion (60 min) on -tobacco prevention, -physical activity -healthy eating Other: None reported Environmental factors: None reported Instruments use: - Pre-tested self-administered questionnaire - Anthropometric measurement | Intervention group Pre vs post Diet (fruit and veg.): NS Recommended PA: p<0.001 BMI = NS Control group Pre vs post Diet (fruit and veg.): p= 0.03(increase of fruit an veg) Recommended PA (>30 min/day): p<.001 BMI = NS Control vs Intervention group Diet (fruit and veg.): NS Recommended PA (>30 min/day): p<.001 BMI = NS |
| J. M. Maatoug et al. (2013), Tunisia | Age: $12 - 16$ years Mean (13.4 ± 1.1) Sample: Middle school Sample size: Intervention (n = 1247) Control (n = 1091) Total (n = 2338) Study Design: quasi experimental | Duration of intervention: 1 academic year Follow-up: None reported Teacher involvement: None reported Parent involvement: None reported Digital component: None reported Behavioural intervention: Promotion on healthy nutrition and physical activity for at least 30 min a day/5days/week and a sedentary activity for less than 2 hour per day Other: None reported | Intervention group Pre vs post Intention of Diet (fruit and veg.): p<0.001 Behaviour of Diet (fruit and veg.): p<0.001 Intention of Recommended PA (>30 min/day p<.001 Behaviour of Recommended PA (>30 min/day p<.001 Control group Pre vs post Intention of Diet (fruit and veg.): NS |

| | Behavioural intervention | Environmental factors: None reported | Behaviour of Diet (fruit and veg.): p= 0.03 |
|----------------------------|----------------------------------|---|---|
| | Follow up study | Instruments use: | Intention of Recommended PA (>30 min/day) |
| | | - Pre-tested self-administered questionnaire | NS |
| | | - No anthropometric measurement | Behaviour of Recommended PA (>30 min/day) NS |
| | | | • Control vs Intervention group |
| | | | Not reported |
| | | Duration of intervention: six months period | |
| | | Follow-up: None reported | |
| | | Teacher involvement: None reported | • Intervention group Pre vs post |
| | | Parent involvement: None reported | Diet (fruit and veg.): p<0.001 |
| | Age: 12 – 15 years | Digital component: None reported | PA (>10 min/day walk): p<.001 |
| | Sample: Intermediate Schools | Behavioural intervention: One-day counselling session (lectures, | Weight : NS |
| | grades 7-9), all female students | open discussions, role-playing, games, and | BMI: NS |
| Awad Elkarim Elfaki et al. | Sample size: | questions) | Control group Pre vs post |
| (2020), Saudi Arabia | Total $(n = 565)$ | -Health education classes (for healthy eating and physical | Diet (fruit and veg.): NS |
| | Study Design: | activity) | PA (>10 min/day walk): NS |
| | quasi experimental | - physical activity | Weight : NS |
| | Behavioural intervention | (morning sessions) | BMI: increase in obesity (p=0.015) |
| | Follow up study | Other: None reported | Control vs Intervention group |
| | | Environmental factors: None reported | |
| | | Instruments use: | Not reported |
| | | - Pre-tested self-administered questionnaire | |
| | | - Anthropometric measurement | |
| | Age: 11 – 16 years | Duration of intervention: six months period | • Intervention group Pre vs post |
| | Intervention = 13.1 ± 0.96 | Follow-up: 4 months | Diet (daily calorie decrease) : p<0.001 |
| Jihen Maatoug et al. | $Control{=}13.5\pm0.89$ | Teacher involvement: None reported | Recommended PA (>30 min/day): p= NS |
| (2015a), Tunisia | Sample: Grades 7 and 8 | Parent involvement: None reported | BMI Z-score = <0.001 |
| | (overweight and obese) students | Digital component: None reported | BMI =NS |
| | Sample size: | Behavioural intervention: The "Contrepoids" program for 1 year; | Control group Pre vs post |

| | Intervention (n = 317) Control (n = 268) Total (n = 585) Study Design: quasi experimental Behavioural intervention Follow up study | 1 hour of Counselling, (Healthy eating and regular physical activity); Twice a week physical activity Other: None reported Environmental factors: None reported Instruments use: 24 hours food recall -3-day PA recall Anthropometric measurement | Diet (daily calorie increase): p<0.001 Low Recommended PA (>30 min/day): p<0.00 BMI Z-score= p<0.001 (<i>increased BMI</i>) BMI = p<0.001(<i>increased BMI</i>) • Control vs Intervention group Not reported |
|---|---|---|--|
| Ben Cheikh et al. (2020), Tunisia | Age: $6 - 12$ yearsIntervention = 8.89 ± 1.6 yearsControl = 8.55 ± 1.7 yearsSample: first-sixth grade childrenand their parents (primary school)Sample size:Intervention (n = 9)Control (n = 11)Total (n = 20)Study Design:quasi experimentalBehavioural interventionEnvironmentalchangeinterventionFollow up study | Duration of intervention: five months Follow-up: Not reported Teacher involvement: None reported Parent involvement: Role modelling and healthy dietary choices Digital component: None reported Behavioural intervention: Promotion of healthy eating habits only Other: None reported Environmental factors: (Provision of healthy snacks and limited accessibility snacks) Instruments use: pre-tested self-administered questionnaire (parents and children) Anthropometric measurement | Intervention group Pre vs post Diet (decreased morning snacks) : p=0.009 Control group Pre vs post Diet (decreased morning snacks) : p=0.009 Control vs Intervention group Not reported |
| Kutbi et al. (2019), Saudi Arabia | Age: $10 - 15$ years Mean = 14.45 ± 2.32 years Sample: Male adolescents Sample size: Intervention (n = 79) Control (n = 69) Total (n = 148) | Duration of intervention: 2 mons Follow-up: 2 months Teacher involvement: None reported Parent involvement: Role modelling and healthy dietary choices Digital component: None reported Behavioural intervention: -Health education consumption of healthy diet and doing regular PA | Intervention group Pre vs post Not reported Control group Pre vs post Not reported Control vs Intervention group PA (weeks, minutes)= NS BMI= NS |

| | dropout rate 18.8% | (2 weeks), -counselling (2 week) | |
|---|--|---|---|
| | Study Design: | -Presentation about healthy life style and discussion (2 weeks each) | |
| | Cluster Randomized controlled trial | Other: None reported | |
| | Behavioural intervention | Environmental factors: none reported | |
| | Environmental change intervention | Instruments use: - Validated self-administered questionnaire | |
| | Follow up study | - Anthropometric measurement | |
| Allafi (2020), Kuwait | Age: 9 – 11 yearsSample: Students from six publicelementary schoolsSample size:Boys (n = 110)Girls (n = 115)Total (n = 225)Study Design:Randomized controlled trialBehaviouralintervention(Physical activity)Follow up study | Duration of intervention: 6 weeks Follow-up: 6 weeks Teacher involvement: None reported Parent involvement: None reported Digital component: None reported Physical activity intervention: Rewards for walking And its impact on increasing children's physical activity Other: None reported Environmental factors: none reported Instruments use: -pedometers (measures number of steps) -Anthropometric measurements | Intervention group Pre vs post Not reported Control group Pre vs post Not reported Control vs Intervention group PA (Number of steps) : Control mean (lowest steps)vs Feedback vs Feedback & reward (highest steps) = p<0.001 BMI : not reported |
| Ayman Bani Salameh et al. 2017), Jordan | Age: 12 – 18 yearsMean (15.3 years)Sample: overweight or obeseadolescents/studentsSample size:Intervention (n = 205)Control (n = 196)Total (n = 401)Study Design:Single blinded Randomizedcontrolled trial | Duration of intervention: 3 months Follow-up: 3 months Teacher involvement: None reported Parent involvement: None reported Digital component: None reported Behavioural intervention: 12 week program Promotion on healthy nutrition and physical activity Other: None reported Environmental factors: none reported Instruments use: -Anthropometric measurements | Intervention group Pre vs post P value not reported Control group Pre vs post P value not reported Control vs Intervention group Weight (kg): p<0.001 |

| | Behavioural intervention | - Blood glucose measurements | |
|---------------------------------------|--|---|---|
| | Follow up study | | |
| El Ansari et al. (2010), Egypt | Age (mean±SD)Intervention $(15.7\pm1.8 \text{ years})$ Control ($15.4\pm1.6 \text{ years})$ Sample: Secondary school pupilsSample size:Intervention (n = 80)Control (n = 80)Total (n = 165)Study Design:Randomized controlled trialBehavioural intervention(Physical activity)Follow up study | Duration of intervention: 3 months Follow-up: 3 months Teacher involvement: None reported Parent involvement: None reported Digital component: None reported Behavioural intervention: 12 week physical activity only: (30 minutes two sessions per week with moderate intensity) Other: None reported Environmental factors: none reported Instruments use: -Anthropometric measurements - Physiologic measurements | Intervention group Pre vs post P value not reported Control group Pre vs post P value not reported Control vs Intervention group BMI(both girls and boys): p<0.05 Body fat(both girls and boys): p<0.05 |

RCT: Randomised controlled trials; NS: Not Significant, PA: physical activity

3.3 Quality Appraisal of Included Articles

3.3.1 Randomisation

To assess the strength and weaknesses of the included studies, the methodological and statistical analysis was tabulated in a form of quality appraisal (see Tab 3) (Jackson et al., 2006). Most studies (n=16) recruited their eligible participants or schools using random or randomly stratified proportional sampling (Allafi, 2020; Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Ben Cheikh et al., 2020; Dendana et al., 2017; El Ansari et al., 2010; Ghammam et al., 2017; Habib-Mourad et al., 2020; Habib-Mourad et al., 2014; Harrabi et al., 2010; Kebaili et al., 2014; Kutbi et al., 2019; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b; J. M. Maatoug et al., 2013; Zammit et al., 2016) and two studies only included obese or overweight participants (Ayman Bani Salameh et al., 2017; Jihen Maatoug et al., 2017; Jihene Maatoug et al., 2015a).

Table 3. Quality appraisal

| Author citations | RECRUITMENT (were participants representative) | ALLOCATION (how were participants allocated to control and intervention? Randomly?) | M) MAINTENANCE (did participants remain in the groups) | BLIND O) OBJECTIVE M) MEASUREMENT -were outcome assessors blind? -Were outcomes measured objectively? | Analysis -sufficient power -reported effect estimates |
|----------------------------------|--|--|--|---|--|
| Kebaili et al. (2014) | -Yes, stratified and proportional sampling | -Not randomly allocated | Yes, maintained in the same group, 6% drop out | -blinding not mentioned -Yes, validated questionnaire and Outcomes measured objectively | - power not reported -only P-value reported |
| Zammit et al. (2016) | -Yes, randomly selected from eligible participants | -Not randomly allocated | Yes, dropout not mentioned | -questionnaire used, blinding not mentioned Yes, standard, validated questionnaire | Yes sufficient power -reported effect estimates |
| Jihene Maatoug et al. (2015b) | - Yes, randomly selected from eligible participants | -Not randomly allocated | Yes, control and intervention group from different schools. No dropouts | -questionnaire used, trained interviewers but blinding not mentioned Yes, Outcomes measured objectively | Yes, sufficient power -reported effect estimates |
| Ghammam et al. (2017) | - randomly selected from eligible participants | - Not randomly allocated | No, possible that the control group was contaminated by the intervention effect, dropouts not clear | -questionnaire used, trained interviewers but blinding not mentioned Yes, Outcomes measured objectively | Yes, sufficient power -reported effect estimates |
| Harrabi et al. | -Yes, stratified and proportional | - Not randomly allocated | Yes, maintained in the same | -blinding not mentioned | Yes, |

| (2010) | sampling | | group, 6% drop out | -Yes, validated questionnaire | sufficient power -reported effect estimates |
|--------------------------------------|--|--------------------------|---|--|---|
| J. M. Maatoug et al. (2013) | Yes, multiple classes were selected stratified and proportional sampling | - Not randomly allocated | Yes, maintained in the same group, 6% drop out | -blinding not mentioned -Yes, validated questionnaire | Yes, sufficient power -reported effect estimates |
| Awad Elkarim Elfaki et al. (2020) | Yes, schools were randomly chosen only 79.2% response rate | - Not randomly allocated | Not mentioned | -blinding not mentioned -Yes, objectively measured | Yes, appropriate analysis was displayed |
| Dendana et al. (2017) | Yes, stratified proportional sampling | -Not randomly allocated | High, 92.9% response rate post intervention | Objectively measured but no blinding of assessors | Yes, sufficient power -reported effect estimates |
| Jihen Maatoug et al. (2015a) | No, but only overweight and obese school children | - Not randomly allocated | 71% post intervention and 57% follow-up in intervention group and 67% post assessment and 59% follow-up for control group | -blinding not mentioned -BMI and meal recall measured objectively by trained interviewers | Yes, sufficient power -reported effect estimates |
| Ben Cheikh et al. (2020) | Yes, stratified proportional sampling | - Not randomly allocated | Not mentioned | -blinding Not mentioned Only questionnaire, no objective assessment | Yes, sufficient power -reported effect estimates |
| Kutbi et al. (2019) | Yes, random sampling of the clusters | Yes, | 11% dropout from intervention and 19% from control group | -blinding not mentioned Yes objectively measures | Yes, sufficient power -reported effect estimates |
| Allafi (2020) | Yes | Yes | No mentioned | -blinding not applicable Objectively measured using Pedometers | Yes, sufficient power -reported effect estimates |

| Habib-Mourad et al. (2014) | Yes | Yes | 3% dropout from intervention and 3% from control group | -blinding not mentioned Yes, Outcomes measured objectively | Yes, sufficient power -reported effect estimates |
|--|-----|-----|--|---|--|
| Habib-Mourad et al. (2020) | Yes | Yes | Nutrition group – 9% dropout Teacher group - 12 % dropout | -blinding not mentioned Yes, Outcomes measured objectively | Yes, sufficient power -reported effect estimates |
| Ayman Bani Salameh et al. (2017) | Yes | Yes | Yes Dropouts not mentioned | Yes -Blinding not mentioned Yes, Outcomes measured objectively | Yes, sufficient power -reported effect estimates |
| El Ansari et al. (2010) | Yes | Yes | No dropout after enrolment | -Blinding not mentioned Yes, Outcomes measured objectively | Yes, sufficient power -reported effect estimates |

3.3.2 Attrition

Acceptable level of attrition in interventional studies is considered to be up to 20% (55). None of the studies reported high levels of dropout (Dendana et al., 2017; El Ansari et al., 2010; Habib-Mourad et al., 2020; Habib-Mourad et al., 2014; Harrabi et al., 2010; Kebaili et al., 2014; Kutbi et al., 2019; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b; J. M. Maatoug et al., 2013), although six studies did not discuss attrition (Allafi, 2020; Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Ben Cheikh et al., 2020; Ghammam et al., 2017; Zammit et al., 2016).

3.3.3 Instrument and Outcome Measurement

As discussed, most of the tools used to measure study outcomes included validated questionnaires, pedometers and validated weight measurement which were objectively measured. One study used pedometers to measure the steps taken during exercise (Allafi, 2020). Apart from one study (Ayman Bani Salameh et al., 2017), no concealment or assessor blinding was reported during the measurement of the outcomes. The nature of the interventions such as altering calorie intake, regular physical activity and counselling in most studies made participant blinding difficult to execute. Overall, most studies reported all necessary statistical analysis with only one study (Kebaili et al., 2014) reporting p-values without the mean and standard deviation of the outcome of interest.

4. Discussion

The purpose of this scoping review was to compile evidence regarding the effectiveness of school-based interventions on prevention and/or reduction of obesity among children and adolescents in Arab speaking countries in the last decade. As most of the studies were with adolescents, our findings provide greater evidence on the effect of school-based interventions among adolescents compared to children in the region. A total of 16 studies were included from six countries. The school-based interventions focused on physical activity and/or nutritional changes as well as the changes in knowledge and attitude in regard to physical activity and nutrition. Some of the studies engaged parents and others were implemented by teachers and/or nutritionists.

Obesity in children and adolescents has serious implications and thus it is critically important to implement effective interventions aimed focusing on prevention and/or reduction. Articles included in this review have evaluated the impact of different types of interventions on prevention or reduction of obesity among children and adolescent. These interventions have used behavioural, environmental or multicomponent strategies to prevent and/or reduce childhood and adolescent obesity. While some studies used weight reduction strategies for those who were already obese, others focussed on maintaining the health routine of exercise as well is healthy diet. Although the ultimate principles of weight management in children and adolescents are to reduce energy intake and increase energy expenditure, intervention approaches differ (weight reduction vs weight maintenance). Therefore, intervention frameworks should be suitable for specific age groups, and include strategies for prevention and reduction of overweight and obesity.

Interventions to prevent obesity among school-aged children usually focus on promoting healthy lifestyles such as good nutrition and physical activity (Mulrine, 2013). Based on this scoping review, the implementation of strategies to address behavioural changes resulted in reduction in weight and/or obesity in six (6) studies (Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Dendana et al., 2017; Ghammam et al., 2017; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b). The characteristics of studies in this review varied from six (6)which involved large sample sizes (Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Dendana et al., 2017; Ghammam et al., 2017; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b), three (3) with long term follow up of 1-3 years (Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b), five (5) studies which used random participant selection (Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b), two (2) with low dropout rate (Dendana et al., 2017; Jihene Maatoug et al., 2015b) and four (4) which used validated questionnaires (Awad Elkarim Elfaki et al., 2020; Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b). However, five (5) studies (Awad Elkarim Elfaki et al. (2020); Dendana et al. (2017); Ghammam et al. (2017); Jihen Maatoug et al. (2015a); Jihene Maatoug et al. (2015b)) did not randomly allocate participants, while non-blinding approach to assessing outcome measures was used in six (6) studies (Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Dendana et al., 2017; Ghammam et al., 2017; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b). In addition, Elfaki and colleagues selected only female participants in a quasi-experimental study (Awad Elkarim Elfaki et al., 2020).

Conversely, a combination of behavioural changes and physical activity did not show significant effect on reduction of obesity or BMI in four (4) studies (Habib-Mourad et al., 2014; Harrabi et al., 2010; Kutbi et al., 2019;

Zammit et al., 2016). However, despite non-significant effect on obesity or BMI strengths and limitations are worthy of discussion. Strengths include large sample sizes (Habib-Mourad et al., 2014; Harrabi et al., 2010; Kutbi et al., 2019; Zammit et al., 2016), long term follow up of 1–3 years (Zammit et al., 2016), random participant selection (Habib-Mourad et al., 2014; Harrabi et al., 2010; Zammit et al., 2016), random allocation of participants (Habib-Mourad et al., 2014; Kutbi et al., 2019), and use of validated questionnaires (Harrabi et al., 2010; Zammit et al., 2016). High dropout rate was observed (Kutbi et al., 2019) or dropout rate was not mentioned in these studies (Harrabi et al., 2010; Zammit et al., 2010; Zammit et al., 2010; Zammit et al., 2016). For two studies intervention duration was less than 1 year (Habib-Mourad et al., 2014; Kutbi et al., 2019). Non-random allocation of participants (Harrabi et al., 2010; Zammit et al., 2010; Mon-random allocation of participants (Harrabi et al., 2010; Zammit et al., 2019). Non-random allocation of participants (Harrabi et al., 2010; Zammit et al., 2010; Zammit et al., 2010; Zammit et al., 2010; Mon-random allocation of participants (Harrabi et al., 2010; Zammit et al., 2010; Zammit et al., 2010; Zammit et al., 2010; Mon-random allocation of participants (Harrabi et al., 2010; Zammit et al., 2010; Mon-random allocation of participants (Harrabi et al., 2010; Zammit et al., 2010; Mon-random allocation of participants (Harrabi et al., 2010; Zammit et al., 2010; Mon-random allocation of participants (Harrabi et al., 2010; Zammit et al., 2010; Mutbi et al., 2019; Zammit et al., 2016) was observed.

Our scoping review demonstrated that intervention type is important for changes in outcome variables to occur (Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Dendana et al., 2017; Ghammam et al., 2017; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b). In this regard, interventions with more than one component were associated with significant changes in outcome variables related to knowledge, attitude and behavioural changes (Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Dendana et al., 2017; Ghammam et al., 2017; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b). Habib-Mourad et al. (2020) demonstrated a statistically significant improvement in both knowledge and self-efficacy among intervention versus the control groups. This intervention focused mainly on dietary behaviours, as well as physical activity and was delivered via a randomized trial by experts in nutrition in one arm and non-nutrition specialists (trained schoolteachers) on the other. The intervention involved parents as role models. When the programme was delivered by trained schoolteachers, frequency of breakfast intake was increased, crisps consumption was reduced, but no change in fruit and vegetable consumption was observed, however the latter increased when delivered by nutrition experts (Habib-Mourad et al., 2020). Habib-Mourad and colleagues did not report statistically significant improvement in physical activity between the arms of the study. Several studies which evaluated multicomponent interventions have reported similar results to that demonstrated by Habib-Mourad et al. (2020). (Awad Elkarim Elfaki et al., 2020; Ayman Bani Salameh et al., 2017; Dendana et al., 2017; Ghammam et al., 2017; Jihen Maatoug et al., 2015a; Jihene Maatoug et al., 2015b). However, there are mixed results with regards to the impact of multicomponent intervention on outcome variables related to reduction in body weight or obesity.

In relation to the intervention duration, the present review showed that time is an essential variable for changes to occur. Interventions with a duration of less than 1 year (Habib-Mourad et al., 2014; Kutbi et al., 2019) mostly did not show significant impact on body weight than those whose duration ranged from 1-3 years (Dendana et al., 2017; Ghammam et al., 2017; Jihene Maatoug et al., 2015b). However, one 3-year intervention failed to show significant impact on most of the variables related to obesity (Zammit et al., 2016). According to Zammit et al. (2016) there was a lack of sustainability of the intervention which may be associated with a lack of infrastructure/environmental interventions in the program. Indeed, interventions focusing mainly on education may not be effective long-term as a supportive and enabling environment is essential (Zammit et al., 2016). It is recommended comprehensive, targeted programs including a combination of strategies/interventions including changes in infrastructure such as adapted environment to practice physical activity, increased affordability of healthy foods and decreased access to unhealthy foods which complement behavioural educational programs be implemented.

Interventions appear to improve behavioural and outcomes related to physical activity in the short to medium term (3 months – 1 year) however the impact either diminishes or stagnates when interventions lasted more than 1 year. Since studies evaluated school-based health promotion programs, it is plausible the teachers' difficulty to motivate, capture the students' attention, and maintain it overtime could explain this observation. Duration of intervention is an important consideration as short-term strategies have previously demonstrated to be ineffective in treating obesity compared long-term strategies (Gonzalez-Suarez, Worley, Grimmer-Somers, & Dones, 2009; Kothandan, 2014). This may in part explain the non-significant effect of behavioural changes or physical activity interventions on obesity or BMI seen in a number of studies. While an interventions of excessively short period may not produce effects, and an excessively long-term interventions may diminish or stagnate effect due to decrease in levels of motivation over time.

Influences of obesity are multifactorial and the result of complex interconnections among genes, environmental, behavioural (nutrition and physical activity), cultural, social and economic factors (Fishbein, 2001). Literature has revealed that school-based health interventions effective in changing long term health outcomes (Stewart-Brown, 2006). Therefore, a multi-faceted school-based intervention is one of the key solutions to prevent and control the overweight and obesity among children and adolescents. The present scoping review has demonstrated significant and non-significant effects of behavioural interventions on weight reduction and/or obesity which are consistent

with previous a number of systematic reviews (Brown & Summerbell, 2009; Liu et al., 2019; Verjans-Janssen, van de Kolk, Van Kann, Kremers, & Gerards, 2018). Furthermore, while this may not always be applicable, we observed that studies with longer period of follow up showed significant reduction in weight/obesity while studies with shorter term follow up did show significant effect of interventions. Considering the numerous factors, it is not surprising that the treatment of childhood and adolescent obesity is often challenging for public health (Lob-Corzilius, 2007).

5. Limitation

This scoping review has several limitations, some pertain to the findings and some to the conduct of the review. Half of the included studies used quasi-experimental research design which may impact rigour of the studies (Maciejewski, 2020). Based on the quality appraisal result, the overall quality of the included primary studies was moderate, however some, particularly the RCTs, lacked clarity on potential adverse outcomes, appropriate blinding of participants and/or study evaluators, reliable compliance reporting, priori sample size calculations thus power, and maintenance of participants with in the same group throughout the intervention. Other limitations were related to practical issues of completing this scoping review. Study selection was based on eligibility criteria which limited the articles selected that met the criteria of Arabic speaking countries. It is evident that there is a degree of variability occurring in the methodological and theoretical foundation among school-based programs in this review, and this makes evaluating the effectiveness of outcomes more complex and the variability may confound the intervention results (Zenzen & Kridli, 2009).

6. Conclusion

This review has revealed a mixed effect of behavioural interventions on obesity and/or weight. Certain strengths and limitation of studies have influenced the study outcomes. It is necessary to conduct a long-term school-based intervention with rigour methodological and theoretical frameworks as schools can be an avenue or usually seen as a prime site for interventions tackling childhood and adolescent obesity in Arab speaking countries as well as the global context. Tailoring interventions to participants and integrating family and wider environment can give guidance for practitioners and policymakers on how to promote healthy weight in children and address the issue of obesity.

7. Recommendations

This study has several recommendations. Following recommendations for future studies on reduction of weight and obesity:

- 1) Behavioural interventions, including physical activity programs, are effective in reduction of obesity and weight in school children long term.
- 2) Strong methodologies are encouraged to plan these interventions such as large sample sizes, low dropout rate, random selection and allocation of participants to interventions and blinding approach of outcome measures.
- 3) Long term and short-term effect of behavioural interventions on weight/obesity reduction should be investigated further.
- 4) Use of multicomponent interventions with medium term follow up may prevent or reduce obesity among children and adolescents.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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The Efficacy of Probiotics in Treatment of Helicobacter

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| Received: December 14, 2021 | Accepted: March 13, 2022 | Online Published: March 22, 2022 |
|-----------------------------|--------------------------|----------------------------------|
| doi:10.5539/gjhs.v14n4p68 | URL: https://doi.org/10. | 5539/gjhs.v14n4p68 |

Abstract

Background: The standard triple therapy has lost a considerable proportion in it efficiency in treating *Helicobacter pylori* infection. As such several alternatives and adjuvants have been proposed. One the most promising modulation is the supplementation this therapy with probiotics.

Aims: This study aimed to investigate the efficiency of probiotic supplementation to traditional triple therapy in the eradication of Helicobacter pylori infection and alleviation of side effects.

Patients and Methods: This is a cross-sectional study included 310 consecutive patients newly diagnosed with gastritis or dyspepsia and infected with *H. pylori*. Patients were randomly divided into three groups based on treatment regimes. Group A: 100 patients received triple therapy consisting of omeprazole, amoxicillin and levofloxacin for two weeks. Group B: 100 patients received tinidazole, levofloxacin and omerprazole for two weeks. Group C: 110 patients received the second protocol plus the probiotic. All patients were reinvestigated four weeks after accomplished treatment by stool antigen test for *H. pylori*.

Results: The rate of successful H. pylori eradication was 77.74%. In multivariate analysis, each of age \leq 35 years (OR=0.51, 95%CI=0.28-0.93), being married (OR= 0.37, 95%CI=0.21-0.71), never smoker (OR= 0.55, 95%CI=0.32-0.95) and treatment regime with triple therapy supplemented probiotics (OR= 3.36, 95%CI=2.5-21.7) were significantly associated with increased the eradication rate. The overall incidence of side effect in group C was (7.27%) was lower than that B (19%) with significant difference, and group A (15%) with no significant difference.

Conclusions: The use of probiotics as an additive for the standard triple therapy significantly increases the eradication of *H. pylori* and may reduce the incidence of side effect of the traditional therapy.

Keywords: Helicobacter, probiotics, treatment

1. Introduction

1.1 Definition

Helicobacter pylori is a common bacteria infecting about half of world's population, with higher prevalence in developing countries, where *H. pylori* could infect up to 80% of the population, than in developed ones. It also associated with the development of gastrointestinal disorders as chronic gastritis, peptic ulcer, and gastric adenocarcinoma and involved in the development of other extra-gastric disorders such as mucosa-associated lymphoid tissue (MALT) lymphoma, idiopathic thrombocytopenic purpura, vitamin B12 deficiency, and iron

deficiency (Goderska, Pena, & Alarcon, 2018).

1.2 Treatment

1.2.1 Classical Treatment and Difficulties

In adults, the current standard eradication treatment for *H. pylori* infections comprises triple or quadruple combination therapies. Triple therapy involves a proton pump inhibitor (PPI) as pH-control pharmaceutic, and the concomitant or consecutive treatment with two antibiotics (clarithromycin, metronidazole or amoxicillin) for 1-2 weeks. The success of this therapy is unfortunately under pressure due to a rising antibiotic resistance (Gatta et al., 2013).

Antibiotic resistance stems from escape mutations, drug inactivation, drug efflux pumps and altered membrane permeability but also antibiotic tolerance due to the presence of biofilm-embedded or dormant, nonreplicating bacteria can cause recalcitrant and recurrent infection (Francesco et al., 2013).

A meta-analysis of 87studies showed that average rates of H. pylori antibiotic resistance were 47.22% (30.5-75.02%) for metronidazole, 19.74% (5.46-30.8%) for clarithromycin, 18.94% (14.19-25.28%) for levofloxacin and 14.67% (2-40.87%) for amoxicillin, 11.70% (0-50%) for tetracycline, 11.5% (0-23%) for furazolidone and 6.75% (1-12.45%) for rifabutin (Thung et al., 2016).

For this reason, the Maastricht group in Europe reviews H. pylori eradication efficacies and optimal treatment regimens per region on a 2-year basis (Malfertheiner et al., 2017). Currently, treatment being prolonged to 2 weeks and quadruple therapy, which includes bismuth or a third antibiotic (tetracyclin, levofloxacin or furazolidone), is becoming more strongly recommended as a first-line treatment (Malfertheiner et al., 2017; Fallone et al., 2016). The high dosage and longitude of these treatments places a heavy burden on the patient and a lack in patient compliance is, therefore, another main reason for treatment failure. When treatment fails, rescue therapy is considered, but is recommended only in patients who have failed to respond with three or more prior treatments (Fallone et al., 2016).

1.2.2 Probiotics

Probiotics are defined as living microorganisms that, when administered in adequate amounts, can improve microbial balance in the intestine and exert positive health effects on the host (FAO/WHO 2002), including beneficial effects on the prevention of intestinal infections, cardiovascular disease, cancer, and anti-allergic effects (Pianoa et al., 2006).

Probiotics can be microorganisms from the bacteria or yeasts group. However, most of probiotics are bacteria, among them lactic acid bacteria, typically associated with the human gastrointestinal tract, which are the most widely used (Rodes et al., 2013). They include Gram positive cocci and rods *Lactobacillus* and *Bifidobacterium*, which are the two most common species used as probiotics and are extensively investigated for their beneficial effects on the host, including promotion of gut maturation and integrity, antagonism against pathogens, and modulation of the immune system and tumor promoting agents (Goderska et al., 2018).

Non-immunological Mechanism

The first line of defense against pathogenic bacteria is acidity of the stomach and the gastric mucosa barrier. this first line of defense could be stronger due to the production of antimicrobial substances competing with *H. pylori* for adhesion receptors, stimulating mucin production and stabilizing the gut mucosal barrier (Goderska, Pena, & Alarcon, 2018).

Antimicrobial Substances

Probiotics may inhibit *H. pylori* growth by secreting short chain fatty acids and antibacterial substances (Cheng et al., 2008).

Immunologic Mechanisms

Probiotics could modify the immunologic response by the modulation of anti-inflammatory cytokines secretion, which would result in a reduction of gastric activity and inflammation (Boulang'e et al., 2016).

1.3 Aims of the Study

This study aimed to investigate the efficiency of probiotic supplementation to traditional triple therapy in the eradication of *Helicobacter pylori* infection and alleviation of side effects.

2. Patients and Methods

2.1 Design and Settings

This is a cross-sectional study on a consecutive series of patients newly diagnosed with gastritis or dyspepsia and infected with *H. pylori* admitted to department of Gastroenterology / Baghdad Medical City and Gastro-Intestinal Tract (GIT) center with medical wards during the period from October 2018 to December 2019. Patients were entered consecutively into the study until an arbitrary sample size of 150 patients was reached after application of the inclusion and exclusion criteria.

2.2 Inclusion Criteria

Patients with the following criteria were included:

- \triangleright age 18–60 years;
- Both sexes are involved
- > presented with upper gastrointestinal symptoms,
- confirmed H. pylori infection;

2.3 Exclusion Criteria

Patients with the following conditions were excluded from the study:

- chronic diseases, e.g. renal failure and cirrhosis;
- ➤ malignancies;
- > gall bladder disorders;
- History of gastrointestinal surgery.
- Pregnant and lactating women
- > The use of antibiotics or probiotics in the past month
- Prior history of treatment of H. pylori infection
- ➢ known allergy to the used medications.

2.4 Ethical Consideration

A verbal consent from each participant was obtained prior to data collection after explaining the aim of study. Each patient was given the complete unconditioned choice to withdraw anytime. The confidentiality of data throughout the study was guaranteed and the patients were assured that data will be used for research purpose only.

2.5 Definitions

- H. pylori infection was defined as positivity to one or more of these tests: H. pylori antigen in stool; histopathological confirmation of H. pylori and/or and rapid urease test.
- ➤ H. pylori eradication is defined in this study as concomitant negativity to all previously positive tests 4 weeks after the end of therapy (6 weeks after the end of the standard triple therapy).

2.6 Patient Assessment

Eligible patients were underwent to the following evaluation.

- ▶ Full history-taking and full clinical examination.
- > The infection with *H. pylori* was established by one of following criteria:

A positive serology test, culture or urea breath test.

- Detection of *H. pylori* antigen in a stool sample (On Site *H. pylori* Ag Rapid Test, USA). This is a qualitative detection of *H. pylori* antigens based on the monoclonal anti-*H. pylori* antibodies conjugated with colloid gold. According to the test, positive cases are characterized with two bands of color changes.
- After 4 weeks of therapy, the *H. pylori* antigen was re-examined in stool and urea breath test was also conducted.

2.7 The Study Groups

According to treatment protocol, patients were randomly allocated to three groups

Group A: 100 patients treated with standard triple therapy compromising omeprazole 40 mg b.d., amoxicillin 1000 mg b.d., and levofloxacin 500 mg o.d. for two weeks

Group B: 100 patients received tinidazole 500 mg, levofloxacin 500 mg and omerprazole 40 mg, balance two capsule daily for two weeks.

Group C: 110 patients received the second protocol plus the probiotic (Protexin Balance/UK). This probiotic provides a complex blend of 7 strains of friendly bacteria and prebiotic in easy to swallow capsules. probiotics are *Lactobacillus casei*, *Lactobacillus rhamnosus*, *Streptococcus thermophilus*, *Bifidobacterium breve*, *Lactobacillus acidophilus*, *Bifidobacteriumlongum*, *Lactobacillus bulgaricus*, (TVC: 200 million colony forming unit (CFU) TVC: 2×10⁸ CFU) and also FOS (fructooligosaccharide-prebiotic), magnesium stearate (source: mineral and vegetable), and vegetable capsule (hydroxypropyl methyl cellulose).

All patients were asked to have full and regular usage of the treatment protocolin order for effective eliminating *H.pylori*. They were also encouraged to maintain complete abstinence smoking, eating chocolate, cheese or eggs and not to use antidepressants.

All patients were re-examined4 weeks after completion the treatment by stool antigen test for *H. pylori*. Accordingly, successful treatment was set as a negative stool antigen test for *H. pylori*.

2.8 Statistical Analysis

Student t test and analysis of variance (ANOVA) were use compare means between two and three groups, respectively. Univariate and multivariate logistic regression were used to find out the independent predictors for successful H. pylori eradication after the treatment period. In these tests, the odds ratio (OR) and its corresponding 95% confidence interval (CI) were calculated.

3. Results

3.1 Demographic and Clinical Characteristics of the Patients

This study included a total of 310 patients with a confirmed infection with *H. pylori*. The mean age of the patients was 36.3 ± 10.7 years (range= 18-65 years). The male female ration was almost 1:1. Most patients were overweight with a mean BMI of 29.39 ± 4.33 . About two-third of the patients were married, and one-third of them were smokers. The coexistence of another illness was reported in 54.19% of the patients with hypertension was the most frequent comorbidity reported in 21.29% of the patients followed by diabetes (17.1%). Three therapeutic regimes were used: Amoxicillin-levofloxacin –PPI in 100 patients (32.26%), Tinidazole-levofloxacin –PPI with probiotic in 110 patients (35.48%) as shown in Table 1.

| Frequency (%) | |
|---------------|--|
| | |
| 78(25.16%) | |
| 160(51.61%) | |
| 39(12.58%) | |
| 33(10.65%) | |
| | |
| 157(50.65%) | |
| 153(49.35%) | |
| 29.39±4.33 | |
| | |
| 199(64.19%) | |
| 111(35.81%) | |
| | 78(25.16%) 160(51.61%) 39(12.58%) 33(10.65%) 157(50.65%) 153(49.35%) 29.39±4.33 199(64.19%) |

Table 1. Baseline Characteristics of the Patients (N=310)

| Smoking | |
|---------------------------|-------------|
| Never | 206(66.45%) |
| Ex/current smokers | 104(35.55%) |
| Comorbidities | |
| No comorbidity | 142(45.81%) |
| Hypertension | 66(21.29%) |
| Diabetes mellitus | 53(17.1%) |
| Hypertension and diabetes | 28(9.03%) |
| Others | 21(6.77%) |
| Treatment Regime | |
| Amox-levof-PPI | 100(32.26%) |
| Tinid-levof-PPI | 100(32.26%) |
| Tinid-levof-PPI+Prob | 110(35.48%) |
| | |

3.2 H. pylori Eradication

After 4 week of treatment, out of 310 patients, 241(77.74%) had a successful eradication of *H. pylori* according to confirmatory tests. The other 69(22.26%) patients had no complete cure of the infection (Figure 1).

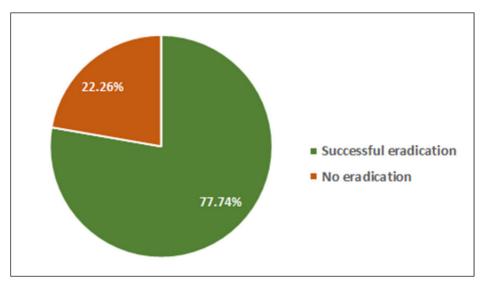


Figure 1. proportion of successful eradication

3.3 Factors Associated with Successful Eradication of H. pylori

Five factors were found to be significantly associated with successful eradication of H. pylori. Patients with successful eradication had significantly younger age than those with no eradication $(34.79\pm9.58$ years vs. 38.98 ± 11.13 years). Furthermore, 68.57% of patients with successful eradication were married compared with 52.94% amongst no eradication with a significant difference. Ex/current smoking was more frequent among patients with persistence than eliminated cases (44.93% vs. 30.29%). The absence of comorbidities in general seems to facilitate *H. pylori* eradication as 50.21% of cured patients showed no comorbidity compared with 30.43% of non-cured patients who had such privilege. Finally, and most importantly, the addition of probiotic significantly increased the cure rate which was 84.55% in patients receiving probiotic additive compared to only 79% in Tinid-levof-PPI and 69% in Amox-levof-PPI group (Table 2).

| Variables | Successful eradication (n=241) | n=241) No eradication (n=69) | |
|------------------------------|--------------------------------|------------------------------|-------|
| Age (years) | 34.79±9.58 38.98±11.13 | | 0.026 |
| Sex | | | |
| Male | 121(50.21%) | 36(52.22%) | 0.773 |
| Female | 120(49.79%) | 33(47.83%) | |
| Marital status | | | |
| Married | 162(68.57%) | 37(52.94%) | 0.038 |
| Single | 79(31.43%) | 32(47.06%) | |
| Smoking | | | |
| Never | 168(69.71%) | 38(55.07%) | 0.023 |
| Ex/current smoker | r 73(30.29%) 31(44.93%) | | |
| BMI (Kg/m ²) | 29.45±4.61 | 29.34±3.6 | 0.692 |
| Comorbidities | | | |
| No comorbidity | 121(50.21%) 21(30.43%) | | 0.011 |
| Hypertension | 45(18.67%) | 21(30.43%) | |
| Diabetes mellitus 35(14.52%) | | 18(26.09%) | |
| Hypertension and DM | 22(9.13) | 6(8.7%) | |
| Others | 18(7.47%) | 3(4.35%) | |
| Treatment Regime | | | |
| Amox-levof-PPI | 69(69%) | 31(31%) | 0.024 |
| Tinid-levof-PPI | 79(79%) | 21(21%) | |
| Tinid-levof-PPI+Prob | 93(84.55%) | 17(15.45%) | |

| Table 2. Factors | associated | with | successful | eradication | of <i>H</i> . | pylori |
|------------------|------------|------|------------|-------------|---------------|--------|
|------------------|------------|------|------------|-------------|---------------|--------|

3.4 Predictors of Successful Eradication of H. pylori

In order to find out whether probiotic is independent factor that interfere with H. pylori eradication, all factors that showed significant association with patient's outcome were entered with univariate and then multivariate models.

In univariate model, all the aforementioned factors demonstrated a significant association with the patient's outcome. Each of younger age (\leq 35 years), being married, never smoking, or present no comorbidity increases the eradication rate by almost double (odds ratio in most cases close to 0.5). On the other hand, the combination of Tinid-levof-PPI+Prob increase the eradication rate by about 4-time compared with Amox-levof-PPI protocol (OR= 4.22, 95%CI=1.63-10.9, p= 0.008). However, in multivariate analysis, comorbidity lost it significant effect, while age, marital status, smoking and treatment regime remained significant. In this regard, Tinid-levof-PPI+Prob was found to increase the eradication rate by 3.36-time compared with Amox-levof-PPI protocol (OR= 3.36, 95%CI=2.5-21.7, p= 0.012) as shown in Table 3.

| | No eradication | Successful | Univaria | te analysis | Multivar | riate analysis |
|-------------------------|----------------|---------------------|----------|-----------------|----------|-----------------|
| Variables | (n=69) | eradication (n=241) | P-value | OR(95%CI) | P-value | OR(95%CI) |
| Age (years) | | | | | | |
| ≤35 | 32(46.38%) | 146(60.58%) | 0.027 | 1.0 Reference | 0.020 | 1.0 Reference |
| >35 | 37(53.23%) | 95(39.42%) | 0.037 | 0.56(0.33-0.97) | 0.029 | 0.51(0.28-0.93) |
| Marital status | | | | | | |
| Married | 37(52.94%) | 162(68.57%) | 0.020 | 1.0 Reference | 0.022 | 1.0 Reference |
| Single | 32(47.06%) | 79(31.43%) | 0.038 | 0.54(0.31-0.96) | 0.022 | 0.37(0.21-0.71) |
| Smoking | | | | | | |
| Never | 38(55.07%) | 168(69.71%) | 0.022 | 1.0 Reference | 0.026 | 1.0 Reference |
| Ex/current smoker | 31(44.93%) | 73(30.29%) | 0.023 | 0.55(0.32-0.95) | 0.026 | 0.55(0.32-0.95) |
| Comorbidities | | | | | | |
| No comorbidity | 21(30.43%) | 121(50.21%) | 0.014 | 1.0 Reference | 0.063 | 1.0 Reference |
| Hypertension | 21(30.43%) | 45(18.67%) | 0.952 | 1.04(0.28-3.85) | 0.561 | 0.66(0.61-2.7) |
| Diabetes mellitus | 18(26.09%) | 35(14.52%) | 0.128 | 2.8(0.74-10.56) | 0.501 | 1.37(0.39-6.87) |
| HTN and DM | 6(8.7%) | 22(9.13) | 0.101 | 3.1(0.8-11.88) | 0.425 | 1.82(0.42-7.95) |
| Others | 3(4.35%) | 18(7.47%) | 0.525 | 1.64(0.36-7.45) | 0.814 | 0.82(0.16-4.17) |
| Treatment Regime | | | | | | |
| Amox-levof-PPI | 31(31%) | 69(69%) | 0.027 | 1.0 Reference | 0.036 | 1.0 Reference |
| Tinid-levof-PPI | 21(21%) | 79(79%) | 0.109 | 2.64(0.78-4.72) | 0.142 | 1.41(0.66-6.58) |
| Tinid-levof-PPI+Prob | 17(15.45%) | 93(84.55%) | 0.008 | 4.22(1.63-10.9) | 0.012 | 3.36(2.5-21.7) |

| Table 3. | Predictors | of successi | ul eradication | of H. pylori |
|----------|------------|-------------|----------------|--------------|
|----------|------------|-------------|----------------|--------------|

3.5 Side Effects

A total of five side effects were reported in treated patients. The frequency of these side effects ranged from 0 to 6 cases in the different groups. Amox-levof-PPI group showed slightly higher rate of some of these effect, than other groups with no significant differences. However, the overall incidence of side effect in Tinid-levof-PPI+Prob was (7.27%) was lower than that of Amox-levof-PPI group (19%) with significant difference, and Tinid-levof-PPi group (15%) with no significant difference (Table 4).

Table 4. Side Effects

| Side effect | Side offect Amore Level DBL (n-100) | | Amox Lovef BBL (n=100) Tinid-levef-PPI | | Tinid-levof-PPI+Prob | P-value | |
|-----------------------------------|-------------------------------------|----------|--|---------|----------------------|---------|--|
| Side effect Amox-Levof-PPI (n=100 | | (n= 100) | (n=110) | r-value | | | |
| Dyspepsia | 3(3%) | 1(1%) | 1(0.91%) | 0.408 | | | |
| Nausea/ vomiting | 2(2%) | 3(3%) | 2(1.82%) | 0.829 | | | |
| Dry mouth | 4(0%) | 2(0%) | 0(0%) | 0.110 | | | |
| Diarrhea | 6(6%) | 5(5%) | 1(0.91%) | 0.125 | | | |
| Abdominal Pain | 4(4%) | 4(4%) | 2(1.82%) | 0.582 | | | |
| Total | 19(19%) | 15(15%) | 8(7.27%) | 0.04 | | | |

4. Discussion

In the early years of *H. pylori* treatment, the results of the standard triple therapy were satisfactorily successful, yielding eradication rates of 95-96% (Lind et al., 1996). However, during the recent decades, several reports had

indicated a serious decline in the eradication rate with this therapy (Chey & Wong, 2007). This has alarmed investigators to find an alternative treatment either by changing the antibiotics, adopting new systems and schedules of therapy, or adding adjuvants that may help enhancing the response to the standard treatment.

According to the result of the present study, the overall eradication of *H. pylori* after different treatment protocols was 77.74%. The effectiveness of eradication therapy regimens has been stratified as excellent (>95%), good (91%-95%), borderline (85%-89%), and unacceptable (<85%) (Graham, Lee, & Wu, 2014). In viewof this suggestion, the present eradication rate unacceptable.

Studies worldwide used different protocols and demonstrated different eradication rates. In a Tanzanian study, Jaka et al. (2019) recruited 210 patients positive for *H. pylori*. First line treatment failure with clarithromycinbased triple therapy was observed 31% of patients (only 69% eradication). In Egypt, Abd-Elsalam*et al.* (Abd-Elsalam et al., 2016) used the standard triple therapy to treat 1090 patients infected with *H. pylori*. Six weeks after completion the treatment, the eradication rate was 59.36% in intention-to-treat population and 62.03% in per-protocol. However, a retrospective analysis performed on 156 American patients treated with similar therapy demonstrated that the cumulative eradication rate for the intent-to-treat population was 84%, while the per-protocol rate was 86% (Nayar, 2018).

This variation between different studies can be attributed to several factors, the most important of which is the massive use of antibiotic in developing countries compared with the strict legislations for antibiotic use in the developed countries. Furthermore, the compliance to the treatment seems to be better in developed countries. Both factors (massive use of antibiotic and incompliance) play a vital role in the development of antibiotic resistance by H. pylori, and eventually reduce the eradication rate.

Based on the results of the current study, four factors other than treatment regime were found to be significantly associated with successful eradication of H. pylori. These were younger age, married individuals, never smokers, and the absence of comorbidities. In a Japanese study including 369 patients, Yokota et al. (2019). reported that failed eradication was significantly associated only with older age. In another study in Ethiopia, patients living in rural area were 2.7-time more likely to achieve eradication compared to urban residents (Gebeyehu, Nigatu, Engidawork, 2019). In Taiwan, Yao et al. (2019) investigate the impact of T2DM on the eradication rate in 719 patients positive for H. pyloriand previously treated with 7-day standard first-line triple therapy. The study revealed that *H. Pylori* was completely eradicated in 74.1% of the T2DM group and 85.3% of the T2DM-free group (p=0.005). Sargýn et al. (2003) reported eradication rate of 50% of patients with T2DMcompared to 85% in the non-diabetic group when a standard triple therapy was used for 10-day treatment (p<0.001). In another study by Vafaeimanesh et al. (2013), it was found that the 14-day protocolresulted in an eradication rate of 63% in the DM group and 87.7% in the control group (p=0.017).Camargo et al. (2007) evaluated the evaluated the eradication rate of *H. pylori* 264 patients. The eradication rate was only 41.3% for active smokers compared with 57.1% in non-smokers Multivariate logistic regression analysis showed that smokers had a 2-fold higher probability of failure in *H. pylori* eradication than non-smokers.

These factors in general influence the patient's general health. Elderly patients generally use many mediations, often experience some cognitive decline, and many of them have physical limitations. All these factors can affect medication compliance and possibly associated with unsuccessful outcome of therapies (Yokota et al., 2019). DM can impairs the immune system to a variable extent. Furthermore, those patients are more susceptible to infections (especially bacterial and mycotic), causing frequent use of antibiotics, which may in turn contribute to the development of resistance. Moreover, DMcancause a damagefor microvasculature of gastric mucosa associated to some reduction in the absorption of antibiotics (Jaap, Shore, & Tooke, 1997). Smoking on the other hand, can decrease the blood flow in the gastric mucosa with the eventual lower delivery rate of antibiotics to the this mucosa. Furthermore, smoking induces acid gastric secretion, which reduces the efficiency of several acid labile antibiotics, likeclarithromycinand amoxicillin (Camargo et al., 2007). No available previous studies indicated the significant role of marital status in *H. pylori* eradication. The significant association in the present study may be attributed to the improvement in the general hygiene of married individuals and the regular taking of medication under the influence of his/her spouse. Elderly patients generally have many medica-tions prescribed, often suffer from cognitive decline, and frequently have physical limitations, which would affect their medication com-pliance and possibly result in unsuccessful outcome of therapies.

In the present study, Tinid-levof-PPI+Prob was found to increase the eradication rate by 3.36-time compared with Amox-levof-PPI protocol (OR= 3.36, 95%CI=2.5-21.7, p= 0.012) which implies that patients using Tinid-levof-PPI+Prob had 3.36-time more like to cure than those using Amox-levof-PPI protocol. The eradication rate for Tinid-levof-PPI+Prob, Tinid-levof-PPI and Amox-levof-PPI was 84.55%, 79% and 69%,

respectively. Such a result was frequently reported by many previous studies worldwide. In one study, 120 patients positive for *H. pylori* were randomized to receive triple therapy, either with or without a lyophilized and inactivated culture of L. acidophilus twice daily. A significantly more eradication rate was perceived in the augmented group (88 %), than non-probiotic treated control group (72 %) (Moodley et al., 2012). Almost similar results were stated by Bekar et al. (2011) from Turkey, who examined the impact of conjoining standard triple anti H. pylori therapy with kefir, a fermented milk derived product containing probiotics. The eradication rate was 78.2% versus 50% in favor of supplemented therapy. Ojetti et al. (Ojetti et al., 2012) used a single strain of Lactobacillus for 14 days also associated with a triple regimen of eradication (PPI + Levofloxacin + Amoxicillin) with 7 days in duration and obtained both increasing eradication and a reduction in adverse effects. Ahmed et al. (2013) investigated the effect of probiotic on eradication rate in 66 Iranian patients positive for *H. pylori*. The study revealed that 90% of supplanted group achieved eradication compared to 69.7% in control group (OR= 4.37, 95%CI= 1.07-17.62, p=0.04). In Saudi Arabia, Dajani et al. (2013) conducted an open randomized observational study to test three different regimes of *H. pylori* eradication treatment. The eradicationrate for the traditional standard therapy was 68.9%, and adding the probiotic "Bifidusinfantis" to triple therapy, led to a successful rate of eradication of 83% (P < 0.001). Pre-treatment with 2 weeks of B. infantis before adding it to standard triple therapy increased the success rate of eradication to 90.5%.

The wide variety and controversial results in previous studies may be attributed to the differences in study design, patient groups, different therapeutic regimens, probiotic dose, and probiotic species.

On the other hand, some studies did not verify significant benefits in probiotic use (Yoon et al., 2011) (Kindermann, 2009). Yoon et al. (2011) prepared a compound of 4 probiotics and used them for 4 weeks, to a treatment for *H. pylori* with PPI + amoxicillin + moxifloxacin. The study revealed neitherincrease eradicationnor a reduction in the adverse effects. The different results are probably due to the different products used, their different concentrations, probiotic strain, dose and duration of use and also the strain of *H. pylori* in question, as suggested by Vitor and Vale (Wilhelm, Johnson, & Kale-Pradhan, 2011) and Wilhelm (Vitor & Vale, 2011).

In the current study, the overall incidence of side effect in Tinid-levof-PPI+Prob was (7.27%) which was lower than that of Amox-levof-PPI group (19%) with significant difference. In accordance with this result is the study of Park et al. (2007) who established that conjoining first line anti *H. pylori* therapy with probiotic bacteria, compromising *Bacillus subtilis* and *Streptococcus faecium* decreased the side effects, enhanced patient's tolerance and improved the eradication rate of *H. pylori*. Also in line with this result is the study of Lakovenko et al. (2006) in which the authors reported that *H. pylori* eradication rate was 89.1 % in the group of probiotics supplementation to standard triple therapy and 63.5 % in the group of standard triple therapy. In a meta-analysis, Szajewska et al. (2015) demonstrated that *Saccharomyces boulardii* supplementation to standard triple therapy could increase the *H. pylori* eradication rate and markedly reduce the side effects, especially the diarrhea. Another meta-analysis showed that multi-strain probiotics improved *H. pylori* eradication rates, prevented any adverse reactions, and reduced antibiotic-associated diarrhea, especially probiotics including Lactobacillus and Bifidobacterium (McFarland et al., 2006). Many other studies have obtained similar results when *L. reuteri*was used as adjuvant to the triple therapy in *H. pylori* eradication (Ojetti et al., 2006; Francavilla et al., 2008; Efrati et al., 2012).

One of most important effect of probiotics in alleviation of side effects is creating an appropriate environment for the growth of normal intestinal anaerobic microbiota, and inhibiting the growth of harmful bacteria such as *Escherichia coli*, dysentery bacili, *Staphylococcus aureus*. As such, probiotics can reduce the side effects associated with these pathogenic bacteria (Tompkins et al., 2008).

5. Conclusions and Recommendations

- 1) The overall eradication of *H. pylori* after different treatment protocols was 77.74%, which is globally unacceptable.
- 2) Each of younger age, married individuals and never smoking are independent factors that can increase the eradication rate of *H. pylori*.
- 3) Supplementation of the standard triple protocol with probiotic increased the eradication rate from 79% to 84.55%.
- 4) Using of probiotic as additives with standard treatment can reduce the incidence of antibiotic side effects

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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General Practitioners' Attitudes toward Traditional Indonesian Herbal Medicine and Integrative Care in the Universal Health Coverage System

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Received: February 18, 2022Accepted: March 22, 2022Online Published: March 25, 2022doi:10.5539/gjhs.v14n4p82URL: https://doi.org/10.5539/gjhs.v14n4p82

Abstract

Implementation of the Universal Health Coverage (UHC) in Indonesia has created renewed momentum for integrating traditional Indonesian herbal medicine (TIHM) in healthcare delivery under the national health insurance program (NHI). At present, little is known about the attitudes of conventional healthcare practitioners towards the clinical use of TIHM. This study aimed to explore the attitudes of general practitioners (GPs) towards TIHM use in conventional care and their perception of the integration of TIHM in the NHI. A total of 30 GPs from 28 conventional health facilities were purposively selected to participate in the study. Both quantitative and qualitative data were collected through administered-questionnaire and interviews. The majority of participating GPs demonstrated a favourable view towards TIHM role in conventional care and the potential integration of TIHM under the NHI. Being used as an adjunct therapy in the conventional treatment of chronic diseases, including degenerative disease and metabolic syndrome, and in palliative care, seemed to be the most promising areas to emphasize TIHM role in conventional care in the anticipated integration. However, only a few GPs had formally prescribed TIHM to their patient. The barriers of TIHM use in their practice include knowledge gap, unclear regulatory procedure, unreliable provision of TIHM and exclusion of TIHM in the NHI. While the GPs accepted the idea of integrative care under the NHI, to achieve an institutional integration, their knowledge base in TIHM must be improved while also addressing regulation, development of TIHM's formal list, and issues of safety of TIHM to ensure evidence-based practice.

Keywords: attitude, integrative care, Indonesia, Universal Health Coverage (UHC)

1. Introduction

Traditional, complementary, and alternative medicine (TCAM) is a form of primary health care that is culturally embedded in the daily health-seeking behaviours of populations in many parts of the world, particularly in African, Asian, and Pacific nations (Park & Canaway, 2019). The prevalence of TCAM has progressively increased over the years, and it varies among and within countries attributable to socio-economic and cultural factors (Harris & Rees, 2000). It was reported that 9% to 76% of the general population in developing countries frequently utilised TCAM for primary healthcare (Pengpid & Peltzer, 2018). For these countries, availability, accessibility and affordability are primary reasons behind the pervasive use of TCAM, particularly for rural populations. In Indonesia, TCAM use continues to be ubiquitous, despite the increasing provision of healthcare services (Elfahmi et al., 2014; Rahayu et al., 2020). The predominant practice of TCAM in Indonesia is based on the use of local herbal medicine — the traditional Indonesian herbal medicine (TIHM) (Rahayu et al., 2021), and it has increased in recent years (Rahayu et al., 2020). The national survey reported that 44.3% of Indonesian households utilised TCAM; out of these, 79.8% used TIHM (Menkes RI, 2018).

Traditional healthcare has been incorporated into the Indonesian health policy since the issuance of the law on health in the 90's when it first gained formal recognition as one of the national healthcare systems (Presiden RI,

2009). It has served as a foundation for the Indonesian government to develop regulations and strategies to maximize the potential contribution of TCAM products and practices to public health care. It reached an important milestone when the Ministry of Health issued the National Policy of Traditional Medicines (KONTRANAS), envisaging a cross-sectoral guideline covering various aspects of TIHM development from cultivation and conservation, research and development, monitoring and supervision to industrialization and commercialization (Menkes RI, 2007). Furthermore, research institutions and other relevant bodies have been set up to ensure evidence-based TIHM products and practices. In 1975, the Institute of Healthcare Research and Development/IHRD (Balitbangkes) was established to address quality and safety issues in TIHM use by scientifically validating the therapeutic effects of herbal preparations. The National Agency of Drug and Food Control/NADFC (BPOM) was formed later in 2001 to administer control and supervision of TIHM. Based on the preparation method and verification of its efficacy, NADFC classified TIHM into three categories, i.e., jamu, standardized herbal medicines (OHT), and phytomedicines (fitofarmaka/FF). While the efficacy of OHT and FF has been proved in pre-clinical and clinical trials, the therapeutic effects of *jamu* are only supported by empirical data. Of 13,462 TIHM products officially registered at NADFC, there are only 87 that are classified as standardized products (62 OHTs and 25 FFs) (BPOM RI, 2020). In 2010, as an initial step towards integrating TIHM in the national healthcare system, IHRD, through the Center for Research and Development of Medicinal Plants and Traditional Medicines (B2P2OOT), introduced the 'Jamu Scientific' (Saintifikasi Jamu) program to develop scientific evidence of TIHM (jamu) through service-based research in flagship healthcare facilities (Menkes RI, 2010). Recent integration policy in Indonesia has been aligned with the WHO strategy for traditional healthcare, which includes the establishment of the Directorate of Traditional Healthcare Services/DTHS (Dirjen Yankestrad) that oversees the practice of traditional healthcare providers (Menkes RI, 2015; WHO, 2002, 2013). The provision of traditional healthcare in the national healthcare delivery, TIHM included, has been promoted based on the 'Strategic Plan' (Rencana Strategis) (Menkes RI, 2017).

Despite the increasing collaboration between traditional and conventional healthcare, TCAM remains poorly integrated with the national healthcare system (Siswanto, 2018). The practice of TIHM use in healthcare delivery services in Indonesia is lower than that of herbal medicines in other countries (Widowati et al., 2012). The provision of TIHM in public health facilities has been progressing at a slow pace. Currently, approximately 50% of primary healthcare facilities provide TIHM, 25% lower than the targeted plan of 75% (Menkes RI, 2020). Many programs aiming to promote the integration of the two healthcare systems are yet to achieve their objective. For instance, the adoption of the 'Jamu Scientific' program is only limited to a certain region of central Java (Kristiana et al., 2017). Other issues include the lack of standard medicinal plants required for TIHM preparation in the facilities. Moreover, the traditional healthcare system receives less government support and funding and is inadequately considered under the national health insurance program.

The attitudes toward TCAM use differ among medical health professionals (Gyasi et al., 2017; Kwan et al., 2006). A study reported that 41% of medical doctors in Nigeria believed that herbal medicine could be effective for some chronic diseases, but it could only be effective as a complementary medicine (Awodele et al., 2012). In Japan, doctors' perceptions and attitudes towards Kampo medicines (traditional Japanese medicines) varied tremendously depending on the speciality, with higher usage and a more positive perception of Kampo among obstetrics/gynaecology specialists (Moschik et al., 2012). On the other hand, many conventional medicine practitioners often stigmatised TCAM practices with derogatory labels that may hinder collaboration towards integration, such as 'unconventional', 'alternative', and 'unproven' (Jafari et al., 2021; Pengpid & Peltzer, 2018). Furthermore, a few studies indicated that although some health workers possessed personal experience with TCAM, they were less likely to recommend it to patients (Boateng et al., 2016; Bodeker, 2001). These reports suggest that conventional healthcare practitioners' attitudes towards TCAM mainly controlled their preference for integration.

The adoption of the UHC system in Indonesia was realised with the introduction of the universal health insurance program—*Jaminan Kesehatan Nasional/JKN* (National Health Insurance/NHI)—in 2014. However, TIHM is not reimbursed under the insurance program. There has been a great deal of discourse among multi-government agencies to incorporate TIHM in the NHI, but the discussions lack a perspective of conventional healthcare practitioners (Kristiana et al., 2017; Widowati et al., 2020). The attitudes of conventional healthcare practitioners towards TCAM largely determined the degree to which TCAM and conventional medicine can be integrated (Kretchy et al., 2016) and may significantly impact the implementation of policies and strategies. Therefore, it is essential to understand the extent to which conventional healthcare practitioners (GPs) towards TIHM use in conventional care and their perception of the integration of TIHM in the NHI. The barriers to the clinical use of

TIHM were presented. The findings from this study will provide policy relevance, with implications for professional training, regulatory procedure, and clinical practice.

2. Method

2.1 Selection of Participants

The present study is part of a larger study employing a cross-sectional mixed-method design to examine TIHM use at the community and institutional level in the UHC system in Indonesia. Data for this paper drew on findings from the part that explored institutional use of TIHM by examining the attitudes of conventional healthcare practitioners, particularly GPs. A total of 30 GPs were purposively selected to participate in the study. For the responses to be in line with study objectives, the participants were selected with the criteria: 1) GP practising in a conventional (non-traditional) health facility, and 2) those of no. 1 criterion who have been practising for at least one year. The participants were chosen from 28 healthcare facilities in 14 cities in seven provinces of Indonesia to maximise the variation in the number of years in practice and represent the major cities in Indonesia. In addition, in-depth individual interviews were conducted with three GPs involved in the research and advocacy of TIHM (*jamu*) to obtain insight into their activities related to TIHM. In this paper, a conventional healthcare facility was defined as a healthcare facility wherein the service is based on conventional (non-traditional) medication by a doctor—not a traditional healthcare practitioner. The term conventional medication was used interchangeably for conventional treatment or conventional medicine and included biomedicine/drugs.

2.2 Data Collection and Analysis

The data were collected between January and September 2021. We conducted a pilot study involving four GPs to assess the validity and appropriateness of the interview guide. The pilot study allowed some aspects to be included or excluded in the study guide following questions from the participants. The questionnaire was modified from a study about the perception of conventional healthcare practitioners on integrative medicine (Kretchy et al., 2016). Before starting the interview, participants were informed about the purpose of the study, procedures and their rights, and all participants provided verbal and written informed consent.

The questionnaire comprising closed-ended questions was used to gather basic information (age, gender, years of practice, and practice facility) and characteristics of participants related to their TIHM use, including the level of knowledge on TIHM and its regulatory, sources of knowledge, and the experience of using THIM. Four questions with a Likert scale were also included to assess their perceptions about aspects of THIM, including efficacy, safety, and its role in conventional care and integration of TIHM under the NHI program. Subsequently, these four aspects measured by the Likert scale were used as the topics to guide the interview to obtain further detail on participants' perceptions and attitudes towards TIHM, its use related to their practice, and its integration in the NHI.

Questions related to the barrier of using TIHM were asked to the participants who had never used TIHM or had only given an informal recommendation to the patient. A thematic analysis was used to identify the themes of barriers emerging from participants' comments. The responses were coded before grouping into themes, summarised, and further analysed. The results from the interview, including the attitudes toward TIHM and its practice, its integration, and barriers of clinical use of TIHM, was analysed based on the inductive approach of grounded theory, a method that generates theory during the process of conducting research (Glaser & Strauss, 1967). To improve the reliability of the analysis, two co-authors analysed the result of interviews independently and then discussed each categorisation with all authors until reaching a consensus. The interviews were conducted online individually and lasted 30 to 40 minutes. To ensure the participants' privacy, confidentiality and their information, each participant was anonymised and identified by a unique ID, which has been used in the presentation of the results. The interviews were recorded and transcribed. All interviews were digitally recorded and transcribed in English. This study was approved by the health research ethics committee of the Ministry of Health, Bandung Health Polytechnic, Indonesia (No.01/KEPK/EC/V/2021).

3. Results

The interviews were conducted among 30 GPs practised in various conventional healthcare facilities with 7.3 average years of practice. The ages of participants ranged from 25 to 55 years, with the majority falling between the ages 25 and 38. There were more females (n = 26) than males (n = 4). The majority of participants work in the hospital (n = 16), followed by private clinics (n = 10), and a few of them work in a community health centre (n = 4). GPs' characteristics and questions with Likert scale responses were summarized by frequency distributions (Table 1 and Figure 1).

| Tharacteristics Sample size (%) | |) |
|---|----|------|
| Self-assessed knowledge on TIHM | | |
| Knowledgeable | 6 | (20) |
| Somewhat knowledgeable | 14 | (47) |
| Not knowledgeable | 10 | (33) |
| Source of knowledge | | |
| Formal education | 7 | (35) |
| External training | 4 | (20) |
| Self-learn (family, readings) | 15 | (75) |
| Knowing regulation on TIHM practice | | |
| Yes | 7 | (23) |
| No | 23 | (77) |
| Experience in using TIHM in formal practice | | |
| Informal recommendation | 8 | (27) |
| Formal prescription | 5 | (17) |
| Never | 17 | (57) |

Table 1. Characteristics of general practitioners interviewed about their knowledge and clinical use of TIHM (n= 30).

3.1 Characteristics of Participants

Characteristics of participating GPs were organized into three aspects: knowledge of TIHM, knowledge of the regulatory procedure of TIHM practice, the experience of clinical use of TIHM (Table 1).

Based on the participants' self-assessment, the majority (n = 24) reported an average to no knowledge about TIHM. Nonetheless, all of them are familiar with the self-prepared TIHM (*jamu*). Those who evaluated themselves as 'knowledgeable' (n = 6) reported had received formal education regarding TIHM. Most participants had no formal training on TIHM, and knowledge mainly was acquired through self-learning (n = 15), such as from their readings and family tradition. Of those who received training (n = 11), seven were introduced to the knowledge as part of curricula of their formal education, and four through their participation in training programs held by government institutions. The majority of participants (n = 23) did not acknowledge the regulation related to practising TIHM in a conventional healthcare facility. A little over half of the participants (57%, n = 17) never use TIHM in their practice. While 27% of them have experience recommending TIHM informally and 17% of them had formally prescribed it to their patients.

3.2 Attitudes towards TIHM

A total of four topics were developed to guide the interview on the attitudes of GPs towards TIHM and its integration in conventional care under the NHI program (Fig. 1.).

Overall, participants demonstrated a favourable view towards TIHM role in conventional care. Participants had varied opinions, but they agreed on several notions regarding the efficacy of TIHM: 1) it is effective in treating ailments in their early development stage, 2) its usage is effective in preventive and promotive health purposes, and rehabilitative care 3) it is effective as complementary (not a substitute) to conventional medicine in curative therapy. When further asked about clinical usage of TIHM, more participants favour the adjunct utilization (n = 22) than those of the sole use of TIHM (n = 6). It was elaborated that TIHM is particularly effective in treating degenerative disease, metabolic syndrome, and palliative care.

In curative therapy, herbal is effective to treat mild illnesses such as mild hypertension, mild hyperuricemia, mild diabetes, mild hypercholesterolemia, but for a severe case, it can be used as a complementary therapy to support conventional treatment. (ID 30)

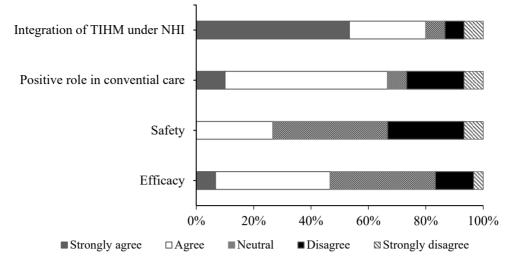


Figure 1. Attitudes towards TIHM aspects and its integration under the NHI

Most unfavourable attitudes towards TIHM were associated with concern regarding its safety. While it was widely perceived that TIHM generally shows fewer side effects or adverse reactions, most of them also acknowledged that no medicine is without side effects or entirely safe for long-term use.

For long-term use (treatment), herbal medicine is relatively safer than drugs, as long as it [herbal medicine] is used rationally. (ID 4)

Participants also reported some negative attributes to TIHM in healthcare service delivery, such as promoting non-adherence to conventional treatment and the main reason for the delay in help-seeking behaviour among patients with conditions that need immediate care. This delay often led to most likely preventable complications.

Indeed, some TIHM have a positive role in supporting conventional therapies, but sometimes information on the interaction between TIHM and [biomedicine] drug is unclear. It would be better if we could easily know such information. Sometimes patients focus on herbal use, neglect conventional therapy, and are reluctant to check their (chronic) illness routinely. Some alternative [therapy] could also hamper the treatment of conventional therapy, for instance, in a cancer patient who does consultation [with a doctor] when it is too late and a patient with a bone fracture who had inappropriate treatment from a bonesetter. (ID 12)

In this respect, participants had a consensus regarding the importance of rational use of TIHM and their preference of the standardized type over the self-prepared one—*jamu*.

3.3 Attitudes towards Integrationg TIHM in the NHI

The majority of participants also showed positive attitudes for integration of TIHM in conventional care within the NHI program (Fig. 1). They supported the call for expanding NHI payment coverage to include TIHM. Among the most frequently mentioned reason for their support was demand from patients.

In some cases, the patients interested in using TIHM instead [of biomedicine], we should get it listed on the NHI's medicine list, so they will have the treatment they want without having to pay again. (ID 24)

It was also suggested that the integration could facilitate effective service delivery by negating the irrational use of and ensuring a reliable TIHM.

I support integration as it will help streamline the rational use of herbal medicines. (ID 25)

I think it [integration] will be good for the TIHM system to help eliminate fraud, like fake jamu that spiked with chemical. (ID19)

The opinion that 'some cases are better to be treated with TIHM' was another popular reason.

While the cases of irrational use of TIHM exist, the cases of misappropriate use of [biomedicine] drug also happen. Many people use drugs not according to its indication, the conditions which should be given TIHM instead. Something like these can be eliminated if TIHM can be integrated into our practice to ensure rational use of TM while reducing patient dependency on drug. (ID 5) Generally, participants recognized that each mode of healthcare has its own advantage, and conventional medicine does not have the solution to all our healthcare needs. Thus, it is necessary to consider alternative forms to complement the conventional practice. However, aside from supportive views, the exact reason for the negative attitudes toward TIHM, concern regarding the safety of TIHM was also the reason for participants' disfavour or doubt of integration under the NHI. Participants discussed how the issue was about safety more than efficacy in some cases. They agreed to better documentation on the safety of the unstandardized TIHM and emphasized the necessity for more extensive research to provide more scientific evidence and standardized products.

Before integrating this mode [TIHM] in the mainstream practice, we have to look at the safety issue, because, unlike biomedicines that has been undergone a standardized trial, not all TIHM, especially jamu [unstandardized TIHM], have this safety information, so supporters of this integration must take steps to ensure patient safety. (ID 29)

3.4 Barriers of Use of TIHM in the Conventional Healthcare Setting

Overall, TIHM was infrequently used among the participating GPs. Table 1 showed that only a small number of participants actually practised TIHM (n = 5). A total of 17 participants who never used TIHM or had only given an informal recommendation to patients had provided comments on the barrier of using TCAM. A thematic analysis of comments identified four themes: knowledge gap, uncertainty on regulatory procedures, unreliable TIHM provision, and exclusion of TIHM in the NHI program, which are further examined below.

3.4.1 Lack of Knowledge Base on TIHM

The participants often mentioned their lack of knowledge of TIHM as the major barrier to their professional use of TIHM. It appeared that TIHM use was unpopular among these GPs because they did not know much about it. The most common explanations, such as 'I do not know about herbal medicine,' 'I am not confident,' and 'I am not sure with its safety and efficacy,' suggest that their reservation recommending TIHM to their patients stems from their lack of confidence in its use, in particular for curative purpose. Participants also described the lack of advocacy of TIHM use.

Public is not the only one who needs to be familiarized with the information of TIHM, we also need support from the TIHM advocacy associations to obtain information that we cannot access, especially on mediating TIHM use in our practice. (ID 1)

3.4.2 Uncertainty on the Regulation of Clinical Use of TIHM Use

Lack of knowledge on a legal basis in practising TIHM in a conventional healthcare facility was also frequently mentioned as the reason for hesitation in using TIHM to a patient. Although some of the participants were aware of the existence of statutory bodies to help streamline and regulate TIHM practice in Indonesia, most of them were unsure or had no knowledge regarding regulatory procedures to use TIHM in conventional healthcare practice.

Is there any regulation? I'm not sure know about that, so in case the patients demand [TIHM], and I think [TIHM] suitable for their problem, I usually recommend [the patients] the standardized TIHM, or ask them to prepare it by themselves from fresh herbs, to ensure the safety. (ID 31)

I know that herbal have been recognized in the healthcare system in Indonesia. There is also common knowledge among doctors allowing the prescription of TIHM but limited to the standardized products. However, as far as I know, the regulations for TIHM services for medical personnel (doctors) have not been made yet. It makes us uncertain in prescribing herbal medicines. (ID 17)

Only 23% acknowledge legislations of TIHM practice (Ministerial Decree No.121/2008 on standard service herbal medic), and all of them had TIHM training and or had attended seminars advocating in TIHM practice. Nonetheless, all participants agreed that current regulations on TIHM use in clinical practice are outdated.

3.4.3 Unreliable Provision of THIM in the Health Facilities

The lack of provision of TIHM was mentioned as one of the barriers by participants practising at primary healthcare facilities.

Even if I want to [use TIHM] or the patient asked for it, oftentimes we don't have the stock [of TIHM] (ID 6).

It was widely implied that allocation of the budget for expenses related to TM provision by primary care facilities is low and that the facilities prioritize the procurement of biomedical drugs covered by the NHI.

It is not uncommon that we run out of stock of THIM [in the HF], because sometimes no budget left to purchase it [TIHM]. (ID 2)

In the facility where I work, the drug is always the priority over the TIHM because it is paid (by the NHI), so the patient will choose drugs. (ID 10)

Regarding the standardized TIHM products (i.e., OHT and FF), the participants elaborated that a poor marketing strategy of the manufacture in promoting TIHM to health facility authorities hampered its procurement.

Unlike for drugs, the sales representative for THIM rarely comes, so TIHM shortage frequently happens in the clinic. (ID 25)

3.4.5 Exclusion of TIHM in the NHI Payment System

It is worth noting that all participants agreed that the fact that the NHI scheme does not cover TIHM reserved them to use it in their clinical practice. This reservation was seen to stem from the concern over the out-of-pocket burden for the patient.

In some cases, the patients interested in using herbal medicine instead [of drug], we should get the herbal medicines listed on the NHI's medicine list, so they will have the treatment they want without having to pay again. (ID 31)

The patients know that they need to pay out of their pocket if we give them THIM, and recently they often asked me if there is a chance that the insurance can reimburse their herbal prescription. I wish NHI can cover at least the standardized herbal medicine. (ID 30)

4. Discussion

The majority of participating GPs demonstrated a positive view towards TIHM in conventional care. Generally, they agreed that TIHM is effective for disease prevention, rehabilitation, health promotion and an adjuvant to conventional medicine in curative therapy. Interest, attitude, and positive behaviour towards TCAM could indicate their preparedness to accept its integration into conventional practice (Gyasi et al., 2017; Jafari et al., 2021). We also found that the integration of TIHM under the NHI program received almost all positive responses from the participants, with evidence suggesting that integrating the two systems would improve care delivery by supplementing the shortcomings of conventional care (Kristiana et al., 2017; Widowati et al., 2020). For example, Widowati et al. (2020) reported that implementing TIHM and acupuncture as complementary therapy led to faster recovery patients: reducing the in-patient period and visitation of out-patients. Similarly, evidence suggested that traditional Chinese medicine and acupoint massage demonstrated positive results in the alleviating functional constipation among schizophrenia patients in China (Ye et al., 2020). Notably, GPs in this study were more inclined toward adjunct use of TIHM than TIHM alone. This attitude aligns with the current situation of TIHM utilisation. Albeit the gold standard for evaluating TCAM therapies is a randomised controlled trial, TCAM practitioners commonly use combination TCAM treatment (TCAM and conventional therapies) instead of one TCAM therapy alone (Ye et al., 2020). Although scanty reports verifying the effectiveness of sole use of TCAM in curative treatment, many studies found that TCAM might enhance the efficacy of biomedicine when applied as adjunct treatments (Thirthalli et al., 2016; Ye et al., 2020; Zulkarnain & Triyono, 2017). Accordingly, most GPs in this study agreed that THIM is effective as complementary to the long-term conventional treatment of non-communicable diseases, including degenerative disease and metabolic syndrome, and in palliative care. This finding indicates that the anticipated integration should focus on using TIHM as an adjunct or complementary treatment to optimise the effectiveness of conventional care.

Despite the generally favourable view towards TIHM in conventional care, only a few of participating GPs actually practised. Among 30 participants, 17 never used TIHM in their practice because they did not know about TIHM and or how its practice is mediated in the health facility. The thematic analysis result demonstrated that participants' lack of confidence in TIHM use stems from lack of knowledge, extended to their unwillingness to recommend them to their patients. Previous studies involving conventional healthcare professionals had also mentioned the barrier due to lack of knowledge (Boateng et al., 2016; Gyasi et al., 2017; Liu et al., 2021). The fact that all of the knowledgeable participants had taken a TIHM course during their biomedical studies indicates that a lack of formal training of TIHM may contribute to the low self-rated knowledge. It should be noted that the GPs' enrolment in the TIHM course was not mandatory; to this date, TIHM is taught as an elective course. A similar situation was reported in other countries such as Ghana, Saudi Arabia, and New Zealand, whereby the lack of TCAM curricula of their academic training contributed to insufficient knowledge of TCAM of healthcare professionals (Albedah et al., 2012; Kretchy et al., 2016; Liu et al., 2021). Another identified barrier within the spectrum of knowledge gap was little knowledge of the regulatory procedure of TIHM practice, which has also been reported in the previous studies (Gyasi, 2018; Kretchy et al., 2016). In addition to a formal education or training program, the aspect regarding the regulation and how TCAM is mediated within the national healthcare

system can be obtained through advocacy activities (Ye et al., 2020), which the participants perceived to be lacking. This observation is consistent with a recent report that advocacies and training programs of TIHM for conventional healthcare practitioners in Indonesia were insufficiently disseminated (Siswanto, 2018). These two barriers point toward one direction: lack of TIHM emphasis in the academic training programs of a medical practitioner. This suggests that TIHM education should be given more portion than it is now to improve medical practitioners' knowledge base.

For decades, integration of traditional and conventional medicine has been evident in medical education in the People's Republic of China, Japan and the Republic of Korea and has been growing in developing countries such as India and Cuba (Dresang et al., 2005; Park et al., 2012; Robinson, 2006; Sharma, 2001). It is suggested in the national Indian Systems of Medicine (ISM) policy that the ISM education system should be thoroughly reformed and that graduates of modern medicine should be taught the principles of ISM, including Ayurveda and Yoga (Sharma, 2001). Additionally, a survey among medical practitioners in Australia concluded that the inclusion of TCAM in the education of junior doctors might improve patient safety and management (Pierantozzi et al., 2013). However, Brinkhaus et al. (2011) found a limited integration of TCAM into curricula in the education systems of medical schools in South Africa, Austria, and Switzerland, despite the emphasis on training. Although the association between the training and practice of TCAM remains uncertain, surveys among medical practitioners showed that formal TCAM education programs provided by the government are a preferred approach to promote TCAM service (Chung et al., 2011; Moschik et al., 2012). The present study adds that advocacy on the clinical use of TIHM among medical practitioners is another fundamental approach to enhance understanding of TIHM practice's regulatory aspect in a conventional healthcare facility.

The barrier due to little knowledge on the mediation of TIHM practice in a healthcare facility also indicates that the current regulatory procedure was widely perceived to be unclear. While legislation to regulate traditional healthcare practitioners and providers exists in Indonesia, there has not been any detailed guideline regulating TIHM practice by conventional healthcare practitioners. A comparable situation is also shown in other Asian countries 'in-process' of developing integration like Malaysia and Cambodia (Abuduli & Aljunid, 2011; Clarke et al., 2016). The participating GPs mentioned that the lack of guidelines on internal prescription for TIHM had held them back in prescribing or recommending it for patients even when they knew that TIHM would be more effective in treating the health problem. Currently, Ministerial Decree No.121/2008 is the closest thing to providing a standard of TIHM service by a conventional health practitioner, which was not widely known and perceived to be outdated. The participants desired that TIHM practice in conventional healthcare facilities could be properly and clearly regulated. In Japan, where (western medical-educated) medical practitioners may practise the traditional Japanese Kampo under the law, more than 70% of doctors are using Kampo medicine in their daily practice together with modern medical treatments (Moschik et al., 2012). Similarly, TCAM practice in the conventional setting is clearly regulated in Germany; a physician can practice TCAM but must hold the corresponding CAM qualification for reimbursement by public health insurance (Joos et al., 2011). As a result, physicians in Germany used many TCAM modalities in their practice, including neural therapy, phytotherapy, and acupuncture (Stange et al., 2008).

Despite a global expectation for integration of TCAM into mainstream practice, particularly for resources limited regions, the integration process in Indonesia has not been optimal (Suharmiati et al., 2018). The barriers due to unreliable provision and exclusion of TIHM in the NHI payment system suggest that GPs want to use TIHM but often refrain from using it due to these factors. Corespondingly, Thirthalli et al. (2016) reported that psychiatrists in India, to some extent, prefer conventional treatments to reduce the patients' financial burden of the patients. In general, the cost of TCAM therapies in LMICs is not fully covered by public medical insurance or commercial schemes (Ye et al., 2020). In the NHI program, the provision of TIHM in a primary healthcare facility is admissible and can be covered through the capitation payment mechanism (Mboi, 2015). However, the participating GPs mentioned that the procedure is complicated because it requires particular circumstances (i.e., when the needed drug is out of stock). Additionally, approval from the head of the health facility is also required (Handayani et al., 2018). Although the capitation payment system has lowered the medical and administrative expenditures of the providers, a lack of sufficient understanding of the system among the providers may have resulted in technical capacity constraints in the implementation (Jing et al., 2016). Moreover, a primary healthcare facility in Indonesia commonly allocated the largest portion of capitation fund for medical workers' service payment and much less for supporting its daily operations, including the provision of TIHM products (Budiarto, 2015). This situation was also implied in our observation. The lack of TIHM provision impedes TIHM use by GPs even further. These reports and our findings indicate that the current procurement of TIHM within the NHI program is ineffective. Integration of Kampo formulas with modern Japanese medicine under the national health insurance system led to physicians

being more willing to prescribe Kampo formulas, and increased their usage nationwide (Moschik et al., 2012). Increasing use of TCAM products and services due to national health insurance coverage was also observed in Australia (Maclennan et al., 1996), Taiwan (Chen et al., 2007), and the Republic of Korea—where both the national and private health insurance systems cover Traditional Korean Medicines (Kang et al., 2017; Park et al., 2012). The DTHS admitted that the exclusion of TIHM in the NHI's medicine list is among the factors hindering success in achieving the targets of the traditional healthcare 'Strategic Plan' to promote the provision of TIHM in a public healthcare facility (Dirjen Yankestrad, 2018). These reports suggest that incorporating the standardized TIHM into the medicine list covered by the NHI can enhance its use in a conventional health facility in Indonesia.

Finally, the disadvantages of TIHM associated with its safety should be noted. Research has reported that herbal medicines could be harmful to users, such as the possible adulteration, herb-induced side effects, adverse drug reactions resulting from herb-drug interactions, and delay in starting treatment among patients with the condition that needs immediate care (Elfahmi et al., 2014; Izzo & Ernst, 2009; Kretchy et al., 2016; Picking et al., 2011). Integration of TIHM in the NHI program is expected to overcome such disadvantages. GPs in this study viewed that the inclusion of TIHM in the NHI would likely create a more rigorous regulatory for TIHM safety. Inclusion of TCAM products and services in the health insurance payment system led to increasing their scrutiny by health authorities as seen in countries with 'well-established integration', such as the People's Republic of China, Japan and the Republic of Korea (Park et al., 2012). Correspondingly, despite having less insurance coverage, the Indian health authority has strengthened the Good Manufacturing Practices rules to improve the quality and standard of Traditional Indian Medicine to promote the integration between traditional and modern medicine (Kang et al., 2017; Sharma, 2001). Indian medicine policies have also included the revision of the Drugs and Cosmetics Act to cover plant-based products. In line with this, similar to biomedicines, the participating GPs desired the health authority to issue a formal list for TIHM to anticipate the integration.

Nonetheless, most TIHM products currently available in Indonesia, which predominantly are *jamu*, are yet to meet appropriate standards of safety, quality, and efficacy (Elfahmi et al., 2014). This suggests that developing a formal list of TIHM and improving the provision of standardized TIHM may not be possible without providing more or better evidence for the safety and efficacy of TIHM, as highlighted by participants with apprehension toward integration. A recent study reported that TIHM was not used as the primary therapy in a healthcare facility because the number of subjects in the clinical trials is still considered insufficient (Widowati et al., 2020). Thus, the efforts to achieve integrative care in Indonesia depend partly on the health authority mandate to develop the national formulary of TIHM and strategies to facilitate high-quality research in evaluating TIHM, not only to ensure the provision of evidence-based TIHM but also provide clinical governance assurance.

This study acknowledges the following limitation: the results of the study do not allow generalization because a qualitative approach was adopted. It is suggested that in the future, a study be conducted to investigate the perception of a larger number of conventional healthcare practitioners concerning the practice of TIHM and its integration into the national healthcare system.

5. Conclusions

The participating GPs hold a positive attitude towards TIHM use in conventional care. They recognised that conventional medicine does not have the solution to all our healthcare needs, and thus, it is necessary to consider alternative forms to complement the conventional practice. The GPs also accepted the idea of integrative care under the NHI program. They indicated that the anticipated integration should focus on using TIHM as an adjunct or complementary treatment to optimise the effectiveness of conventional care. Given the GP's preference toward adjunct treatment of TIHM, its potential risks and benefits should become a major focus within the public health agenda of Indonesia. At the same time, some challenges need to be addressed to facilitate and anticipate the integration of TIHM in the conventional delivery system. The knowledge base of these practitioners in TIHM must be improved through developing a standard education program for herbal medicines.

Additionally, through more advocacy on the clinical use of TIHM, medical practitioners' understanding of the regulatory aspect of TIHM practice will be enhanced and might lead to an increase in TIHM use in clinical practice. However, increasing TIHM use in clinical practice will require updating the regulation of standard TIHM service and establishing detailed guidelines for its internal prescription by a medical practitioner. Having greater confidence in regulatory procedures will enable them to endorse TIHM confidently. Furthermore, GPs indicated that incorporating the standardised TIHM into the medicine list covered by the health insurance may also enhance its use in a conventional health facility, suggesting the necessity of health authorities to issue a formal list for TIHM. Developing a TIHM's formal list will necessitate the provision of more or better evidence for the safety of TIHM. In addition, to improve the provision of standardised TIHM, efforts toward promoting more high-quality

research in evaluating TIHM should be accompanied by increasing efforts to facilitate scale-up of TIHM research. This can be accomplished with more financial support, human resources, and research regulation.

Finally, these results should be interpreted cautiously due to the potential perception bias resulting from the purposive method of selecting participants. The purposive sampling of GPs means that results may reflect only GPs who meet the selection criteria. Thus, the implementation of policy recommendations should also consider this potential perception bias. Future research with a larger number of GP covering more areas selected through random method is needed to minimise this bias. Regardless of the potential perception bias, the results provide essential insights necessary as baseline information on the question of the attitudes of GPs towards TIHM use in conventional care and integration of TIHM in the NHI.

Acknowledgements

This work was supported by JSPS KAKENHI (grant Number JP19KK0166). We would like to acknowledge the contribution of Dr. Noerhadiwijaya and Dr. Ulfatun Nisa, who provided expert advice. Additionally, we are grateful to the general practitioners for participating in the study.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Dietary Recommendations for Active and Competitive Aerobic Exercising Athletes: A Review of Literature

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Received: January 30, 2021Accepted: March 16, 2022Online Published: March 28, 2022doi:10.5539/gjhs.v14n4p95URL: https://doi.org/10.5539/gjhs.v14n4p95

Abstract

Aerobic exercise is a common sport activity participated by numerous individuals in many parts of the world. Individuals involved in this sport may participate for various reasons, for instance, improved health and weight management while others are involved for competitive purposes. Recommendations, therefore, vary according to the aim and the intensity of the engagement. Depending on the purpose, dietary practices related to the type of foods or meals to be consumed, timing of intake and hydration strategies used by athletes remain important. There is a concern, however, that dietary recommendations for aerobic sport lack scrutiny. It is important for athletes involved in aerobic exercises to adhere to recommendations for them to enjoy their sports engagement while maintaining good health. Therefore, the purpose of this review is to discuss the aerobic exercise nutrition recommendations for aerobic focus on energy, macro- and micronutrients, nutrients dosing, and timing thereof.

Keywords: Aerobic exercises, Macronutrients, Micronutrients, Recommendations

1. Introduction

Aerobic exercises use several muscles, rhythmically, for 15–20 minutes or even longer while maintaining 60–80% of maximum heart rate (Abdulla et al., 2016). This exercise activity is popular at health clubs and community centers (Ciomag et al., 2013) for improving cardiovascular function and local muscular endurance. It further contributes towards improved ideal body weight, reduced body fat mass, and plays a vital role in the prevention of osteoporosis (Haskell et al., 2007). A combination of aerobic exercises with appropriate dietary interventions and nutrient timing, can accelerate improvements in health, enhance training and recovery from exercises (Jäger et al., 2017; Trakman et al., 2017). Individuals involved in sport and exercise may often require guidance towards food and nutritional choices. Some athletes being influenced by social, economic and physiological factors, may ignore the significance of nutrition when making food choices (Birkenhead & Slater, 2015). Individuals originating from low socioeconomic areas may, at times, find difficulties in matching the required needs for their specific sports. Trainers, the internet, and/or fellow gym mates, usually serve as a nutrition information guide to most athletes. However, some of these nutrition information sources may hold insufficient scientific support (Hornstrom et al., 2011). Good nutrition supports the ability to train intensely, muscle recovery and metabolic adaptations during exercises, increasing performance (Potgieter, 2013). The purpose of this review is therefore, to explore aerobic exercise categories, nutrient recommendations for those categories and further discuss nutrient timing in an attempt to guide these athletes in their life-long sport.

1.1 Aerobic Exercises

Exercises that deliver oxygen to muscles to generate energy to support muscles during exercise are classified as aerobic exercise (Armstrong & McManus, 2017). Aerobic exercises, especially done two to three times per week for 30–60 minutes are important for weight management (Barrow et al., 2019). This activity depends much on functional physiological and metabolical mechanisms to perform better during exercise or performance (Harrison et al., 2015). For instance, the conversion of lactate produced during exercise requires a functional liver to convert it to glucose for the muscles to utilize as energy (Armstrong & McManus, 2017). To determine an individual's characteristics of aerobic ability, lactate threshold (LT) and maximal oxygen uptake (VO_{2Max}) can be measured (Armstrong & McManus, 2017; Harrison et al., 2015). The VO_{2Max} is the highest rate at which exercising muscles consume oxygen. Aerobic exercises can be classified into cardiodynamic, moderately intense, and heavy intense phases. The cardiodynamic phase is independent of oxygen and usually lasts for 15–20 minutes. The moderately intense exercise lasts between 30–60 minutes while the heavy intensity lasts for 60–120 minutes. As aerobic

exercise intensifies, lactate is produced (Harrison et al., 2015). A few monitoring models to measure the success of athletes during competitions have been implicated elsewhere (Armstrong & McManus, 2017). However, due to a lack of clear guidelines, monitoring of dietary practices and the timing by athletes remain a challenge. Nutrition intervention strategies should be designed the specific exercise programs. Therefore, sports nutrition professionals should, among other things, assist in adjusting nutritional needs, sports performance goals, and practical challenges related to food, diets and fluids for athletes (Thomas et al., 2016). For this reason, the current review attempts to deliberate on this identified gap related to dietary recommendations for active and competitive aerobic exercising athletes for them to enjoy aerobic sports involvement while maintaining good health.

2. Nutrient Recommendation

2.1 Energy

Individuals may participate in exercises for health and weight management (Barrow et al., 2019), while for some, for competitive purposes. In groups aiming to achieve weight maintenance, the amount of energy required is usually lesser than what is required during training (Helms et al., 2014). Energy serves as a fuel during exercise, and the main sources of supply are protein, carbohydrates (CHO), and fat (van Heerden et al., 2014). Adequate energy intake is important to regulate impaired bone density, compromised immunity, and endocrine functioning (Sale & Elliott-Sale, 2017). Individuals involved in aerobic exercises or sport are encouraged to practice intake of smaller frequent meals throughout the day to obtain the required nutrients. The intake of frequent meals has a potential to minimize fatigue, replenish glycogen stores, build and repair tissue muscles, and maintain the desired (sports-specific) weight (Odysseos & Avraamidou, 2017). Therefore, individuals involved in exercise and performance should strive for energy balance as this determines the capacity for macro- and micronutrient intake. Generally, energy amount of 25–35 kcal/kg/day (105–147 kJ/kg/day) should be adequate to evade energy deficits for both active and competitive aerobic exercising athletes (Kerksick et al., 2018).

2.2 Macronutrients

Adequate intake of macronutrients specific to sport and exercise category is recommended to maintain body weight, replenish glycogen stores, and build and repair tissues (Rodriquez & Dimarco, 2009; Wierniuk & Wlodarek, 2013). Therefore, the appropriate selection of foods, fluids, and timing of nutrient intake for optimal health and exercise performance is important (ADA/AC/ACSM, 2009). Nutrient intake timing is a strategy involving the consumption of certain nutrients before, during and after exercise sessions (Aragon & Schoenfeld, 2013) to enhance tissue repair, muscle protein resynthesizes and injury recovery (Jäger et al., 2017).

2.2.1 Carbohydrates

Carbohydrates (CHO), stored in the body as glycogen, serve as the main nutrient during muscle contraction (Indoria & Singh, 2016). Varying intakes of energy and macronutrients including CHO amongst different genders were reviewed (Spendlove et al., 2015). While some macronutrients intake were reported adequate, some were suboptimal. Diets that are low in CHO generally impair performance resulting in fatigue. Therefore, to offset this complication, CHO amount of 5–10 g/kg/day is generally recommended (Kerksick et al., 2017). For moderate exercises lasting for up to an hour, lower end of the range 5–7 g/kg/day is recommended; while 6–10 g/kg/day is reserved for athletes exercising for more than an hour or more (1–3 hours) per day. The latter would include individuals participating in aerobic exercises for competitive purposes (van Heerden et al., 2014).

Glycogen stores are easily depleted in prolonged high intensity exercises (Dunford & Doyle, 2019). Therefore, a meal containing 1–4 g/kg of CHO should be consumed at least three to four hours leading to exercise or training (Kreider et al., 2010; Kerksick et al., 2018). Fructose should, however, be avoided as it is slowly metabolised and may induce some gastrointestinal distresses. Preference should be given to high glycaemic index CHO to fasten the entry of glucose in circulation (Dunford & Doyle, 2019).

During the aerobic exercise or performance, CHO amounts of 30–60 g/hour in events lasting for an hour or more are encouraged (Smith et al., 2015). Athletes should further sustain blood glucose levels throughout the exercise or competition every 15–20 minutes through a CHO solution (Llorenten-Cantarero et al., 2018). The solution used for hydration should preferably be high in glycemic index to sustain glucose supply. Again, fructose containing solutions should be avoided as it is slowly metabolised. To replenish muscle glycogen stores immediately after the exercise, CHO intake of 1–1.2 g/kg is generally recommended (Dunford & Doyle, 2019). Additional amounts of 1.5 g/kg are encouraged 30 minutes to 6 hours after exercise to achieve optimal glycogen resynthesis (Pritchett et al., 2017).

2.2.3 Protein

Protein is another nutrient of importance during aerobic exercises. For training individuals, protein recommendations are usually 2–3 times above the recommended daily intakes (Odysseos & Avraamidou, 2017).

Protein is required as a building material for muscles, transport for nutrients, and a substrate for increased muscle glycogen storage (Potgieter, 2013; Indoria & Singh, 2016). Some athletes may habitually consume high protein diets or supplements in an attempt to increase muscle mass (Kim, 2007). This practice has, to some extent, been associated with increased urea production leading to gout (van Heerden et al., 2014) and osteoporosis later in life. For individuals participating in a general fitness program, a protein amount of 0.8–1.0 g/kg/day is recommended (Kreider et al., 2010). In a review by Odysseos and Avraamidou (2017), a high-quality protein amount of 1.4–1.7 g/kg/day was generally recommended for exercising athletes. A marginally lower amount of 1.2 g/kg/day is, however, recommended (van Heerden et al., 2014) for individuals involved in moderate-intensity exercises. Amounts of 1.8 g/kg/day or higher were further recommended by Kreider et al. (2010) to constantly support the building and maintenance of lean body tissues. These protein amounts should be spread evenly throughout the day.

A pre-exercise meal containing 0.25–0.4 g/kg of protein should be taken 1–4 hours before physical activity (Egan, 2016). To repair damaged muscles, exercising individuals need to consume 0.25–0.3 g/kg (Dunford & Doyle, 2019) or 20g or of high-quality protein combined with CHO intake immediately after exercise/performance (van Heerden et al., 2014).

2.2.4 Dietary Fat

The fat recommendation for exercising individuals does not differ from that of general population, 25–30% of total energy (Smith et al., 2015). Fat serves as fuel during low to moderate intensity activities (Indoria & Singh, 2016). In general, fat intake should be optimal to minimize essential fatty acid deficiencies, increase the absorption of fat-soluble vitamins, and the production of cholesterol (Smith et al., 2015). Chronic fat restriction (<20% TE) is associated with the risk of essential fatty acid and fat-soluble vitamin deficiencies, imbalances in high–and low–density lipoproteins, and inability to form reproductive hormones (Dunford & Doyle, 2019). Intake of fat above 30% of TE is associated with adverse health outcomes (Phillips, 2012) such as cardiovascular diseases, and weight gain (Smith et al., 2015). Therefore, the general recommendation for athletes is to consume 0.5–1 g/kg/day of fat (Kerksick et al., 2018). Summary of recommendations for energy and macronutrients are presented in Table 1.

| Energy (kJ/kg/day) | 105–147 (Distributed throughout the day) | |
|----------------------|--|--|
| CHO (g/kg/day) | 5–7 (General fitness/Moderate exercise programs) | |
| | 8–10 (Intense exercise programs) | |
| Pre-exercise (g/kg) | 1–4 (2–3 hours before exercise) | |
| During exercise (%) | 6–8 (CHO solution, every 15–20 minutes) | |
| Post-exercise (g/kg) | 1-1.5 (Within 30 minutes post exercise, then up to $3-4$ post) | |
| Protein (g/kg/day) | 0.8–1.2 (General fitness); 1.4–1.8 (Intense programs) | |
| Pre-exercise (g/kg) | 0.25–0.4 (2–3 hours before exercise) | |
| Post-exercise (g/kg) | 0.25–0.3 (High-quality protein within 30 minutes post-exercise) | |
| Fat (g/kg/day) | 0.5–1 (Excessive fat should be avoided to minimize gastrointestinal problems) | |

Table 1. Energy and Macronutrients

2.3 Micronutrients

Micronutrients play an important role during energy production, hemoglobin synthesis, and maintenance of bone health for aerobic exercising athletes (Dunford & Doyle, 2019). Chronic micronutrient deficiencies among athletes usualy affect health and exercise performance outcomes (Wardenaar et al., 2017). Naturally, aerobic exercises predispose athletes to increased oxidative stress. Therefore, adequate consumption of micronutrients to reduce oxidative stress, hemolysis, and muscle degradation is recommended (Heaton et al., 2016).

2.3.1 Vitamins and Minerals

In general, exercise results in an increased need for vitamins and minerals, due to losses through urine, sweat, decreased gastrointestinal absorption, and/or high demands of exercise. Several vitamins are required to facilitate physiological processes. Other than solubility, vitamins can also be classified according varying functions, such as, effects in energy metabolism, red blood cell formation, and the antioxidant function (Dunford & Doyle, 2019). For instance, vitamin C is water-soluble, while vitamin E is fat-soluble (Kerksick et al., 2018). Additionally, both vitamins can serve as antioxidants, limiting the damage caused by free radicals during exercise (Heaton, 2016). In balancing the redox reactions, vitamin C acts by donating an electron. Consumpsion of food sources containing vitamin C as part of dietary plans may help reduce the negative health burden imposed by supplemental antioxidants (Heaton, 2016). Vitamin E is beneficial in reducing oxidative stress, neurodegenerative changes, and hemolysis. Therefore, vitamin C and E dietary intake or supplemental amounts of 250–1000mg/day and 15mg/day

are recommended to positively influence training adaptations and antioxidative properties respectively (Kreider et al., 2010).

The B-vitamins, especially thiamine and riboflavin, were also highlighted as of importance in sports by Dunford and Doyle (2019). These two serve an important role during the chemical reactions. Vitamin B_{12} together with folate are recommended by the same authors for enhancing the immune system and preventing anaemia. Additionally, Madden et al. (2017) explored the role of calcium and vitamin D for exercising athletes. These micronutrients are responsible for developing bone structure during sports. Vitamin D is classified as a fat-soluble vitamin linked with enhanced calcium absorption in the body (Kreider et al., 2010) and improved muscle strength (Kerksick et al., 2018). Therefore, vitamin D and calcium amounts of 15 mcg/day and 1000 mg/day are recommended respectively (Kreider et al., 2010).

Iron is another mineral of importance forming part of the hemoglobin component and is involved in oxygen delivery to tissues (van Heerden et al., 2014). Individuals involved in aerobic exercises or sports may often experience anemia from haemodilution, reduced dietary intakes, hemolysis, gastrointestinal bleeding, and lastly, losses through menstrual cycles, particularly in women (Pritchett et al., 2017). Anemia in sports may predispose athletes to early fatigue, weakness, and ultimately limit sports performance (Madden et al., 2017). Therefore, iron recommendations for both men and women involved in sports are 8 mg/day and 18 mg/day respectively (Rodriquez & Dimarco, 2009). Recommendations are higher among female athletes due to the explained iron losing mechanism earlier (Madden et al., 2017). The recommended daily allowance and Upper Tolerable Limits (UL) for specific vitamins and minerals are summarized in Table 2.

| Micronutrient | Gender | *RDA (per day) | [#] UL |
|------------------------------|--------|----------------|-----------------|
| Vitamin C | Male | 90 mg | 2 000 mg |
| Vitamin C | Female | 75 mg | |
| V' D | Male | 15 mcg | 100 mcg |
| Vitamin D | Female | 15 mcg | - |
| Vita min E | Male | 15 mg | 1 000 mg |
| Vitamin E | Female | 15 mg | |
| Coloium | Male | 1000 mg | 2 500 mg |
| Calcium | Female | 1000 mg | |
| Iron | Male | 18 mg | 45 mg |
| | Female | 8 mg | |
| | Male | 1.2 mg | - |
| Thiamine (B ₁) | Female | 1.1 mg | |
| | Male | 1.3 mg | - |
| Riboflavin (B ₂) | Female | 1.1 mg | |
| Ningin (D) | Male | 16 mg | 35 mg |
| Niacin (B ₃) | Female | 14 mg | |
| Cyanocobalamin | Male | 2.4 mcg | - |
| (B ₁₂) | Female | 2.4 mcg | |
| Falata | Male | 400 mcg | 1 000 mcg |
| Folate | Female | | |
| | # | | |

Table 2. Summary of Micronutrients (Dunford & Doyle, 2019)

*RDA=Recommended Daily Allowance; [#]UL=Upper Tolerable Limit.

2.3.2 Hydration

Fluid, particularly water, is important for temperature regulation, lubrication of joints, and nutrients transportation to active tissues during exercises (Indoria & Singh, 2016). Due to the nature of aerobic exercises, more fluids including electrolytes may be lost through sweats and insensible loses. Therefore, athletes should not rely entirely on the thirst for hydration (Kerksick et al., 2018). Athletes should strive for the consumption of adequate amount of fluids containing electrolytes (Casazza et al., 2018). Adequate amounts can be accomplished through distributed intakes of 150–200 ml every 5–20 minutes during the exercise duration (Potgieter, 2013). Athletes involved in the competitive aerobic sport should habitually hydrate using 500 ml of water a night before the competition. Additional 400–600 ml of water or sports drink 20–30 minutes before the competition is recommended (Kerksick et al., 2018). Lastly, athletes are encouraged to consume 1.0–1.5 liters of water for every 1 kg of body mass lost

(Kerksick et al., 2018). A summary of fluid recommendations for individuals involved in aerobic exercise (competitive and non-competitive) is given in Table 3.

| Timing | Recommendations (ml) |
|-----------------------------------|-------------------------------|
| The night before the competition | 500 |
| Thirty minutes before competition | 400–600 |
| During sports performance | 250-300 (every 15-20 minutes) |
| Every 1 kg lost | 1.0–1.5 liters |

Table 3. Summary of Fluid recommendations

4. Conclusion of literature and recommendations

Nutrition, diet, and exercise for sports performance are inseparable (van Heerden et al., 2014). To obtain the desired nutritional status, athletes should aim to balance the energy, macro- and micronutrient intakes. Sufficiently planned diets offering optimal nutrients or nutrition education advice through the involvement of nutrition practitioners (Dietitians) may assist individuals involved in exercise and sport to strike a balance while enjoying aerobic sports as a career (Barrow et al., 2019; Masoga, 2019). All categories of aerobic individuals, competitive and non-competitive, are advised to consume smaller frequent meals spread throughout the day to meet specific nutrient requirements. Furthermore, the timing of consumption of meals; before, during, and after the exercise or training is important to replace losses during the event.

Acknowledgments

The Nutrition and Dietetics team of the University of Limpopo for peer-reviewing this document.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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A Cell That Acts Like a Pill: Using iPSC-Derived Cholinergic Neurons to Treat Alzheimer's Disease

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Received: February 6, 2022Accepted: March 26, 2022Online Published: March 30, 2022doi:10.5539/gjhs.v14n4p102URL: https://doi.org/10.5539/gjhs.v14n4p102

Abstract

Alzheimer's disease (AD), the most common subtype of dementia, affects approximately 44 million people worldwide. One of the most major and direct causes of AD, as proposed by the cholinergic hypothesis, is a severe deficiency of cholinergic neurons located in the basal forebrain. This paper proposes a novel approach of using replacement therapy to treat Alzheimer's disease with stem cell technology. The overarching idea is to inject new cholinergic neurons, which are developed from induced pluripotent stem cells (iPSC), into the brains of AD patients to reverse the cholinergic deficit outlined in the cholinergic hypothesis. The proposed idea is founded on a similar study carried out recently by a team lead by Jeffrey S. Schweitzer that used iPSCs to create dopaminergic neurons which were injected into the brain of a Parkinson's disease patient and has been proven successful. The proposed treatment development plan would consist of three stages: development of induced pluripotent stem cells (APCs); animal studies where researchers inject APCs into the basal forebrain of AD mice models and track progress and improvement in cognitive behavior; and clinical trials involving volunteer AD patients when the procedure of APC development and injection will be repeated, and results will be analyzed. The resulting effects of this treatment can be expected to yield medical, economic, and social benefits.

Keywords: acetylcholine, Alzheimer's disease, cholinergic, dementia, induced pluripotent stem cells, neurons, replacement therapy

1. Introduction

1.1 Alzheimer's Disease

Alzheimer's disease (AD) impairs memory, cognitive skills, and thought processing ability (Centers for Disease Control and Prevention [CDC], 2020). Symptoms worsen with the passage of time as AD is a progressive and neurodegenerative disease (Alzheimer's Association, n.d.). AD weakens memories, through shrinkage of the hippocampus; thinking, communication, and reasoning skills, through shriveling of the cerebral cortex; and motor coordination as displayed in Figure 1 (CDC, 2020). The severity of symptoms depends on the stage of the victim's disease. In the mild stages of Alzheimer's, individuals may experience mild memory loss, confusion with speech, and delayed responses to everyday tasks. In the moderate stage of AD, individuals may experience problems with recognizing family members, reliance on assistance for walking and eating, and even hallucinations. In the sever stage of AD, individuals fully depend on palliative care and may spend most of their time in a sleeping state (National Institute on Aging [NIA], 2021). AD belongs to a family of dementias, such as Parkinson's Disease, Huntington's Disease, Lewy Body Dementia, and Vascular Dementia, and it is the most common out of all dementias accounting for 60-80% of all diagnoses (Alzheimer's Association, n.d.). Contrary to popular belief, Alzheimer's is not a natural result of aging, and individuals should receive proper treatment and care to ensure quality of life (Alzheimer Society, n.d.).

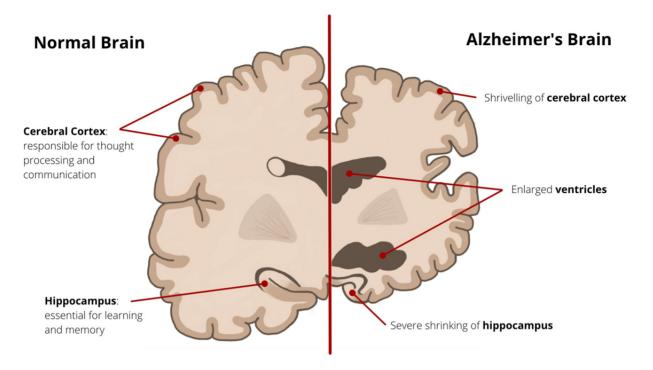


Figure 1. Artistic illustration comparing the brain of an Alzheimer's patient to a healthy brain. Depicts sagittal section of normal brain (left) compared to AD brain (right) which shows shrinkage of brain volume and hippocampus along with enlargement of ventricles

1.2 Impact of Disease

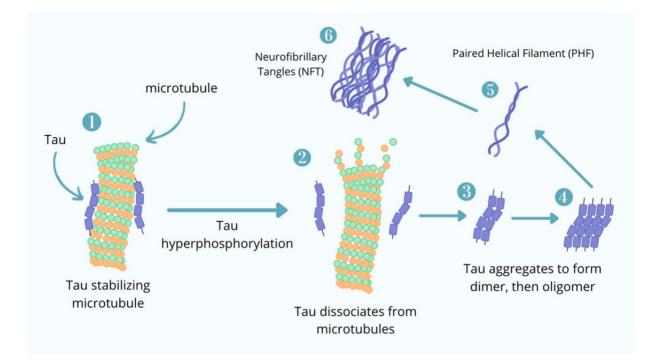
Alzheimer's disease afflicts around 44 million people, and rising, worldwide, and researchers estimate that an AD diagnosis is given around the globe every three seconds (Alzheimer's News Today, n.d.; BrightFocus Foundation, n.d.). The annual costs of treating the disease in the US may surpass \$1.1 trillion by 2050, according to researchers, making AD ever more burdensome on the American economy (Alzheimer's Association, 2021). However, despite research throughout the 20th and 21st centuries, scientists have still not uncovered a precise etiology of AD in order to develop a cure for the disease.

1.3 Hypotheses for Causes of Alzheimer's Disease

A few hypotheses outline current known causes of Alzheimer's, such as the amyloid hypothesis, tau hypothesis, and cholinergic hypothesis.

The amyloid hypothesis ascribes that a major cause of AD is the accumulation of beta-amyloid plaques in the brain, which trigger immune cells, causing inflammation and neuron death (Alzheimer's Association, 2017). Beta- amyloids are produced as a result of the enzymatic splicing of activated amyloid precursor proteins (APP), which are found on the surface of neurons (Alzheimer's Association, 2017). In a normal brain, these beta-amyloids are broken down and cleared away by microglial cells, but a brain affected by AD fails to do so (NIA, 2017). Resulting beta-amyloids cluster into fibrils, then beta-sheets, and finally, chemically stick together to form plaques. These beta-amyloid plaques build up outside neurons, blocking synapses and neuron communication, causing neurodegeneration (Alzheimer's Association, 2017).

Similar to the amyloid hypothesis, the tau hypothesis assigns cause not to beta-amyloid plaques, but to neurofibrillary tangles (NFT) caused by the tau protein (Mohandas, Rajmohan, & Raghunath, 2009). The tau protein functions to stabilize microtubules in neurons, but in AD, tau proteins are hyperphosphorylated and cause the microtubules to depolymerize, which triggers tau proteins to misfold (Mohandas et al., 2009). This in turn creates a chain reaction, which can be spread from cell to cell, as other tau proteins are triggered to misfold the same way, leading to tau oligomers aggregation (TauRx Pharmaceuticals, n.d.). Afterwards, the tau oligomers develop into paired helical filaments and form NFT which accumulate inside neurons, hindering normal cell processes (Mohandas et al., 2009). This whole process is simplified and shown in Figure 2. Eventually, neurons



filled with NFT burst and cause neurodegeneration (TauRx Pharmaceuticals, n.d.).

Figure 2. Schematic illustration of the tau hypothesis. Shows hyperphosphorylation and aggregation of tau to form neurofibrillary tangles

The cholinergic hypothesis describes a diminution of acetylcholine (ACh) at synapses in the brain, otherwise known as a cholinergic deficit, as a major cause of AD (Ferreira-Vieira, Guimaraes, Silva, & Ribeiro, 2016). Acetylcholine, a common neurotransmitter, plays a significant role in thought processing, attention, and short-term memory (Ferreira-Vieira et al., 2016). Healthy neuronal synapses store acetylcholine in vesicles in the presynaptic neuron and release it into the synapse when an action potential arrives at the presynaptic axonal terminals as illustrated in Figure 3 (Ferreira-Vieira et al., 2016). ACh then binds to the receptors of the postsynaptic neuron to relay the electrochemical signal. To ensure a transient response, acetylcholine is rapidly cleared from the synaptic cleft by (i) diffusion, (ii) break down into choline and acetate by acetylcholinesterase, and (iii) reabsorption into the presynaptic neuron (Ferreira-Vieira et al., 2016). In patients with Alzheimer's, a progressive death of cholinergic neurons results in an insufficient amount of acetylcholine, impeding synaptic activity and signal transduction, and causing learning impairment and memory loss (Ferreira-Vieira et al., 2016).

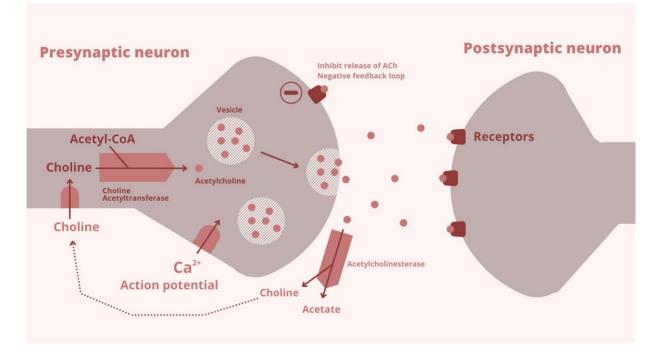


Figure 3. Schematic illustration of the cholinergic neurotransmission. Shows the transmission of ACh from presynaptic terminal (left) to postsynaptic terminal (right). The deposition of ACh into the synaptic cleft is cleared by the enzyme acetylcholinesterase and uptake of choline by the presynaptic neuron

1.4 Current Therapeutic Strategies for AD

Therapeutic strategies for clearance or reduction of beta-amyloid have not succeeded in producing clinical benefits. Current effective drugs for Alzheimer's mainly target the cholinergic system, preventing acetylcholine from getting broken down into acetate and choline, therefore maintaining a sufficient amount of acetylcholine at synapses (Ferreira-Vieira et al., 2016). Agents like Donepezil, Rivastigmine, and Galantamine, ease symptoms of AD but do not cure the disease completely.

These beneficial drugs target one of the brain's neuromodulatory systems that uses acetylcholine and plays a significant role in cognitive processing and short-term memory (BrainFacts.org, 2012). The drugs that target cholinergic neurotransmission maintain a healthy level of ACh despite a gradual decrease in the number of cholinergic neurons associated with AD.

The treatment idea this paper outlines builds on the success of these drugs but uses a different approach. Instead of maintaining reasonably high ACh levels, this program aims to replenish the population of cholinergic neurons using stem cell technology by generating new cholinergic neurons from induced pluripotent stem cells (iPSCs).

1.5 Stem Cell Technologies and a New Approach

This paper outlines a novel treatment approach that relies upon the potential of stem cell technologies. Stem cells are cells which can either replicate to form new stem cells or differentiate into other types of cells such as muscle cells, nerve cells, bone cells, or skin cells (Mayo Clinic, 2022). They are the only type of cells that have the ability to become any specialized cell in the body. Stem cells are of interest to scientists as they can be used to differentiate into any desired cell type to replace damaged cells caused by diseases (Mayo Clinic, 2022).

In 2006, Japanese scientist Shinya Yamanaka made a revolutionary breakthrough in the field of stem cell technology and became a Nobel Prize laureate in 2012 for his work (Rogers, 2020). Yamanaka's lab discovered that stem cells could be developed from somatic cells using four specific transcription factors – Myc, Oct3/4, Sox2, and Klf4 – which reversed specialized cells back to a pluripotent stem cell state (Rogers, 2020). Prior to this discovery, stem cells could only be derived from embryos and caused controversy surrounding ethical issues of destroying a human embryo, which were also linked to debates over abortion rights, as well as unpredictable immunity reactions in test subjects. Yamanaka's work on creating induced pluripotent stem cells provided a

better solution and a safer alternative.

The overall procedure for the treatment development program outlined by this paper is founded on a study by neuroscientist Kwang-Soo Kim and neurosurgeon Jeffrey S. Schweitzer titled "Personalized iPSC-Derived Dopamine Progenitor Cells for Parkinson's Disease" (Schweitzer et al., 2020). Individuals with Parkinson's disease suffer a shortage of the neurotransmitter dopamine, which restrains muscle control and movement, causing muscle spasms, loss of balance, and other symptoms (Begley, 2020). Kim had been working on successfully differentiating induced pluripotent stem cells into dopamine neurons free of mutations, and by 2016, his experiments proved effective in mouse trials as their Parkinson's symptoms were improved after treatment of the injected neurons (Begley, 2020). Schweitzer and his team harvested skin cells from a 69-year-old patient with Parkinson's disease and reverted them into iPSCs before differentiating them into dopamine progenitor cells into the patient through MRI- guided surgical procedures (Begley, 2020). The treatment proposed by this paper would extend this therapeutic approach to target AD by focusing on replenishing cholinergic neurons instead of dopaminergic neurons as a replacement therapy.

Although the idea of injecting foreign cells into the brain may appear risky and futuristic to many, this methodology is involved in many clinical trials regarding neuroscience. One example is the study mentioned above and another example is a current study being conducted by researchers at the University of California San Diego School of Medicine. The team, lead by Mark Tuszynski, is injecting brain-derived neurotrophic factors (BDNF), proteins needed in promoting neuron growth and regeneration, into the brains of 12 patients with AD or mild cognitive impairment (UC San Diego Health, 2021). Their experiment differs from this proposed treatment program in that they are injecting viral vectors carrying BDNF into the brain to deliver the proteins into existing neurons, a technique known as gene therapy (UC San Diego Health, 2021).

Despite differences in details, the common denominator between these studies and my novel treatment approach is the delivery of foreign genetic material into the brain as a form of treatment, whether the materials being injected are dopaminergic neurons, modified viruses carrying proteins, or cholinergic neurons differentiated from iPSCs.

Although there are risks involved with this form of therapeutic approach, they are overweighed by the potential clinical benefits.

2. Methods

Below are methods that I envision would be employed for the development of this treatment program.

2.1 iPSC Development and ACh Cell Characterization

All somatic cells used for differentiation would be harvested from patients who have provided their full consent for the procedure and who possess a full knowledge of how these biopsies will be used. First, a skin biopsy would extract skin fibroblasts from patients to be converted into iPSCs using specific transcription factors. Next, researchers would screen the iPSC line with whole-exome sequencing, isolating a single cell to be further characterized and cloned into basal forebrain acetylcholinergic progenitor cells (APCs). Multiple tests would ensure that the APCs remain free of cancer-associated and neurodegeneration-associated mutations, that they secrete ACh, and whole-cell patch-clamp recordings can be used to test that the ACh cells exhibit electrophysiological properties of cholinergic neurons. Injecting undifferentiated stem cells into the brain can cause uncontrolled cell proliferation or unregulated cell replication. To mitigate this risk, treatment of Quercetin would be needed to eliminate undifferentiated iPSCs.

2.2 Pre-Clinical Mouse Study

Researchers would use established mouse models exhibiting characteristics and symptoms of AD (APP_SweDI; overexpressing amyloid precursor protein (APP) with the Swedish K670N/M671L, Dutch E693Q, and Iowa D694N mutations) for pre-clinical mouse experiments (Foidl, Do-Dinh, Hutter-Schmid, Bliem, & Humpel, 2016). APCs developed in Stage 1 would be injected into the basal forebrain of the APP mice. After a couple of months of cell development, researchers would perform a series of behavioral tests focusing on spatial and working memory on the APP mice, such as the Morris water maze, the radial arm maze, the Y-maze, and the T-maze. Subsequently, researchers would conduct histological brain examinations on the mice brain grafts and stain the samples with human markers to check for the survival and integration of transplanted human

iPSC-derived neurons. The development team would analyze tests results and if the team identifies improvement, they would be able to proceed with clinical trials in Stage 3.

2.3 Clinical Trials

The team would need to recruit two groups of volunteers. The first group would be patients who have been diagnosed with early or middle stage of AD, exhibiting symptoms such as mild to moderate cognitive impairment and memory loss, as this treatment program is intended to reverse symptoms in the earlier stages of the disease. The second group would be a control group with volunteers who do not have AD and would not receive treatment.

Recruited patients would be provided with a detailed overview of the plan and procedure of the clinical trials, and further progress would only be made with their full consent. Next, stem cell biologists and lab scientists would harvest the cells of patients from group 1 using a skin biopsy to generate the iPSCs. Following cell development and quality control outlined in 2.1 ACh Cell Development, surgeons would transplant APCs into each patient's basal forebrain using an MRI-guided stereotactic surgical procedure. Neurologists and research technicians would consult computed tomographic (CT) scans on patients to validate accurate placement of the injected cells within the basal forebrain. Researchers would use magnetic resonance imaging (MRI) scans to identify signs of tumors or hemorrhage that would threaten the health and safety of patients. The team would record results of behavior monitoring every three months prior to the first year and every six months for each subsequent year. Researchers would use positron-emission tomography (PET)-CT scans throughout the trial to visualize presynaptic acetylcholine activity and record any instances the treatment did not perform as expected, supported by recounts from the patients. To evaluate the behavioral performance of patients, the research team could use the Sandoz Clinical Assessment-Geriatric (SCAG) scale, the Integrated Alzheimer's Disease Rating Scale (iADRS), and the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog). Furthermore, results would be analyzed by comparing brain imaging before the treatment to after the treatment as well as comparing with that of the control group.

2.4 Scientific Team

This treatment development program would require a team of stem cell biologists, lab scientists, neurologists, surgeons, experts in pharmacology, medical doctors, and research technicians. Stem cell biologists and lab scientists would be vital in the process of developing the iPSCs and manipulating the cells for desired results. Neurologists and surgeons would be key in implanting the neurons into animal and test subjects, as well as conducting functional MRI scans and behavioral testing. Medical doctors would primarily assist with clinical trials and care of patients, and research technicians would support the research process in general. A director would supervise the entire process along with the rest of the team.

3. Results

Overall, this treatment plan would restore normal levels of ACh in the brain of AD patients by injecting new nerve cells developed from patient-derived iPSCs. Patients would not need any immunosuppressive drugs for surgery as injected cells are developed from their own skin fibroblasts. The approach to carrying out this treatment plan would follow three steps: stage 1, ACh cell development; stage 2, pre-clinical experiments in mice; and stage 3, human clinical trials, as outlined in Figure 4. Stage 1 and stage 2 should each take approximately 1 year, and stage 3 should take around 1 to 2 years with the whole treatment program spanning 3 to 4 years. It is important to clarify that stages 1 and 2 are essentially lab work acting as the prerequisite for stage 3, where patients will receive treatment in clinical trials.

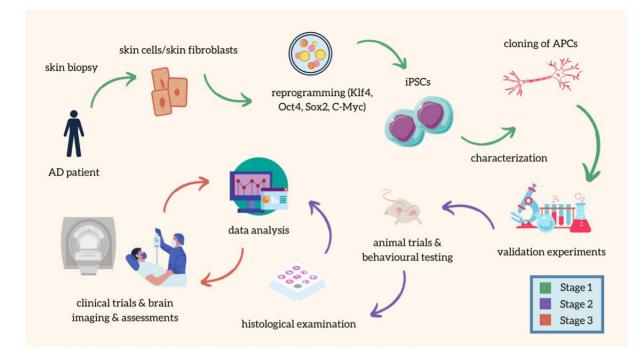


Figure 4. Schematic overview of the proposed project. Each stage is color coded with stage 1 as green, stage 2 as purple, and stage 3 as brown

With regards to the pre-clinical mouse experiments, previous research suggests that scientists can expect to see improvement in AD induced behavior in APP mice as soon as 12 weeks after transplantation (Song, B., et al., 2019). Although the time it takes to see results vary for each behavioral test, depending on difficulty, researchers should find significant improvement between 16 to 20 weeks after transplantation for simpler tasks, and around 24 weeks for more complicated tasks, such as the Morris Water Maze. (Song, B., et al., 2019). The resulting improvements from the transplanted cholinergic neurons should be well sustained, as long as up to 52 weeks (Song, B., et al., 2019).

For clinical trials, two surgical injections of ACh neurons delivered bilaterally, which can be delivered in one surgical procedure or alternatively in two, should be sufficient for each AD patient. Researchers should expect an overall improvement of cognitive behavior and function through using the rating scales listed in *2.3 Clinical Trials* by comparing results measured before the implantation and at regular intervals after the implantation.

4. Discussion

If successful, this treatment protocol will impact the medical, economic, and social facets of Alzheimer's disease treatment and patient experiences.

4.1 Medical Impact

This method of iPSC-developed neurons can be used for other fields in medicine, beyond neuroscience, such as for cancer treatment, diabetes, heart disease, and more. Although iPSC technology in the treatment of diseases is still a novel concept, as research involving stem cells expands, the potential of stem cell technology may demonstrate a wide array of benefits. This experimental treatment program, if successful, will showcase advantages of iPSCs for personalized treatment, and demonstrate its potential in various aspects of medical treatment in the future.

4.2 Economic Impact

If successful, this protocol will reduce the cost of medication for AD. After AD patients undergo nerve cell injections, their need for medication will decrease over time as new neurons supersede the effects of AD drugs.

Currently, the total cost for treatment of all AD patients in America is around \$305 billion, making AD one of the costliest diseases to treat (Wong, 2020). With new drugs being developed, costs for treatment can climb to \$56,000 per year for one individual. However, with pharmaceutical demand decreased by effective stem cell treatments such as this, drug expenditure needs for AD victims may decrease drastically.

4.3 Social Impact

This proposed treatment would free AD patients from requiring prescribed medication daily, removing from their daily routines the reminders of the burdens of their disease and restoring a sense of living normally. This retained sense of normalcy will affect these patients' social activities. With improved coordination of motor movement, patients will no longer feel the need for assistance with basic activities like walking and eating, restoring independence to AD patients. The treatment will also subdue erratic behavior caused by memory loss, relieving one of the more painful impacts of AD felt by patients, their families, and others within their social circles.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Assessing the Efficiency of Public Health and Medical Care Services in Curbing the COVID-19 Pandemic in Sub-Saharan Africa: A Retrospective Study

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| Received: December 2, 2021 | Accepted: March 28, 2022 | Online Published: March 30, 2022 |
|----------------------------|--------------------------|----------------------------------|
| doi:10.5539/gjhs.v14n4p111 | URL: https://doi.org/1 | 0.5539/gjhs.v14n4p111 |

Abstract

In the late of December 2019, a new coronavirus (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV 2) emerged from the city of Wuhan, China and was subsequently declared a pandemic by the World Health Organization (WHO) on March 11, 2020 after it had spread to many countries across the globe. On February 28, 2020, the Sub-Saharan Africa (SSA) reported its first case in Nigeria, and it has since spread to all countries in SSA. Several public health and medical care measures were rolled out by many countries to stem the tide of the spread at the height of the pandemic, between February 28, 2020 and February 28, 2021, period covered by this study. This paper evaluates the levels of health system efficiency of the COVID-19 public health measures and medical care services and their determinants across Sub-Saharan African (SSA) countries using country-level data for those countries. The data was analyzed using bootstrap data envelopment analysis (DEA) and other advanced econometric analyses that produce robust estimations of the relationship between health systems efficiency and their determinants. The general finding of the study suggests that there is more room for health systems in SSA to improve their technical efficiency in fighting the COVID-19 pandemic. The most important determinants of health system efficiency in the fight against the spread of the virus were GDP per capita, population density, temperature levels, and quality of governance. Adequate health system preparedness and human resource strategies geared towards recruiting and/or retaining well-qualified and experienced healthcare workers to provide professional services would prove critical in containing pandemics of this nature.

Keywords: COVID-19, Health systems, Public health, Medical care, Data envelopment analysis, Sub-Saharan Africa

1. Introduction

In the late of December 2019, a new coronavirus (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV 2) emerged from the city of Wuhan, Hubei Province in the People's Republic of China (Arshad Ali et al., 2020), on December 29, 2019, when a cluster of pneumonia of unknown origin occurred (The 2019-nCoV Outbreak Joint Field Epidemiology Investigation Team, 2020). On February 28, 2020, the Sub-Saharan Africa (SSA) reported its first case in Nigeria (Adepoju, 2020), and it has since spread to all the 46 SSA countries. It was subsequently declared a pandemic by the World Health Organization (WHO) on March 11, 2020 after it had spread to many countries and regions across the globe (Mahase, 2020). Health System Strengthening in Sub-Saharan Africa (ASSET) on January 16, 2021 reported that more than 2.2 million people in Africa have been confirmed to be infected and more than 50,000 deaths recorded (ASSET, 2021). Many health systems in the SSA region are limited in their ability to respond robustly to this pandemic due to decades of under-investment in healthcare, relying heavily on out-of-pocket payment and donor support. Out of 46 countries in the SSA region 41 are classified as having weak health systems, languishing in the bottom 5th of countries worldwide ranked by Healthcare Access and Quality (Fullman et al., 2018).

Even though the younger age distribution and warmer temperature in the SSA region are factors recognized to

potentially mitigate the effect of COVID-19 (Kissler, Tedijanto, Goldstein, et al., 2020; Chiyomaru and Takemoto, 2020), the fragile nature of the health systems in the region and many other factors may perhaps combine to worsen the severity of the COVID-19 pandemic, viz.: larger household sizes, intergenerational mixing within households, overcrowded urban settlements, inadequate water and sanitation facilities, severe shortages of intensive care beds and ventilators, high prevalence of undiagnosed and unmanaged pre-existing diseases such as diabetes, tuberculosis, and HIV/AIDS (Zandvoort et al., 2020; Gilbert, Pullano, Pinotti, et al., 2020; The Economist, 2020; Bishop, 2020). It is, therefore, imperative for countries in the sub-region to attenuate the spread of the virus to ensure that health systems can cope with patient numbers and that mortality rates are reduced to the barest minimum.

The absence of mass vaccination in the SSA countries (as at the time of conducting this study), leaves policy makers with limited policy options that largely entail measures to restrict movement and physical interaction of people (i.e. non-pharmaceutical interventions (NPIs)) in order to curb exponential spread of the virus. NPIs usually involve social-distancing measures, border closures, self-isolations of symptomatic patients and public hygiene, and in extreme cases stringent lockdown measures (Correia et al., 2020). Governments across the SSA sprang into action and began rolling out an extensive social distancing measures after the first few cases of COVID-19 were confirmed (Osseni, 2020). Health officials in countries such as Nigeria, Rwanda, Ghana, Benin, South Africa, and Ethiopia embarked on vigorous tracing and testing of people whom COVID-19 patients had contact with. Soon after that most of these countries came up with innovative technology like Mobile Location Data Tracking to lessen the laborious human effort in tracing people who had come into contact with COVID-19 patients (Ekong, Chukwu, Chukwu, 2020). When these initial NPI measures failed to contain the contagion, isolation centers were set up, borders and schools in many SSA countries were closed, and full lockdowns were implemented in some countries while others were partially locked-down to contain the spread (Haider, Osman, Gadzekpo, et al., 2020).

Evidence shows that the speed with which governments implement NPIs determines, to a large extent, how well the spread of the COVID-19 contagion would be contained (Zandvoort et al., 2020). Large amount of resources were expended between February 28, 2020 and February 28, 2021, period covered by this study, to carry through the NPI measures. Besides the direct material and labour cost, the World Bank estimated that COVID-19 pandemic would cost the SSA region between \$37 billion and \$79 billion in output losses, translating into a decline of between 2.1% and 5.1% of GDP, due to economic disruptions caused by this global pandemic (Toure, 2020). The question of whether the resources directed towards curbing the spread of COVID-19 were used efficiently in the SSA region remains unanswered. This study seeks to fill this void in the literature.

The rest of the paper is organized as follows: Section 1.2 reviews the literature on health system efficiency and COVID-19 pandemic. Section 2 covers the applied methodology and estimation procedures used. It presents detailed explanation on the choice of variables, methods and models used in estimation of health system efficiency in the fight against COVID-19 pandemic. Section 3 presents and discusses the empirical results of the technical efficiency scores, consequent rankings, as well as the major determinants of health systems efficiency. The final section, Section 4, presents the conclusions, recommendations, and limitations of the study as well as implications for further studies.

1.2 Literature Review

From the accessible literature, only two studies have been carried out on health system efficiency in curbing the spread of the COVID-19 virus (Shirouyehzad et al., 2020 and Breitenbach et al., 2020). Shirouyehzad et al. (2020) analyzed the efficiency performance of the assessed countries regarding the control of the COVID-19 pandemic. The study was divided into two stages. In the first stage, they assessed the relative performance of countries in preventing the outbreak of the disease. In the second stage, they evaluated in the countries' performance on reducing the negative impact of the pandemic on the health status of the general population (i.e. the efficiency of medical treatment) in terms of the total number of confirmed cases, the death cases, and the recovered cases. The respective average efficiency scores from the contagion control and medical treatment efficiency analyses were used to create four quadrants to evaluate the relative efficiency performance for each assessed country. The results showed that while Belgium, Singapore and Vietnam performed efficiently well in both contagion control and medical treatment and thus can serve as benchmarks, China, Italy, and Iraq performed poorly in both aspects, an indication for a swift response to strengthen their health systems.

On the other hand, Breitenbach et al. (2020) examined the efficiency performance of health systems in flattening the contagion curve in the first 100 days after the outbreak of the COVID-19 disease. They employed the non-parametric method of data envelopment analysis (DEA) to assess 31 countries with the most COVID-19 confirmed cases. The number of spared days, which was calculated as the 100 days minus the number of days of persistent infections, as the only output variable. The input variables used in the study include: number of days to

lockdown, doctors per thousand population, total COVID-19 tests per one million population, and health expenditure as the percentage of GDP. The results of the study showed that while 12 of the assessed countries were efficient 19 were inefficient in their use of resources to flatten the contagion curve. Germany, Canada, USA, and Austria were among the countries that were found to be inefficient.

Both studies were conducted just in the early few months of the outbreak of the COVID-19 pandemic when most countries were at early stages of the viral infections. These two studies, therefore, are limited in scope in terms of examining the disease trajectories of the virus and its associated responses by various health systems. A lot has changed after these two studies were conducted.

No study has been carried out in the setting of SSA, a region predominantly characterized by precarious health systems, widespread inadequate supply of health resources, and frequent outbreak of pandemics and epidemics such as Ebola, yellow fever, cholera, HIV-AIDS, and dengue fever (Mboussou et al., 2019). Even though the SSA is prone to outbreak of epidemics and pandemics, to the best of my knowledge, no research has been conducted to evaluate the efficiency with which mobilized resources are used to curb their spread. The study intends to assess the efficiency of health systems in SSA in fighting an outbreak of an epidemic or pandemic using the COVID-19 pandemic as a case study. This study is motivated to fill these gaps in the literature, making significant and original contribution by estimating the levels of efficiency in the fight against COVID-19 and identifying the sources of the inefficiencies in the SSA setting.

2. Methodology

2.1 Conceptual Framework

In order to address the objectives of this study, three models were employed to assess the efficiency of healthcare resources spent on curbing the COVID-19 pandemic as depicted in Figure 1. Each of the three models included different input and output variables to distinguish between a production function that consisted of inputs that are mostly geared towards COVID-19 preventive and preparedness of public health measures (Model 1), a production function that incorporates inputs typically based on flattening the COVID-19 contagion curve (Model 2), and a production function that comprises mainly of inputs aimed at medical treatment of COVID-19 patients (Model 3). Table 1 presents the definitions and data sources of the input and output variables included in health production functions.

| Model | Level of Health System Efficiency | Inputs | | | Outputs |
|---------|---|--|----|----------------------------------|---|
| Model 1 | Efficiency of Public Health Services | Average of 13 HRCC IndexNPIs Stringency Index | \$ | Health Production Function | • Cases per 1M Pop. |
| Model 2 | Efficiency of Flattening the COVID-19 Curve | Health Spending % GDP Total Tests/1M Population NPIs Stringency Index | • | Health Production Function | •Number of Days to Flatten the curve |
| Model 3 | Efficiency of Medical Treatment Services | Physicians Density Inpatient Beds Density Total Tests/1M Population NPIs Stringency Index | • | Health Production Function | •Case Survival Rate •Recovered Cases |

Figure 1. The DEA Models of COVID-19 Health Production

This study adopted the two-stage approach, the efficiency indices were first estimated using the health production function (i.e. Efficiency of Healthcare Systems) and then analysis of the effect of health systems' environmental variables on the efficiency indices was undertaken (i.e. Determinants of Health System Efficiency). Thus, the datasets used for this study comprises two different sets of variables. The first set of variables considered were those underlying the health production functions that were used for the estimation of the efficiency indices. The second set of variables consisted of health system characteristics which are outside the purview of the managers of the health systems and healthcare policies that are somehow under the control of policy-makers and influence the functioning of the health production process across SSA countries.

2.2 Data Envelopment Analysis

Two major techniques are widely used in measuring healthcare system performance, namely the stochastic frontier analysis (SFA) and data envelopment analysis (DEA). The DEA approach is particularly useful in measuring efficiency performance of non-profit oriented public organizations such as public healthcare facilities and public utilities. Thus, the use of the DEA approach dominates in literature with regard to measuring efficiency performance of healthcare systems (Hollingsworth & Peacock, 2009). The main advantage of DEA approach is that it can accommodate multiple inputs and multiple outputs measured in different units (Charnes et al., 1994). It is also capable of including exogenously determined environmental variables to explain the differences in the efficiency scores (Banker & Morey, 1994). The DEA model defines efficiency as the ratio of the weighted sum of outputs to the weighted sum of inputs (Mozaffari et al., 2022), which allows for the comparison of performance among countries as to how well each country converts inputs into outputs. Inefficiency is then measured as the production function. It uses non-parametric technique of linear programming to estimate production frontiers without making any a priori assumptions about the functional form of the related production technology. Today, the scope of the use of DEA models has expanded beyond efficiency measurement to many applications in benchmarking and generating indices as have been reported in the literature (Emrouznejad et al., 2008).

This study followed the DEA approach initially developed by Farrell (1957) and later improved by Charnes, Cooper, and Rhodes (called CCR model) in 1978. The CCR model was further enhanced by Banker, Charnes, and Cooper (called BCC model) in 1984. The CCR model assumes that production has a constant return to scale (CCR), denoting that any change in the input results in a proportionate change in the output.

| Variable | Definition | Data Source | | | |
|---|---|---|--|--|--|
| Input Variables | | | | | |
| IHRCC Index | Average of 13 IHRCC scores: Legislation and financing, IHR Coordination and National Focal Point Functions, Zoonotic events and the Human-Animal Health Interface, Food safety, Laboratory, Surveillance, Human resources, National Health Emergency Framework, Health Service Provision, Risk communication, Points of entry, Chemical events, and Radiation emergencies (see Appendix A). | WHO-GHO (2019) | | | |
| NPIs Stringency Index | Average of nine indicators of the governments' NPIs: school closure, stay at home restrictions, cancelling of public events, restrictions on gathering size, public transport closure, workplace closure, internal movement restrictions, international movement restrictions, and public information campaigns. | Oxford COVID-19 Government Response Tracker (2020) | | | |
| Testing intensity | Total cumulative number of COVID-19 virus laboratory tests divided by the total population of the country multiplied by one million. | WHO (2021) | | | |
| Healthcare Spending | Percentage of Gross Domestic Product spent on healthcare services. | WHO-GHO (2019) | | | |
| Physicians' Density | The number of physicians who are actively practicing medicine in public and private institutions (full-time equivalents) per 1,000 population. | WHO-GHO (2019) | | | |
| Hospital Bed Density | The number of available beds in all public and private inpatient health institutions per 1,000 population. | WHO-GHO (2019) | | | |
| Output Variables | | | | | |
| Positivity Rate | The ratio of the total confirmed positive COVID-19 cases to the total number of COVID-19 tests times 100. This was transformed into COVID-19 negativity rate. | JHU COVID-19 Data Hub | | | |
| Number of Days to Flatten COVID-19 curve | Number of DaysThe number days, counting from the day the first infection was confirmed to the day when the COVID-19 infection rate started to fall steadily, showing that infections were markedly declining. That is, the inflection point on the COVID-19 | | | | |
| COVID-19 Case Fatality Rate | The ratio of total confirmed deaths to total confirmed cases times 100. It was transformed into case survival rate (CSR). | JHU COVID-19 Data Hub | | | |
| Recovered Cases | Cumulative number of COVID-19 infected persons who have recovered per 1000 confirmed cases. | JHU COVID-19 Data Hub | | | |

Table 1. Definition and Sources of Data of Variables used in the DEA Models

NPIs = Non-pharmaceutical interventions.

However, the BCC model assumes a variable return to scale (VRS) in production, meaning a change in input results in either an increase or a decrease in output. The ratio of the technical efficiency scores from the CCR model to the BCC model represents scale efficiency (Cooper, Seiford, & Tone, 2007). This study adopted VRS approach since the output variables (such as recovered COVID-19 cases) may not change proportionately with changes in the input variables (such as NPIs Stringency Index). Again, as explained in the literature (Hollingsworth & Smith, 2003; Olesen et al., 2015) the CCR formulation of DEA should not be used when the dataset include ratio rather than absolute numbers as input and/or output variables since the estimation of the efficiency scores is affected. According to Hollingsworth and Smith (2003), if it becomes necessary to use ratio variables in order to reflect accurately the underlying production function and due to the nature of the available data (as in the case of this study), the BCC formulation of DEA should be used as it is verified to handle such data well.

DEA models have different orientations including input-minimization and output-maximization (Aristovnik, 2012; Martic et al., 2009). The former minimizes inputs while maintaining the prevailing levels of outputs and the latter maximizes output while maintaining the current levels of inputs. This paper used the DEA output-maximization orientation because on the SSA region, the need for healthcare services are poorly met (Fullman et al., 2018), thus, it would be unethical to reduce the amount of healthcare services provided to achieve efficiency goal (Hernández & Sebastián, 2014). Again, the use of output-oriented model is justified in healthcare due to limited control of the managers of the healthcare system over inputs. In most countries in SSA, major decisions regarding investment and recruitment into the health sector are mostly taken by political government departments (Cheng et al., 2016). The study adopted VRS approach with output-maximization orientation DEA model to measure technical efficiency of health systems. Thus, assuming there are *s* inputs and *m* outputs for *n* DMUs (health systems). Let *y_j* represents the vector of outputs, *x_j* the vector of the inputs, *X* is the (*s* × *n*) input matrix, and *Y* is the (*m* × *n*) output matrix. Then the standard VRS output-oriented DEA is specified as:

 $Max_{\theta,\lambda} \theta_i$

Subject to the constraints:

$$\theta_j y_j < Y\lambda$$

 $x_j > X\lambda$ (1)
 $n1'\lambda = 1$
 $\lambda \ge 0$

where θ_j is a scalar that satisfies $\theta_i \ge 1$ and $\theta_j - 1$ measures the proportional output expansions which can be attained by the j^{th} health system; and λ is a $(n \times 1)$ vector of constant that measures the weights used to compute the location of an inefficient health system if it were to become efficient.

2.3 Second-Stage Analysis: Determinants of Health System Efficiency

The two-stage DEA is being used to investigate factors such as health-system characteristics and healthcare policies that are associated with the technical efficiency scores estimated at the first stage in the previous section. These factors (including NPIs) are usually under the control of health-policy decision makers but not under the control of decision-makers in the health production process such as healthcare providers and patients (de Cos and Moral-Benito, 2014). In most of the DEA literature, Tobit regression is usually employed to account for the effects of these factors (often referred to as environmental variables) on the technical efficiency. This is done by regressing the technical efficiency scores estimated at the first stage against a set of environmental variables as follows:

$$\theta_i = \beta z_i + \varepsilon_i \tag{2}$$

where θ_j is the technical efficiency score, z_j is the vector of environmental variables that affect the technical efficiency health system, β is a vector of the parameters to be estimated, and ε_j is the error term which is assumed to be identical, independently and truncated normally distributed with constant variance σ and zero mean.

This analysis plays a crucial role in providing useful information on available alternatives to improve efficiency performance of health systems. However, Simar and Wilson (2007) argued that such conventional statistical inferences are inappropriate since the first-stage DEA scores and the environmental variables in the second-stage are highly dependent on each other and hence would violate the basic assumptions of regression analysis. Therefore, Simar and Wilson (2007) recommended the use of bootstrap DEA methods. This study employed the bootstrap DEA model to investigate the determinants of health system performance in curbing COVID-19 pandemic. Algorithm #2 suggested by Simar and Wilson (2007) is used in this study (see Appendix F for the

details). For more details on the bootstrap DEA methodology in healthcare studies see Simar and Wilson (2007; 2018).

2.4 The Output Variables

The COVID-19 pandemic has acted like a litmus test on the capacity and designs of health systems across the globe. There have been similar pandemics in the recent past – Lassa fever, Ebola virus disease, SARS, Zika virus, and H1N1 – and the threat of more frequent future pandemics is real due to increase in international and domestic travel and trade that makes for a very rapid international spread of any highly infectious virus (Sundararaman et al., 2020). It is, therefore, important to learn the right lessons with regard to building a resilient healthcare systems capable of preventing or resisting health emergency shocks by learning from the current COVID-19 experience. Kruk et al. (2015) defined Health systems resilience as "the capacity of health actors, institutions, and populations to prepare for and effectively respond to crises; maintain core functions when a crisis hits; and, informed by lessons learned during the crisis, reorganize if conditions require it". Response to a crisis needs "both a vigorous public health response and a highly proactive and functioning health-care delivery system" (Kruk et al. 2015). Both these systems must work in concert during a crisis—and indeed they can do so only if designed such long before crisis strikes—which is the element of health systems preparedness. For this reason, Model 1 was designed to assess the health systems' efficiency in terms of how resources were utilized to enhance the resilience of health systems during pandemics. Thus, for Model 1, we are interested in data relating to delaying or preventing the outbreak and curbing the rapid spread of the COVID-19 virus, i.e. how resilient the countries are able to resist this global pandemic. Therefore, we selected one output variable – COVID-19 positivity rate. Positivity rate is the ratio of the total confirmed positive COVID-19 cases to the total number of COVID-19 tests times 100. Again, we make an assumption that a country with a lower positivity rate has a strong health system to protect its citizens during pandemics. We needed to transform this variable to meet DEA assumptions. The DEA techniques require that output variables are measured in such a way that "more is better". Since the COVID-19 positivity rate (CPR) does not meet this requirement, we computed COVID-19 negativity rate (CNR) as follows:

$$CNR = \frac{1}{CPR} \times 100$$

The several non-pharmaceutical interventions (NPIs) to flatten the COVID-19 curve have been discussed in the literature (Block et al., 2020; Arshed et al., 2020; and Breitenbach et al., 2020). This approach may not totally eradicate the COVID-19 disease, but it will potentially reduce the stress on health systems (Giesecke, 2020; World Health Organisation, 2020a). A considerable amount of resources and policy interventions including economic lockdowns have been instituted across the globe to achieve the goal of flattening the curve (Koh, 2020; Sharma, Talan, and Jain, 2020; Arshed, 2020). Many countries have struggled in different ways to flatten the curve, but different results emanate. *Model 2* of this paper aims at measuring the efficiency of health systems in flattening the COVID-19 trajectory curve during the first wave of infections. In this regard, we are interested in data relating to the speed at which the curve was flattened, that is, how quickly countries were able to reduce the rate of infections. Thus, the paper adopted an output variable which is computed as the difference between the date when the first case was detected to the date when the COVID-19 infections started to fall steadily, showing that infections were markedly declining. In order to avoid misspecification of the model and ensure that countries that flatten their curves earlier are not represented by low values, this output variable was inverted (see Breitenbach et al., 2020; Arshed et al., 2020; Appendix E for COVID-19 epidemiological curves).

The COVID-19 pandemic has been characterized by significant morbidity and mortality of varying degrees across countries. Medical treatments have been administered to COVID-19 patients in order to control the viral infection. Medical resources such as medical personnel, inpatient hospital beds, ventilators, and others have come under intense usage since the outbreak of the pandemic. Different medical treatment measures have been taken by each country with differing outcomes. In this paper, *Model 3* seeks to compare the relative performance of each sampled country as to whether the resources used in treating COVID-19 patients are being used efficiently or not. In order to empirically carry out this assessment, two output variables were selected – case fatality rate and recovered cases per 1000 confirmed cases. The COVID-19 case fatality rate (CFR), which is measured as the ratio of total confirmed deaths to total confirmed cases times 100, was transformed into case survival rate (CSR) to meet DEA model requirement of 'more is better' as follows:

$$CSR = \frac{1}{CFR} \times 100.$$

2.5 Input Variables

The input variables used in the production function of this paper included physicians' density, inpatient beds density, health spending as a proportion of GDP, and the average of 13 International Health Core Capacity Scores

(IHRCCS). These input variables are widely used in studies of health production efficiency (Breitenbach et al., 2020; Shirouyehzad et al., 2020; See and Yen, 2018; Ambapour, 2015; Sinimole, 2012; Spinks and Hollingsworth, 2009). The average of the IHRCCS is used to reflect the resilience, emergency preparedness capacity against health threat, and the overall public health of national health systems (Sundararaman et al., 2020). The 13 core capacities are: (1) Legislation and financing; (2) IHR Coordination and National Focal Point Functions; (3) Zoonotic events and the Human-Animal Health Interface; (4) Food safety; (5) Laboratory; (6) Surveillance; (7) Human resources; (8) National Health Emergency Framework; (9) Health Service Provision; (10) Risk communication; (11) Points of entry; (12) Chemical events; (13) Radiation emergencies (World Health Organization, 2005). They are all measured on the scale between 0 (minimum score) and 100 (maximum score). Appendix A details the scores for each capacity for all the sampled countries plus the definitions of all the capacities.

Since this paper analyzes the efficiency of health systems in combating the COVID-19 pandemic, we chose two inputs that are unique to COVID-19 for the three models: total COVID-19 tests per one million population and non-pharmaceutical interventions (NPIs) stringency index (SI). The total COVID-19 tests per one million population was used to reflect the level of resources, both human and material, that have been spent in the fight against the spread of the virus (Arshed et al., 2020). On the other hand, the stringency index (SI) is a composite index of nine indicators that captures variations in governments' COVID-19 NPIs to contain the spread of the virus and augment health systems (Hale et al., 2020). The nine indicators of the NPIs are: (1) school closure; (2) stay at home restrictions; (3) cancelling of public events; (4) restrictions on gathering size; (5) public transport closure; (6) workplace closure; (7) internal movement restrictions; (8) international movement restrictions; and (9) public information campaigns. Each of the nine indicators were rescaled to a value from 0 to 100 (100 = strictest). Then the nine scores were averaged to get the composite Stringency Index (For more details on the construction of the NPIs Stringency Index see Appendix B). Table 1 presents the definitions and the sources of data used in the three DEA models.

2.6 Explanatory Variables

In order to investigate the effect of health systems characteristics and healthcare policies on health systems efficiency, we selected some explanatory variables which are defined in Table 2. Based on literature seven explanatory variables were selected as determinants of health system efficiency: (1) governance indicator variable (the average of World Bank's six governance quality indicators); (2) level of economic activities variable (GDP per capita); (3) tobacco use prevalence; (4) proportion of population aged 65 years and above; (5) population density; (6) average temperature levels; and a categorical variable of income groupings of the studied countries (see Wang, Rodrigues, and Barmejo, 2020; Arshed, Meo, and Farooq, 2020; Ahmed, Hassan, MacLennan, et al., 2020; Hadad, Hadad, & Simon-Tuval, 2013).

2.6.1 Governance Quality

World Bank's Worldwide Governance Indicators (WGI) are a research dataset summarizing views on the quality of governance in both industrial and developing countries. These indicators which have been published since 1996 covers six dimensions of governance: control of corruption, government effectiveness, political stability, regulatory quality, rule of law, and absence of violence. This variable is included in the second-stage analysis to assess the impact of the quality of governance in health systems performance in curbing the COVID-19 pandemic. A plethora of empirical evidence indicate a positive correlation between health system performance and quality of governance (Ibrahim et al., 2018; Wranik, 2012). The quality of governance was measured as the average of all the six dimensions from 2016 to 2018. This variable is adopted in Model 3.

2.6.2 Size of Economy

GDP per capita vary markedly across the SSA countries. One empirical study by Mo et al. (2020) found an evidence of a positive relationship between GDP and the spread of COVID-19 virus. A low GDP per capita implies low economic activities and less human interactions. Hence, it is not surprising that territories with higher GPD may appear to have higher COVID-19 cumulative cases. This variable is employed in all the three models.

2.6.3 Tobacco Use Prevalence

Tobacco use prevalence was employed as a proxy of the population's lifestyle and behavior which can impact the severity of the spread of the COVID-19 virus. According to Guan et al. (2020), people who smoke have 3.25 higher odds of developing severe forms of COVID-19 disease as compared to non-smokers. Accumulating evidence indicates that tobacco use affects health outcomes and also the health system efficiency (Allin, Grignon, and Wang, 2016; Afonso and St. Aubyn, 2011; Johansson and Sundquist, 1999). Tobacco use prevalence was

measured as the proportion of the population aged 15 years and above who regularly smoke. This variable is employed in all the three models.

2.6.4 Aged Population

Another social environmental variable in the models of this paper is the aged population, which provides a measure of age-related risk of severe COVID-19 disease. COVID-19 is often more severe in the people advanced in years or with underlying health conditions like lung or heart diseases, diabetes, or conditions that affect their immune system (Novosad et al., 2020; Ghisolfi et al., 2020; Okeahalam et al., 2020). Holts et al., (2020) provides a strong evidence of age-related gradient for risk of severe COVID-19 disease, hospitalization and deaths. The aged population was measured as the proportion of the population aged 65 years and above.

2.6.5 Population Density

Evidence from several empirical studies shows that population density has a significant effect on health system performance (Ahmed et al., 2019; See and Yen, 2018; Greene, 2010; and Kumbhakar, 2010). In this study, we postulate that a health system with a lower population density would have significant positive impact on health system efficiency in the midst of the COVID-19 pandemic due to its implications for social distancing and quality of healthcare services. This variable is measured as the size of the average population living on a kilometer of land area.

2.6.6 Temperature Levels

The relationship between temperature levels and the spread of COVID-19 virus is well documented in the literature (Aidoo et al., 2021; Roy, 2020; Kassem, 2020; Corripio and Raso 2020; Wang, Rodrigues, and Barmejo, 2020). The consensus among these studies is that there is an inverse relationship between the spread of COVID-19 virus and temperature. For instance, Aidoo et al. (2021) found that the risk of the spread significantly decreases when average temperature exceeds 29°C. Wang, Rodrigues, and Barmejo (2020) estimated that every 1°C increase in the minimum temperature leads to a decrease in the cumulative number of cases by 0.86. The average monthly temperature for each country is included in the Model 2.

2.6.7 Level of Economic Development

A categorical variable of three income groupings – low-income, lower-middle-income, and upper-middle-income – of the studied countries was created to examine the influence of their level of development on health system performance in curbing the COVID-19 virus. Table 2 presents the definitions and the sources of variables used in the second-stage analysis.

We also employed the Simar and Wilson (2007) double bootstrap DEA approach to estimate robust bias-corrected efficiency scores from the bootstrapped regression analysis to identify factors associated with these estimated efficiency scores. The *simarwilson* command in STATA Version 15 was used in the analyses.

2.7 Data Sources

Data for the study were obtained from three main sources: the John Hopkins University COVID-19 Data Repository (https://coronavirus.jhu.edu), Worldometer COVID-19 Data Repository (https://worldometer.info), and COVID-19 Data Hub developed by Guidotti and Ardia (2020) (https://covid19datahub.io). COVID-19 indicators of confirmed, recovered, death cases and other quantitative related data were sourced from databases of John Hopkins University and Worldometer COVID-19 databases. However, qualitative indicators on government policy interventions data were sourced from COVID-19 Data Hub developed by Guidotti and Ardia (2020). Due to wide fluctuations in the daily trends of confirmed, recovered, and death cases as a result of irregular intervals of reporting, the study used 21-day moving averages of reported cases in order to better appreciate the trends.

This is a cross-sectional study using data on 46 countries in SSA. These countries were selected based on the fact that the relevant COVID-19 data required for the study's analyses were regularly reported on during the study period, which was between December 29, 2019 and February 28, 2021. According to the list provided by United Nations Statistics Division, there are 50 Sub-Saharan African countries and territories. Six countries and territories (i.e. Tanzania, Sudan, South Sudan, Djibouti, Eritrea, Reunion, and Mayotte) were excluded from the study due to missing data of some selected relevant variables in the databases.

| Variable | Definition | Data Source | | | |
|--|---|----------------|--|--|--|
| AverageAverage of six governance quality indicators: control of corruption,governance qualityeffectiveness, political stability, regulatory quality, rule of law, and absence of | | WB-WGI | | | |
| GDP per capita | Gross Domestic Product (GDP) per capita converted to international dollars using purchasing power parity (PPP) rates. | | | | |
| Tobacco Use Prevalence | The proportion of the population aged 15 years and above who regularly smoke. | | | | |
| Aged population | The proportion of the population who are aged 65 years and above. | | | | |
| Population Density | The size of the average population living on a kilometer of land area. | | | | |
| Temperature (°C) | The average of 12 months temperature measured in degree Celsius. | WB-WDI | | | |

Table 2. Definitions and Sources of Variables used in Second-Stage of Efficiency Analysis

3. Empirical Results and Discussion

3.1 Descriptive Statistics

Table 3 presents the descriptive statistics for the input and output variables used in the study for the efficiency estimations. The performance of health systems in the SSA region in their fight against the spread of the COVID-19 virus was estimated based on six inputs and five outputs in three models - COVID-19 contagion control model, flattening the COVID-19 contagion curve model, and medical treatment model.. A total of 44 SSA countries (representing nearly 90% of all SSA countries) were used in this study based on the availability of relevant data required for the efficiency analysis.

| Indicator | Mean | | Minimum |] | Maximum |
|-------------------------------|--------|-------|-----------|---------|--------------|
| Indicator | Wicall | Value | Country | Value | Country |
| Inputs: | | | | | |
| Total tests per 1M Population | 46,866 | 1,117 | Congo, DR | 281,082 | Botswana |
| NPIs Stringency Index | 47.2 | 12.5 | Burundi | 70.2 | Eritrea |
| HRCC Index (SPAR) | 43.9 | 17.0 | CAR | 71.0 | Rwanda |
| Health expenditure (% GDP) | 5.67 | 2.65 | Djibouti | 17.41 | Sierra Leone |
| Physicians' density | 0.22 | 0.02 | Niger | 2.00 | Mauritius |
| Inpatient bed density | 1.36 | 0.20 | Senegal | 4.40 | Seychelles |
| Outputs: | | | | | |
| Total cases per 1M Population | 4,284 | 171 | Burundi | 27,077 | Cabo Verde |
| Days to flatten the curve | 244.5 | 23 | Mauritius | 355 | Benin* |
| Case fatality rate | 1.84 | 0.10 | Burundi | 4.20 | Mali |
| Recovery rate | 82.8 | 34.2 | Lesotho | 98.3 | CAR |

Table 3. Descriptive Statistics of COVID-19 healthcare inputs and outputs used in the models

*As at the end of the cut-off date (February 28, 2021) used in this paper, 4 countries (i.e. Benin, Gabon, Seychelles, and Togo) had not been able to flatten their COVID-19 contagion curve.

As indicated on the Table 3, an average number of COVID-19 total laboratory tests per one million population is 46,866 and an average non-pharmaceutical interventions (NPIs) Stringency Index and the HRCC Index are 47.2 and 43.9, respectively. The average health expenditure as a proportion of GDP is 5.67%. The average number of physicians per thousand population is 0.22, while the average number of inpatient beds per thousand population is recorded as 1.36, with a maximum value of 4.20 (in Seychelles) and a minimum value of 0.20 (in Senegal).

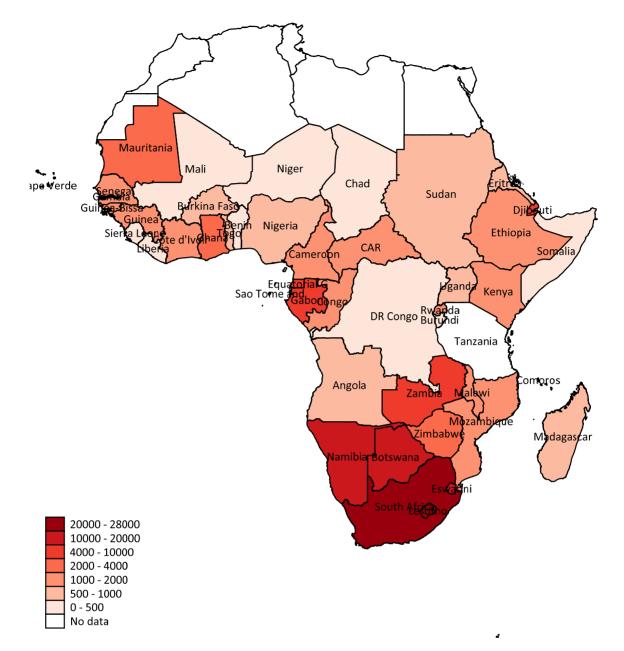
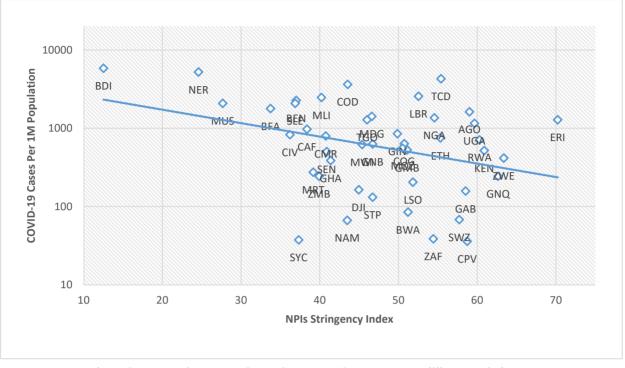


Figure 2. Choropleth map showing incidence of COVID-19 cases per one million population

For the output measures, total number of COVID-19 cases per one million population is averaged at 4,282 across the region. It took an average of 79 days for countries in the SSA region to record their first cases of COVID-19 virus after its emergence in the city of Wuhan, Hubei Province in the People's Republic of China (Newey and Gulland, 2020), on December 29, 2019. An average of 245 days were used by the 44 sampled SSA countries to flattening the COVID-19 contagion curve with a minimum of 23 days (in Mauritius) and a maximum of 355 days (in Senegal). There were four countries (i.e. Benin, Gabon, Seychelles, and Togo) which had not been able to flatten the curve at the end of the cut-off date (February 28, 2021) for this study. The average case fatality rate is 1.84%, while an average recovery rate of 82.8% is recorded in the region.

Figure 2 plots the COVID-19 cases per one million population on the map. It can be observed here that countries like South Africa, Seychelles, and Lesotho have greater values. They are followed by countries like Namibia, Botswana, Gabon, Ethiopia, Ghana, Rwanda Eswatini, and Zambia.

Figure 3 shows a quick scatter plot relating the number of COVID-19 cases per one million population and the NPIs Stringency Index. A quick inspection of the plot reveals that there is a negative correlation, that is, the stricter



governments' interventions are generally associated with lower COVID-19 cases.

Figure 3. NPIs Stringency Index and COVID-19 Cases per 1 Million Population

3.2 First-stage DEA Results: Efficiency Scores, Rankings, and Classifications of Countries

The efficiency scores for all the selected SSA countries' health systems in this study were computed using STATA packages of *teradial* and *simarwilson*. The results of the original DEA scores, bootstrap bias estimates and Farrell bias-corrected output-oriented efficiency scores under VRS, which range from one to infinity, are presented at Appendix C. For easy reading and analysis, the Farrell bias-corrected efficiency scores were converted into Shepherd bias-corrected efficiency scores, which range from zero to one, are ranked and presented in Table 1.4 for each of the three models in this study.

In the given sample of 44 SSA countries, 20 countries are classified as low-income, 17 countries as middle-lower-income, and 7 countries as upper-middle-income or high-income (World Bank, 2020). Based on the proposed methodology, in the first stage of this study, the efficiency of public health measures instituted by the various health systems in the SSA countries to curb the spread of contagious diseases in general and COVID-19 virus in particular were evaluated. In this stage, the average of the 13 IHRCCs, NPIs Stringency Index, and the number of COVID-19 tests per one million population were used as input variables whilst spared days and COVID-19 cases per one million population were used as output variables. The results for the three income groups are presented in Figure 4.

| | Efficiency Score | | Efficiency Score | | Efficiency Score | | |
|---------------------|------------------|------|------------------|------|-------------------|------|--|
| Country | of COVID-19 | Rank | Flattening the | Rank | of COVID-19 | Rank | |
| | Public Health | | COVID-19 Curve | | Medical Treatment | | |
| Angola | 0.5773 | 14 | 0.8459 | 9 | 0.9781 | 37 | |
| Burundi | 0.7236 | 5 | 0.6413 | 23 | 0.9909 | 19 | |
| Benin | 0.5883 | 12 | 0.5591 | 32 | 0.9888 | 25 | |
| Burkina Faso | 0.4921 | 25 | 0.7058 | 19 | 0.9824 | 34 | |
| Botswana | 0.5200 | 21 | 0.4449 | 39 | 0.9913 | 17 | |
| Central Africa Rep. | 0.8333 | 1 | 0.9168 | 4 | 0.9959 | 8 | |
| Cote d'Ivoire | 0.4873 | 26 | 0.8555 | 8 | 0.9809 | 35 | |
| Cameroon | 0.4277 | 41 | 0.7464 | 17 | 0.9892 | 24 | |
| Congo, Dem. Rep. | 0.6748 | 6 | 0.7639 | 16 | 0.9825 | 33 | |
| Congo, Rep. | 0.4541 | 38 | 0.8226 | 11 | 0.9860 | 29 | |
| Cabo Verde | 0.4751 | 34 | 0.7955 | 13 | 0.9940 | 14 | |
| Djibouti | 0.4736 | 35 | 0.5913 | 26 | 0.9949 | 11 | |
| Eritrea | 0.5586 | 18 | 0.6047 | 25 | 0.9946 | 13 | |
| Ethiopia | 0.4816 | 30 | 0.8642 | 7 | 0.9963 | 6 | |
| Gabon | 0.4492 | 39 | 0.0175 | 44 | 0.9978 | 3 | |
| Ghana | 0.4838 | 28 | 0.3251 | 40 | 0.9957 | 10 | |
| Guinea | 0.4798 | 31 | 0.8941 | 6 | 0.9949 | 12 | |
| Gambia, The | 0.4752 | 33 | 0.8396 | 10 | 0.9699 | 40 | |
| Guinea-Bissau | 0.6173 | 9 | 0.9588 | 1 | 0.9896 | 23 | |
| Equatorial Guinea | 0.5947 | 11 | 0.8206 | 12 | 0.9867 | 27 | |
| Kenya | 0.4592 | 36 | 0.7826 | 14 | 0.9835 | 31 | |
| Liberia | 0.5830 | 13 | 0.9464 | 2 | 0.9961 | 7 | |
| Lesotho | 0.7477 | 4 | 0.5602 | 31 | 0.9717 | 38 | |
| Madagascar | 0.6151 | 10 | 0.9079 | 5 | 0.9419 | 44 | |
| Mali | 0.6348 | 7 | 0.6544 | 22 | 0.9653 | 41 | |
| Mozambique | 0.5206 | 20 | 0.4705 | 38 | 0.9904 | 21 | |
| Mauritania | 0.4794 | 32 | 0.6575 | 21 | 0.9827 | 32 | |
| Mauritius | 0.5726 | 16 | 0.7248 | 18 | 0.9981 | 1 | |
| Malawi | 0.5668 | 17 | 0.4977 | 36 | 0.9963 | 5 | |
| Namibia | 0.4828 | 29 | 0.6145 | 24 | 0.9921 | 16 | |
| Niger | 0.8047 | 3 | 0.7710 | 15 | 0.9959 | 9 | |
| Nigeria | 0.4243 | 42 | 0.5278 | 33 | 0.9884 | 26 | |
| Rwanda | 0.4858 | 27 | 0.5000 | 35 | 0.9911 | 18 | |
| Senegal | 0.4148 | 43 | 0.1142 | 42 | 0.9965 | 4 | |
| Sierra Leone | 0.6263 | 8 | 0.4779 | 37 | 0.9860 | 28 | |
| Sao Tome & Principe | 0.5745 | 15 | 0.9296 | 3 | 0.9857 | 30 | |
| Eswatini | 0.4336 | 40 | 0.5725 | 30 | 0.9630 | 42 | |
| Seychelles | 0.5028 | 23 | 0.0189 | 43 | 0.9981 | 2 | |

Table 4. Shepherd Output-Oriented Bias-Corrected Efficiency Scores under VRS and Ranks

| Chad | 0.8165 | 2 | 0.5783 | 29 | 0.9801 | 36 |
|--------------|--------|----|--------|----|--------|----|
| Togo | 0.4547 | 37 | 0.2737 | 41 | 0.9908 | 20 |
| Uganda | 0.5527 | 19 | 0.7024 | 20 | 0.9925 | 15 |
| South Africa | 0.3909 | 44 | 0.5856 | 27 | 0.9707 | 39 |
| Zambia | 0.5195 | 22 | 0.5067 | 34 | 0.9899 | 22 |
| Zimbabwe | 0.4974 | 24 | 0.5824 | 28 | 0.9618 | 43 |

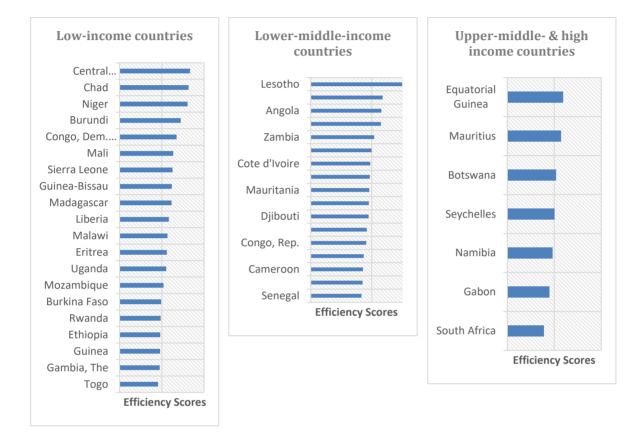


Figure 4. SSA Health Systems Performance: COVID-19 Public Health Measures

The results show that the average efficiency score for the COVID-19 public health division for the low-income countries is 0.60 whereas that of middle-lower-income countries and upper-middle-income countries are 0.51 and 0.50, respectively. From Figure 4, we observe that Central African Republic, Lesotho, and Equatorial Guinea obtained efficiency scores greater than 0.61 and were ranked at the top of the low-income, lower-middle-income, and upper-middle income groups, respectively. Thus, these countries offer useful information for the less efficient countries within the same income groups as they are considered as good references. At the other end of the spectrum, Togo (low-income country), Senegal (middle-income country), and South Africa (upper-middle-income country) had the worst health systems among their respective income groups. The results from the bootstrap DEA framework suggest that with the given capacity and resources, more efficient utilization of their resources could potentially enhance output by 45% in terms of COVID-19 cases per one million population.

In the second model of this study, we examine the efficiency with which health systems in SSA are able to flatten the COVID-19 contagion curve using the NPIs Stringency Index, number of COVID-19 tests per one million population, and healthcare expenditure as a percentage of GDP as input variables and the number of days left in the cycle as the only output variable. The results as presented on Figure 5 show that Guinea-Bissau and Liberia (Low-income countries), Sao Tome & Principe and Cote d'Ivoire (Lower-middle-income countries), and Equatorial Guinea and Mauritius (Upper-middle income countries) are more efficient in comparison to other countries in their respective income groups. Therefore, these countries serve as good peers for the less efficient countries within their respective income groups. The average efficiency score for low-income countries in flattening the curve is 0.70 whereas the middle income and upper-middle income countries registered an average scores of 0.63 and 0.46, respectively.

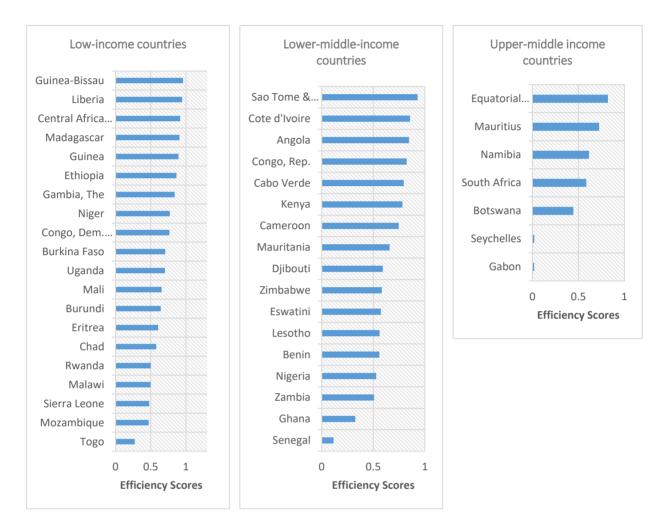


Figure 5. SSA Health Systems' Performance: Flattening the COVID-19 contagion curve

In the third model, based on the proposed methodology, DEA is performed to assess the efficiency performance of health systems in the medical treatment of COVID-19 patients. In this model, NPIs stringency index, number of COVID-19 laboratory tests per one million population, physicians per thousand population, and inpatient beds per thousand population were used as inputs whereas the number of recovered COVID-19 patients per thousand confirmed cases and the inverse of the number of deaths per thousand COVID-19 cases were used as outputs. The results for the 44 studied SSA countries are presented on Figure 6.

The results show that Madagascar (low-income countries), Zimbabwe (lower-middle-income countries), and South Africa (upper-middle-income countries) have had poor performance in the medical treatment of COVID-19 patients in comparison with other countries in their respective income groups in this study. However, countries such as Malawi (low-income countries), Senegal (lower-middle-income countries), and Mauritius (upper-middle-income countries) serve as good role models for the less efficient countries to emulate from in the treatment of COVID-19 patients.

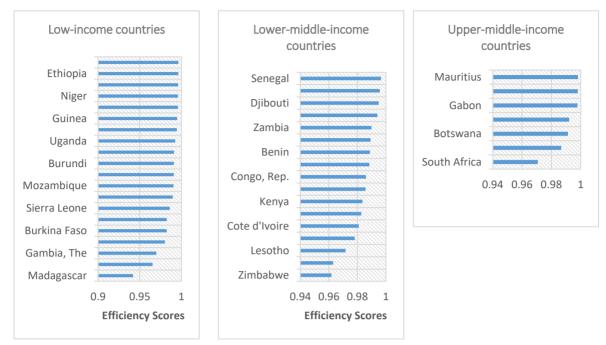


Figure 6. SSA Health Systems Performance: COVID-19 Medical Treatments

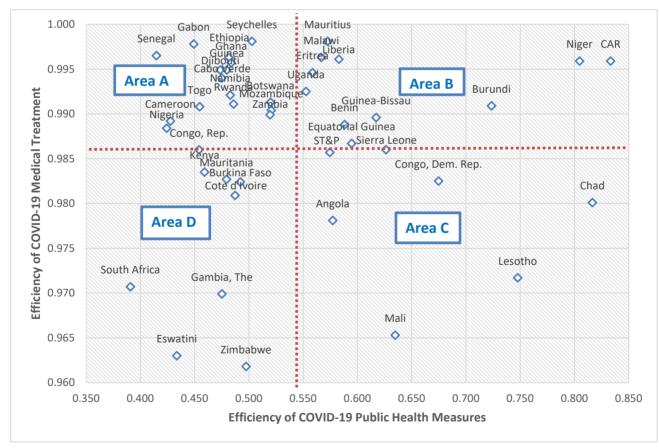


Figure 7. Classification of SSA countries based on COVID-19 efficiency performance

The efficiency scores in the first and the third models of this study (i.e. efficiency of COVID-19 public health measures and efficiency of COVID-19 medical treatments) are used to classify the studied countries by creating a scatter plot. The average efficiency scores for the first and the third models, 0.546 and 0.986, respectively, are used

to divide the scatter plot into four areas: A, B, C, and D as shown in Figure 7. From the plot, it can be observed that countries such as Central Africa Republic (CAR), Mauritius, Niger, Malawi, Equatorial Guinea, Burundi, and Eritrea which are in area B of the plot have been efficient in both public health measures and medical treatment of COVID-19 patients, and can serve as benchmarks. Countries in area A of the plot such as Rwanda, Ghana, Senegal, Gabon, and Seychelles have efficiently carried out medical treatment of COVID-19 infected persons but have been poor in implementing public health measures to curb the spread of the virus. These countries can serve as good references regarding medical treatments of COVID-19 patients.

On the other hand, countries in area C of the Figure7 – Lesotho, Mali, Angola, Chad, and, Democratic Republic of Congo – have been more efficient in the implementation of the public health measures aimed at curbing the spread of the COVID-19 virus but poor in the medical treatment of persons infected with the virus. These countries can serve as benchmarks for implementing public health measures to fight the spread of the COVID-19 virus. Countries in area D are those in worst situation with poor performance in both medical treatment and implementation of public health measures. There is an urgent need for these countries to improve their current conditions. The countries in the area D are South Africa, Zimbabwe, Kenya, Mauritania, Eswatini, Gambia, Cote d'Ivoire, and Congo Republic.

3.3 The Results of Second-Stage Bootstrap DEA

The differences in the efficiency scores of the studied SSA countries' health systems computed by bootstrap bias-corrected DEA could be explained by health systems characteristics which were not included in the first-stage DEA. In this study, after careful review of both COVID-19 literature and health systems studies, GDP per capita (GDP), population density (DENSITY), aged population (AGED), average temperature levels (TEMPERATURE), prevalence of tobacco use (TOBACCO), governance quality (GOVERNANCE), and categorical variable of income groups (LOW-INCOME, LOWER-MIDDLE-INCOME, and UPPER-MIDDLE-INCOME countries), using low-income countries as a reference category, were included as explanatory variables in the second-stage of bootstrap DEA framework. Some of the variables are excluded in some of the three models employed in this study due to collinearity problems and insignificant results. Table 5 presents the estimation results from the bootstrap procedures employing algorithm #2 from Simar and Wilson (2007). The regression procedure uses the estimated inefficiencies (*i.e.* $\theta_m^* > 1$) generated in the first-stage DEA as dependent variable. Thus, a positive coefficient implies that an increase in a relevant explanatory variable is associated with an increase in inefficiency of the countries' health systems.

GDP per capita is included in the analysis to capture the impact of the level of economic activities on the performance of health systems in fighting the COVID-19 pandemic. The relationship between GDP per capita and health system inefficiency is found to be positive for model 1 ($\beta = 0.177, P < 0.01$) and model 3 ($\beta = 0.0254, P < 0.01$). This suggests that higher levels of GDP are associated with poor health system performance in curbing the spread of the disease, particularly in the use of public health measures and medical treatment of COVID-19 infected persons, and portends a conclusion that higher levels of economic growth pose real risk for the spread of infectious diseases. In fact, a simple Spearman correlation test shows that the cumulative cases per one million population were positively correlated with GDP per capita (r = 0.64, P < 0.01). This result is consistent with those obtained in an earlier empirical studies, such as Mo et al. (2020), where increases in GDP was found to increase cumulative COVID-19 cases and Hadad, Hadad, and Simon-Tuvel (2013) where increases in GDP per capita was found to decrease health system efficiency.

Empirically, the tobacco use have not had any significant effect on the performance of health systems efficiency as far as COVID-19 public health measures in model 1 and efforts to flatten the contagion curve in model 2 are concerned. However, in terms of medical treatment of COVID-19 patients, the prevalence of tobacco use have had a significant negative impact ($\beta = 0.0027, P < 0.01$) on health systems efficiency. That is, higher levels of tobacco use are associated with health system inefficiency in the medical treatment of COVID-19 patients. This is in line with earlier empirical studies, such as Allin, Grignon, and Wang (2016) and Afonso and St. Aubyn (2011), which found tobacco use to be significantly associated with lower health systems efficiency.

| VARIABLES | MODEL 1 | MODEL 2 | MODEL 3 |
|-----------------------|-----------|----------|-------------|
| GDP | 0.177** | -5.581 | 0.0254*** |
| | (0.0691) | (3.901) | (0.00598) |
| TOBACCO | -0.0022 | 0.0243 | 0.00266*** |
| | (0.0040) | (0.172) | (0.000374) |
| AGED | 0.0984 | 0.507 | -0.00809*** |
| | (0.0259) | (0.835) | (0.00242) |
| GOVERNANCE | | | -0.0162*** |
| | | | (0.00471) |
| TEMPERATURE | | 1.647** | |
| | | (0.804) | |
| DENSITY | 0.093*** | 4.754** | -0.00147 |
| | (0.0269) | (2.334) | (0.00231) |
| 2.LOWER-MIDDLE-INCOME | 0.4246* | 24.05* | -0.0620*** |
| | (0.2186) | (13.80) | (0.0159) |
| 3.UPPER-MIDDLE-INCOME | 0.2987 | 47.88** | -0.0623*** |
| | (0.2278) | (21.88) | (0.0212) |
| 2.INCGROUP#c.DENSITY | -0.1050** | -3.588 | 0.0116*** |
| | (0.0469) | (2.609) | (0.00346) |
| 3.INCGROUP#c.DENSITY | -0.143*** | -5.350* | 0.00174 |
| | (0.0488) | (2.887) | (0.00486) |
| CONSTANT | -1.164** | -35.31 | -0.194*** |
| | (0.5153) | (30.42) | (0.0500) |
| SIGMA | 0.135*** | 2.158*** | 0.00834*** |
| | (0.0143) | (0.587) | (0.00111) |

Table 5. Results of second-stage bootstrap truncated regressions

Notes. Standard errors in parentheses. Dependent variables: inefficiency scores (*i.e.* $\theta_m^* > 1$). *** p<0.01, ** p<0.05, * p<0.1.

The proportion of aged population is included in the second-stage analysis to assess the effect of age-related risk of severe COVID-19 disease resulting from underlying health conditions that affect their immune systems on health systems performance. Interestingly, it was not found to be associated with the health system's efficiency according to both models 1 and 2. However, as depicted in Table 5, in model 3, aged population was estimated to be negative ($\beta = -0.0081, P < 0.01$), which indicates that countries with more aged population are more likely to be more efficient in medical treatment of COVID-19 patients. This result contradicts a priori expectation but not surprising considering the youthfulness of populations across many SSA countries with a very negligible proportion of the aged population.

The negative relationship between governance quality and health systems inefficiency, which indicates that well governed countries are more likely to have efficient health systems in medical treatment of COVID-19 patients, coincides with Ibrahim et al. (2018) and Wranik (2012).

Temperature is found to be positively associated with health system inefficiency ($\beta = 1.647, P < 0.05$) in flattening the COVID-19 contagion curve. The implication of this result is that countries with higher levels of temperature are likely to be more efficient in reducing the rate of transmission of the COVID-19 virus. The finding is similar to other earlier empirical studies (Aidoo et al., 2021; Roy, 2020; Kassem, 2020; Corripio and Raso 2020; Wang, Rodrigues, and Barmejo, 2020) all of which found temperature to be negatively associated with the rate of COVID-19 virus infections. The comparatively low COVID-19 cases in the SSA region may be attributed to the

higher levels of temperature in the sub-region.

Again, from Table 5, it is observed that among the three categories of countries the low-income countries performance in implementation of COVID-19 public health measures (Model 1) and in flattening the COVID-19 contagion curve (Model 2) is better as compared to lower-middle-income and upper-middle-income countries. However, in terms of medical treatment of COVID-19 patients (Model 3), the performance of lower-middle-income and upper-middle-income countries.

Population density is included in the second-stage analysis to investigate the impact of social distancing on health system efficiency in the fight against the spread of COVID-19 virus. The estimated coefficient for the population density variable is positive for both model 1 ($\beta = 0.0925$, P < 0.01) and model 2 ($\beta = 4,754$, P < 0.05). The results favor the proposition that higher population density does not bode well for social distancing, a public health measure essential in the fight against the spread of the COVID-19 virus. However, the effect differs among the three income groups. The negative impact of population density on efficiency performance is more intense among low-income countries relative to lower-middle-income countries and upper-middle-income countries. These findings are in line with most previous literature (see Kumbhakar, 2010; Greene, 2010; and See and Yen, 2018).

3.4 Sensitivity Analyses and Robustness Checks

In this study, across all the three models employed, the number of DMUs were far in excess of the requirement that the DMUs should be three times more than the number of input and output variables used (Golany and Roll, 1989; Masiye, 2007), hence, it was not a binding constraint (Hollingsworth and Peacock, 2008).

Sensitivity analyses were conducted using two different DEA estimation techniques and various combinations of input and output variables. The two estimation techniques employed here were implemented using two Stata commands: *teradial* and *simarwilson*. The *teradial* command fits DEA models where original radial technical efficiency measures are computed (Fare 1998; Fare and Lovell 1978; Fare, Grosskopf, and Lovell 1994a; Badunenko and Mozharovskyi, 2016) whilst the *simarwilson* command implements DEA two-stage bootstrap bias-corrected radial technical efficiency measures (Simar and Wilson, 1998; 2000; 2002; 2018). The comparison of the technical efficiency estimates from the two estimation techniques (see Appendix C) showed a highly significant positive Spearman rank correlation across all the three models: Model 1 ($\rho = 0.98, P < 0.01$); Model 2 ($\rho = 0.84, P < 0.01$); and Model 3 ($\rho = 0.59, P < 0.01$). Again, consistent results were obtained from various combinations of input and output variables, which strengthens the validity of the findings from this study. For example, the sensitivity of the results obtained from Model 3 was tested, particularly because two of the inputs employed (i.e. inpatient beds per thousand population and physicians per thousand population) are less frequently reported on across SSA countries. When they were replaced by health expenditure per capita (constant at 2011 PPP), it was found that the results did not change significantly.

In order to assess the robustness of the results obtained from the bootstrap regression procedures in the second-stage analysis, the more usual truncated regression procedure was also applied (see Appendix D). The striking similarities of the estimated coefficients in terms of both numerical values and statistical significance across different models and estimation methods confer robustness to the empirical evidence, which enhances confidence in the arrived conclusions.

According to Greene (2004), there is no well-defined theory to guide the selection of environmental and policy variables in the second-stage regression analysis. The choice then becomes empirical. However, in order to discriminate between different competing specifications of the models, the log likelihood ratio test for nested models was used. The test statistics, as reported on Table 6, favor model specifications with interaction terms (A) as against parsimonious specifications (B), at least for Models 1 and 3, since the inclusion of the interaction terms improves the fitness of the models. Accordingly, we report results of model specifications involving the interaction terms for all the three models.

| Models | Competing Specifications | Value of test statistic | Conclusion |
|--------|--------------------------|-------------------------|--------------------|
| 1 | A versus B | 5.72 (0.0573) | A is superior to B |
| 2 | A versus B | 11.06 (0.0040) | A is superior to B |

Table 6. Log likelihood ratio test results

Notes. A = specification with interaction terms; B= parsimonious specification; probabilities values in parentheses.

4. Conclusion and Policy Implications

This study has examined the technical efficiency and its determinants of health systems of 44 SSA countries in curbing the COVID-19 pandemic using three different empirical DEA models. A review of the existing literature revealed an acute insufficient empirical research related to the efficiency of health systems in fighting an outbreak of diseases in general and COVID-19 in particular. Even though several studies have been undertaken to assess how countries in the sub-region can improve their health systems to contain outbreaks of diseases or pandemics, there is little or no known study that examines the efficiency of health systems in fighting pandemics. This paper contributes to fill this gap in the empirical literature. The overarching goal of this study was to assess the technical efficiency of health systems in SSA in curbing the COVID-19 pandemic and identifying the sources of inefficiencies. This general goal was divided into three specific objectives, using three different empirical frontier models to achieve the respective objectives.

The first empirical frontier model was to assess the technical efficiency of public health measures instituted by the various health systems in SSA to contain an outbreak of epidemic or pandemic in general and COVID-19 contagion in particular. The study evaluated the public health measures by assessing the outputs (inverse of COVID-19 cases per one million population) against the inputs directly used as public health measures (average of 13 IHRCC indicators and average of NPI stringency measures). The results from the first stage revealed that inefficiencies were quite high and that countries could have increased the results by 45% using the same resources. It was observed that the average efficiency scores decreased from low-income countries to lower-middle-income and upper-middle-income countries. This finding contradicts some international studies (Ahmed et al., 2019; Grosskopf, Self, and Zaim, 2006) which found that health systems performance was relatively more efficient in the developed countries. The second-stage analysis shows that GDP per capita and population density significantly worsen the health systems performance in terms of using public health measures to curb the spread of COVID-19 virus.

The second empirical model focused on measurement of the level of technical efficiency of the studied countries in flattening the COVID-19 contagion curve (i.e. reducing the rate of infections). This was done by evaluating the output (the number of days left in the cycle) against the inputs directly employed to flatten the curve (number of COVID-19 tests per one million population, NPIs stringency index, and healthcare expenditure as a percentage of GDP). The first-stage analysis revealed that health systems in SSA could have improved the results obtained by 36% given the same resources and the public health measures implemented. Again, the average efficiency scores decreased from low-income (0.70) and lower-middle-income (0.63) countries to upper-middle-income countries (0.46). The second-stage procedure shows that temperature levels and population density are significantly and negatively correlated with the performance of health systems in reducing the rate of COVID-19 infections.

The final empirical frontier model examined the efficiency of medical treatments of COVID-19 patients of the healthcare systems in the SSA. The examination was carried out using two outputs (number of recovered COVID-19 patients per thousand cases and survival rate of COVID-19 patients) against four inputs (number of COVID-19 tests per one million population, NPIs Stringency Index, number of inpatient beds per thousand population, and number of physicians per thousand population). In this model, it was observed that the average efficiency scores increases from the low-income and lower-middle-income countries to upper-middle-income countries. The second-stage analysis shows that good governance and aged population are significantly and positively correlated with the performance of health systems, whereas GDP per capita and prevalence of tobacco consumption worsen the performance from the perspective of medical treatment of COVID-19 patients.

The general finding of the study suggests that there is more room for health systems in SSA to improve their technical efficiency in fighting the COVID-19 pandemic. The findings also suggest that specific environmental factors significantly influence the level of health systems efficiency. These findings provide important policy implications for health systems to improve the technical efficiency in curbing the COVID-19 pandemic in particular, and by inference any other health epidemic or pandemic that may occur in future, by learning from the good performers (benchmarks).

One major revelation from this study is that countries that have made key investments in their health infrastructure and human resources are more efficient in managing the COVID-19 pandemic, at least in terms of the medical treatment of people who become infected with the virus. This implies the need for investment and political will to improve the public health institutions, medical facilities, and scientific expertise to prevent, control, and manage future outbreaks of epidemics. Second, the African Center for Disease Control and Prevention (i.e. Africa CDC) and its five regional collaborating centres must be supported by the Africa Union to carry out its mandate of strengthening and improving the capacity of public health institutions on the sub-region to detect and respond quickly and effectively to threats and outbreaks of diseases based on data- and science-driven interventions. Third, countries in the SSA must take this COVID-19 pandemic period as an opportunity to invest in research into local traditional medicines to reduce reliance on the West for orthodox medicine and vaccines.

Again, Ministries of health, which are mandated to supervise and regulate healthcare delivery, in the various countries must prioritize efficiency of healthcare facilities and personnel prior to and during outbreak of health pandemics. They can do this by strengthening their supervision, monitoring, and training divisions. At the facility level, timely design and distribution of protocols in caring for infected persons, right at the onset of the pandemic and human resource strategies geared towards recruiting and/or retaining well-qualified and experienced healthcare workers to provide professional services would prove critical in containing pandemics of this nature. This can be done by providing both intrinsic and extrinsic motivational packages, not only at the height of pandemics, but throughout their working lifespan.

This current study, like any other research work, suffers from some limitations which present an opportunity for refining and extending the frontiers of the outcomes of this study. The empirical analyses of this study are based on a snapshot of cross-sectional data spanning from 2016 to 2021 and the regression results are largely explorative, hence, places some restrictions on the current relevance and conclusions regarding the levels of health systems efficiency and the sources of inefficiency. It is, therefore, recommended that an extensive qualitative research be conducted in future to carry out in-depth analyses of best performing health systems in order to share best practices across the sub-region.

Another limitation of this study might emanate from the use of the DEA methodology. Since DEA is sensitive to the numeric values in the dataset and relies on the most efficient DMUs for frontier estimation, the use of different set of variables might give different results and conclusions (Hollingsworth and Peacock, 2008). Further, the use of relatively small number of DMUs might have led to overestimation of efficiency scores (Spinks and Hollingsworth, 2009). Future studies might increase the number of DMUs and explore additional variables, as data become available, in order to enhance the understanding of health system efficiency with a greater degree of complexity in curbing outbreak of epidemics and pandemics.

Findings from this study indicate that the most important determinants of health system efficiency in dealing with the COVID-19 pandemic are GDP per capita, population density, governance quality, tobacco use prevalence, and temperature levels. However, health systems have additional policy and environmental features that are not captured here, but might contribute to efficiency, such as financing mechanism, gatekeeping arrangements, burden of diseases, different political institutions, degree of centralization of decision-making within each system, hhealth-seeking behaviors, *inter alia*. Future studies might explore the use of these alternative health systems features in efficiency estimation and its determinants. Again, since untimely access to healthcare can either kill or reduce the quality of life of those who survive, future research could improve the outcome variables by measuring preventable years lost both to death and to poor quality of life.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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| Country | AVE ^a | LAB ^b | RE ^c | FS ^d | ZOO ^e | LNF | CE ^g | RC ^h | SUR ⁱ | HR ^j | NHE ^k | HSP ¹ | POE ^m | IHRC ⁿ |
|-------------------|------------------|------------------|-----------------|-----------------|------------------|-----|-----------------|-----------------|------------------|-----------------|------------------|------------------|------------------|-------------------|
| Angola | 63 | 80 | 60 | 40 | 80 | 20 | 40 | 80 | 100 | 60 | 73 | 53 | 30 | 100 |
| Burundi | 48 | 100 | 60 | 40 | 60 | 20 | 40 | 40 | 70 | 60 | 30 | 40 | 40 | 20 |
| Benin | 35 | 60 | 20 | 40 | 20 | 20 | 20 | 40 | 50 | 60 | 27 | 27 | 20 | 47 |
| Burkina Faso | 44 | 60 | 40 | 20 | 40 | 100 | 20 | 40 | 70 | 80 | 33 | 40 | 30 | 27 |
| Botswana | 32 | 80 | 40 | 40 | 20 | 40 | 20 | 20 | 40 | 20 | 20 | 47 | 20 | 10 |
| CAR | 17 | 40 | 20 | 0 | 20 | 0 | 20 | 0 | 50 | 20 | 20 | 20 | 20 | 0 |
| Côte d'Ivoire | 44 | 80 | 40 | 20 | 60 | 20 | 100 | 20 | 30 | 80 | 33 | 27 | 30 | 90 |
| Cameroon | 42 | 20 | 40 | 40 | 80 | 20 | 20 | 20 | 60 | 60 | 33 | 33 | 30 | 20 |
| Congo, DR. | 35 | 40 | 20 | 20 | 60 | 40 | 20 | 20 | 40 | 60 | 33 | 27 | 30 | 47 |
| Congo, Rep. | 33 | 20 | 20 | 40 | 20 | 20 | 20 | 40 | 50 | 60 | 20 | 20 | 20 | 30 |
| Comoros | 27 | 20 | 0 | 60 | 60 | 20 | 20 | 40 | 40 | 20 | 33 | 20 | 10 | 20 |
| Cabo Verde | 48 | 80 | 20 | 80 | 40 | 60 | 40 | 40 | 60 | 40 | 40 | 53 | 40 | 73 |
| Djibouti | 32 | 20 | 0 | 40 | 40 | 40 | 40 | 20 | 60 | 20 | 20 | 33 | 30 | 53 |
| Eritrea | 49 | 80 | 20 | 20 | 80 | 20 | 20 | 80 | 50 | 80 | 20 | 80 | 50 | 63 |
| Ethiopia | 63 | 80 | 40 | 40 | 40 | 100 | 40 | 80 | 70 | 20 | 27 | 33 | 80 | 83 |
| Gabon | 27 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 40 | 40 | 20 | 27 | 10 | 63 |
| Ghana | 49 | 60 | 60 | 40 | 60 | 40 | 40 | 80 | 80 | 20 | 33 | 40 | 40 | 73 |
| Guinea | 44 | 80 | 20 | 20 | 60 | 60 | 20 | 40 | 80 | 40 | 47 | 33 | 40 | 37 |
| Gambia | 38 | 20 | 20 | 20 | 20 | 40 | 20 | 60 | 70 | 20 | 40 | 27 | 40 | 0 |
| Guinea-Bissau | 25 | 20 | 20 | 20 | 40 | 40 | 20 | 40 | 30 | 20 | 27 | 27 | 20 | 90 |
| Equatorial Guinea | 22 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 40 | 20 | 20 | 27 | 20 | 20 |
| Kenya | 43 | 40 | 20 | 60 | 60 | 60 | 40 | 40 | 50 | 20 | 33 | 40 | 50 | 20 |
| Liberia | 46 | 60 | 20 | 20 | 60 | 40 | 20 | 60 | 80 | 40 | 47 | 33 | 60 | 100 |
| Lesotho | 29 | 80 | 0 | 20 | 40 | 40 | 0 | 20 | 40 | 20 | 20 | 40 | 30 | 83 |
| Madagascar | 29 | 40 | 20 | 40 | 20 | 20 | 20 | 20 | 60 | 20 | 27 | 20 | 30 | 27 |
| Mali | 48 | 60 | 20 | 80 | 80 | 60 | 20 | 60 | 70 | 40 | 55 | 33 | 20 | 30 |
| Mozambique | 60 | 80 | 40 | 60 | 80 | 40 | 40 | 80 | 80 | 80 | 67 | 53 | 40 | 83 |
| Mauritania | 35 | 60 | 40 | 20 | 80 | 40 | 20 | 20 | 40 | 20 | 47 | 40 | 20 | 40 |

APPENDIX A. WHO State Parties Self-Assessment Annual Reports (SPAR) Scores per Capacities and Average Total Score*

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|-----------------------|----------------------------------|-----|-----|-----|----|-----|----|---------|----------------------|----|----|----|----|-----|
| Mauritius | 64 | 100 | 40 | 80 | 20 | 100 | 40 | 80 | 70 | 80 | 67 | 73 | 80 | 100 |
| Malawi | 35 | 80 | 0 | 40 | 40 | 20 | 0 | 20 | 80 | 80 | 27 | 53 | 20 | 100 |
| Namibia | 59 | 100 | 40 | 60 | 80 | 60 | 40 | 40 | 80 | 60 | 33 | 73 | 60 | 90 |
| Niger | 39 | 80 | 20 | 20 | 20 | 20 | 40 | 20 | 80 | 80 | 27 | 27 | 20 | 83 |
| Nigeria | 51 | 40 | 60 | 40 | 60 | 40 | 20 | 20 | 70 | 60 | 47 | 33 | 50 | 83 |
| Rwanda | 71 | 100 | 40 | 100 | 80 | 100 | 40 | 100 | 70 | 60 | 47 | 67 | 40 | 73 |
| Senegal | 54 | 60 | 20 | 80 | 60 | 40 | 60 | 40 | 50 | 60 | 53 | 40 | 40 | 10 |
| Sierra Leone | 40 | 60 | 20 | 20 | 40 | 60 | 20 | 80 | 60 | 20 | 67 | 33 | 40 | 100 |
| Sao Tome and Principe | 32 | 20 | 20 | 40 | 20 | 40 | 20 | 20 | 40 | 40 | 40 | 47 | 40 | 47 |
| Eswatini | 40 | 80 | 20 | 40 | 20 | 60 | 40 | 20 | 70 | 20 | 27 | 33 | 80 | 100 |
| Seychelles | 53 | 100 | 20 | 80 | 80 | 60 | 20 | 60 | 80 | 20 | 27 | 60 | 40 | 100 |
| Chad | 30 | 40 | 20 | 20 | 40 | 20 | 20 | 20 | 70 | 40 | 27 | 27 | 20 | 57 |
| Тодо | 39 | 80 | 20 | 40 | 60 | 20 | 0 | 60 | 70 | 20 | 40 | 27 | 40 | 83 |
| Uganda | 66 | 100 | 60 | 40 | 60 | 60 | 80 | 80 | 80 | 80 | 80 | 67 | 40 | 53 |
| South Africa | 70 | 100 | 100 | 100 | 60 | 80 | 80 | 60 | 40 | 60 | 73 | 33 | 60 | 100 |
| Zambia | 60 | 60 | 40 | 40 | 60 | 80 | 40 | 40 | 70 | 80 | 67 | 67 | 80 | 63 |
| Zimbabwe | 50 | 80 | 40 | 80 | 80 | 40 | 40 | 20 | 70 | 60 | 27 | 40 | 30 | 67 |

*These are 2019 SPAR Scores used to measure the resilience and preparedness of national health systems against health emergency risks. * AVE = Average Total Score for the 2019 13 capacities SPAR Scores. ^b LAB = Laboratory refers to States parties' capacity to establish mechanisms that assure the reliable and timely laboratory identification of infectious agents and other hazards likely to cause public health emergencies of national and international concern, including shipment of specimens to the appropriate laboratories if necessary; RE = Radiation Emergency refers to States parties' capacity to detect and respond to radiological and nuclear emergencies that may constitute a public health event of national or international concern; ^d FS = Food Safety refers to States parties' capacity to detect and respond to food safety events that may constitute a public health emergency of national or national or international concern; ^e ZOO = Zoonotic Events and the Human-Animal Interface refers to States parties' capacity to detect and respond to zoonotic events of national or international concern; ^f LNF = Legislation and Financing refers to States Parties' capacity to have an adequate legal framework to support and enable implementation of all of their obligations and rights; ^g CE = Chemical Events refers to States parties' capacity to detect and respond to chemical events of national and international public health concern; h RC = Risk Communication refers to States parties' capacity to help stakeholders define risks, identify hazards, assess vulnerabilities and promote community resilience, and disseminate information to the public about health risks and events; ⁱ SUR = Surveillance refers to States parties' capacity of rapid detection of public health risks, as well as the prompt risk assessment, notification, and response to these risks; ¹HR: Human Resource refers to States parties' capacity to strengthen the skills and competencies of public health personnel; ^k NHE = National Health Emergency Framework refers to States parties' capacity to facilitate the coordination and management of outbreak operations and other public health events, and capacity to develop national, intermediate and community/primary response level public health emergency response plans for relevant biological, chemical, radiological and nuclear hazards; ¹HSP = Health Service Provision refers to States parties' capacity to provide high-quality health service; ^m POE = Point of Entry refers to States parties' capacity to establish effective surveillance and response at points of entry, and fulfill general obligation; n IHRC = IHR Coordination and National IHR Focal Point Function refers to States parties' capacity to coordinate nationwide resources, including the designation of an National IHR Focal Point. IHR: International Health Regulation; WHO: World Health Organization.

| ID | Name | Description | Measurement | Coding |
|----|-------------------------------|---|----------------------------------|--|
| C1 | C1_School closing | Record closings of schools and universities | Ordinal scale | 0 - no measures 1 - recommend closing or all schools open with alterations resulting in significant differences compared to non-Covid-19 operations 2 - require closing (only some levels or categories, e.g. just high school, or just public schools) 3 - require closing all levels Blank - no data |
| | C1_Flag | | Binary flag for geographic scope | 0 - targeted 1- general Blank - no data |
| C2 | C2_Workplace closing | Record closings of workplaces | Ordinal scale | 0 - no measures 1 - recommend closing (or recommend work from home) 2 - require closing (or work from home) for some sectors or categories of workers 3 - require closing (or work from home) for all-but-essential workplaces (e.g. grocery stores, doctors) Blank - no data |
| | C2_Flag | | Binary flag for geographic scope | 0 - targeted 1- general Blank - no data |
| С3 | C3_Cancel public events | Record cancelling public events | Ordinal scale | 0 - no measures 1 - recommend cancelling 2 - require cancelling Blank - no data |
| | C3_Flag | | Binary flag for geographic scope | 0 - targeted 1- general Blank - no data |
| C4 | C4_Restrictions on gatherings | Record limits on gatherings | Ordinal scale | 0 - no restrictions 1 - restrictions on very large gatherings (the limit is above 1000 people) 2 - restrictions on gatherings between 101-1000 people 3 - restrictions on gatherings between 11-100 people 4 - restrictions on gatherings of 10 people or less Blank - no data |

APPENDIX B: Codebook for Covid-19 Government Response Tracker

| | C4_Flag | | Binary flag for geographic scope | 0 - targeted 1- general Blank - no data |
|----|--------------------------------------|---|----------------------------------|---|
| C5 | C5_Close public transport | Record closing of public transport | Ordinal scale | 0 - no measures 1 - recommend closing (or significantly reduce volume/route/means of transport available) 2 - require closing (or prohibit most citizens from using it) Blank - no data |
| | C5_Flag | | Binary flag for geographic scope | 0 - targeted 1- general Blank - no data |
| C6 | C6_Stay at home requirements | Record orders to "shelter-in-place" and otherwise confine to the home | Ordinal scale | 0 - no measures 1 - recommend not leaving house 2 - require not leaving house with exceptions for daily exercise, grocery shopping, and 'essential' trips 3 - require not leaving house with minimal exceptions (e.g. allowed to leave once a week, or only one person can leave at a time, etc.) Blank - no data |
| | C6_Flag | | Binary flag for geographic scope | 0 - targeted 1- general Blank - no data |
| С7 | C7_Restrictions on internal movement | Record restrictions on internal movement between cities/ regions | Ordinal scale | 0 - no measures 1 - recommend not to travel between regions/cities 2 - internal movement restrictions in place Blank - no data |
| | C7_Flag | | Binary flag for geographic scope | 0 - targeted 1- general Blank - no data |
| C8 | C8_International travel controls | Record restrictions on international travel Note: this records policy for foreign travelers, not citizens | Ordinal scale | 0 - no restrictions 1 - screening arrivals 2 - quarantine arrivals from some or all regions 3 - ban arrivals from some regions 4 - ban on all regions or total border closure Blank - no data |
| H1 | H1_Public information | Record presence of public info campaigns | Ordinal scale | 0 - no Covid-19 public information campaign 1 - public officials urging caution about Covid-19 |

| campaigns | | 2- coordinated public information campaign (eg across traditional and social media) Blank - no data |
|-----------|------------------|--|
| H1 Flag | Binary flag for | 0 - targeted 1- general |
| 111_1 lag | geographic scope | Blank - no data |

Source: Hale, Angrist, Cameron-Blake, et al., 2020

APPENDIX C. Farrell VRA Output-Oriented DEA, Bias, and Bias-Corrected Technical Efficiency Scores

| | COVID-19 Public Health Efficiency Scores | | | Flattening COVID-19 Curve Efficiency Scores | | | COVID-19 Medical Treatment Efficiency Scores | | |
|----------------------|---|--------|--------|--|--------|--------|---|--------|--------|
| Country | | | | | | | | | |
| | DEA | Bias | BC DEA | DEA | Bias | BC DEA | DEA | Bias | BC DEA |
| Angola | 1.264 | -0.195 | 1.458 | 1.000 | -0.175 | 1.182 | 1.014 | -0.009 | 1.022 |
| Burundi | 1.000 | -0.376 | 1.380 | 1.000 | -0.563 | 1.559 | 1.000 | -0.010 | 1.009 |
| Benin | 1.363 | -0.302 | 1.664 | 1.000 | -0.787 | 1.789 | 1.008 | -0.003 | 1.011 |
| Burkina Faso | 1.364 | -0.218 | 1.581 | 1.270 | -0.149 | 1.417 | 1.000 | -0.017 | 1.018 |
| Botswana | 1.471 | -0.427 | 1.899 | 2.128 | -0.117 | 2.248 | 1.007 | -0.002 | 1.009 |
| Central African Rep. | 1.000 | -0.150 | 1.147 | 1.000 | -0.092 | 1.091 | 1.000 | -0.004 | 1.004 |
| Cote d'Ivoire | 1.613 | -0.372 | 1.981 | 1.000 | -0.170 | 1.169 | 1.000 | -0.019 | 1.019 |
| Cameroon | 1.538 | -0.250 | 1.787 | 1.000 | -0.335 | 1.340 | 1.005 | -0.006 | 1.011 |
| Congo, Dem. Rep. | 1.000 | -0.229 | 1.234 | 1.000 | -0.293 | 1.309 | 1.000 | -0.018 | 1.018 |
| Congo, Rep. | 1.640 | -0.422 | 2.060 | 1.000 | -0.205 | 1.216 | 1.011 | -0.003 | 1.014 |
| Cabo Verde | 1.679 | -0.412 | 2.093 | 1.197 | -0.059 | 1.257 | 1.003 | -0.003 | 1.006 |
| Ethiopia | 1.704 | -0.338 | 2.044 | 1.075 | -0.082 | 1.157 | 1.000 | -0.004 | 1.004 |
| Gabon | 1.700 | -0.487 | 2.189 | 46.434 | -10.41 | 57.084 | 1.001 | -0.001 | 1.002 |
| Ghana | 1.680 | -0.381 | 2.059 | 2.673 | -0.406 | 3.076 | 1.001 | -0.003 | 1.004 |
| Guinea | 1.568 | -0.287 | 1.853 | 1.065 | -0.053 | 1.118 | 1.000 | -0.005 | 1.005 |
| Gambia, The | 1.614 | -0.380 | 1.994 | 1.052 | -0.133 | 1.191 | 1.028 | -0.003 | 1.031 |
| Guinea-Bissau | 1.281 | -0.301 | 1.583 | 1.000 | -0.042 | 1.043 | 1.006 | -0.004 | 1.010 |

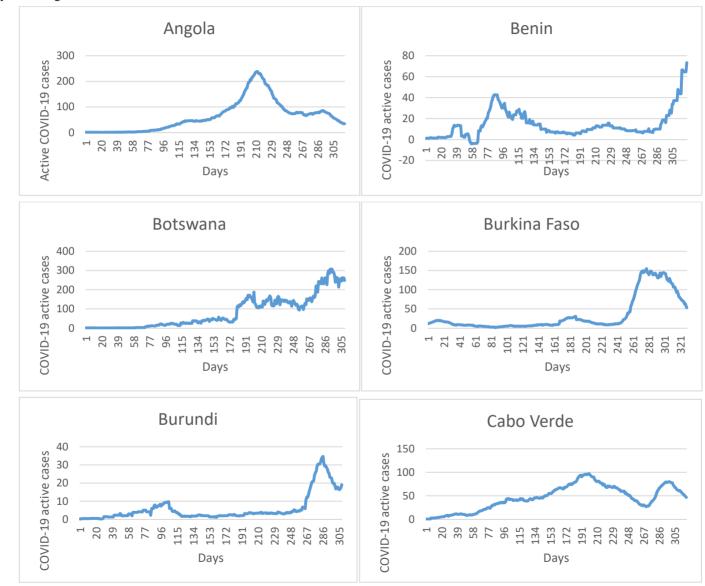
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|---------------------|-------|----------------------------------|-------|--------|--------|--------|-------|--------|----------------------|--|
| | | | | | | | | | | |
| Equatorial Guinea | 1.339 | -0.298 | 1.635 | 1.064 | -0.150 | 1.219 | 1.010 | -0.004 | 1.014 | |
| Kenya | 1.763 | -0.413 | 2.176 | 1.232 | -0.044 | 1.278 | 1.014 | -0.003 | 1.017 | |
| Liberia | 1.419 | -0.268 | 1.686 | 1.023 | -0.033 | 1.057 | 1.000 | -0.004 | 1.004 | |
| Lesotho | 1.000 | -0.326 | 1.327 | 1.728 | -0.056 | 1.785 | 1.024 | -0.005 | 1.029 | |
| Madagascar | 1.090 | -0.200 | 1.293 | 1.000 | -0.098 | 1.101 | 1.000 | -0.063 | 1.062 | |
| Mali | 1.208 | -0.169 | 1.375 | 1.350 | -0.181 | 1.528 | 1.030 | -0.006 | 1.036 | |
| Mozambique | 1.448 | -0.249 | 1.698 | 2.053 | -0.072 | 2.125 | 1.005 | -0.004 | 1.010 | |
| Mauritania | 1.620 | -0.437 | 2.054 | 1.388 | -0.131 | 1.521 | 1.007 | -0.011 | 1.018 | |
| Mauritius | 1.379 | -0.364 | 1.743 | 1.000 | -0.380 | 1.380 | 1.000 | -0.002 | 1.002 | |
| Malawi | 1.187 | -0.256 | 1.441 | 1.910 | -0.099 | 2.009 | 1.000 | -0.004 | 1.004 | |
| Namibia | 1.689 | -0.373 | 2.060 | 1.530 | -0.095 | 1.627 | 1.005 | -0.003 | 1.008 | |
| Niger | 1.000 | -0.189 | 1.184 | 1.000 | -0.310 | 1.297 | 1.000 | -0.004 | 1.004 | |
| Nigeria | 1.774 | -0.252 | 2.024 | 1.708 | -0.186 | 1.895 | 1.005 | -0.007 | 1.012 | |
| Rwanda | 1.708 | -0.342 | 2.050 | 1.933 | -0.063 | 2.000 | 1.006 | -0.003 | 1.009 | |
| Senegal | 1.964 | -0.444 | 2.407 | 8.039 | -0.711 | 8.755 | 1.000 | -0.004 | 1.004 | |
| Sierra Leone | 1.265 | -0.303 | 1.565 | 1.919 | -0.178 | 2.092 | 1.000 | -0.014 | 1.014 | |
| Sao Tome & Principe | 1.343 | -0.379 | 1.723 | 1.025 | -0.049 | 1.076 | 1.013 | -0.002 | 1.015 | |
| Eswatini | 1.813 | -0.472 | 2.287 | 1.682 | -0.062 | 1.747 | 1.036 | -0.002 | 1.038 | |
| Seychelles | 1.618 | -0.360 | 1.975 | 47.128 | -5.840 | 53.046 | 1.000 | -0.002 | 1.002 | |
| Chad | 1.000 | -0.157 | 1.156 | 1.586 | -0.141 | 1.729 | 1.014 | -0.006 | 1.020 | |
| Togo | 1.787 | -0.390 | 2.176 | 3.493 | -0.158 | 3.654 | 1.006 | -0.003 | 1.009 | |
| Uganda | 1.512 | -0.295 | 1.806 | 1.380 | -0.043 | 1.424 | 1.005 | -0.003 | 1.008 | |
| South Africa | 2.061 | -0.483 | 2.543 | 1.640 | -0.065 | 1.708 | 1.027 | -0.003 | 1.030 | |
| Zambia | 1.573 | -0.343 | 1.912 | 1.822 | -0.147 | 1.974 | 1.007 | -0.003 | 1.010 | |
| Zimbabwe | 1.615 | -0.364 | 1.980 | 1.665 | -0.051 | 1.717 | 1.037 | -0.003 | 1.040 | |

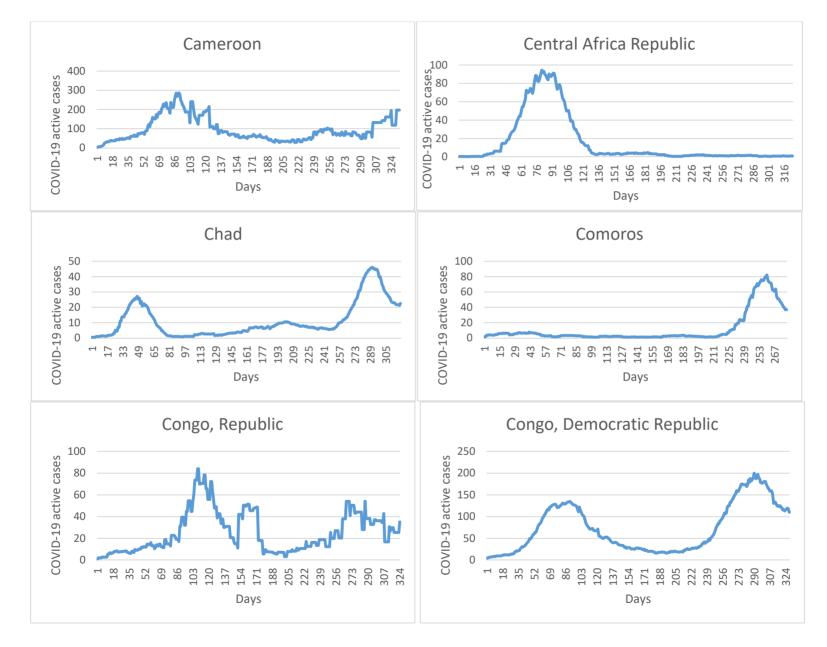
APPENDIX D: Truncated Regression Results (44 countries)

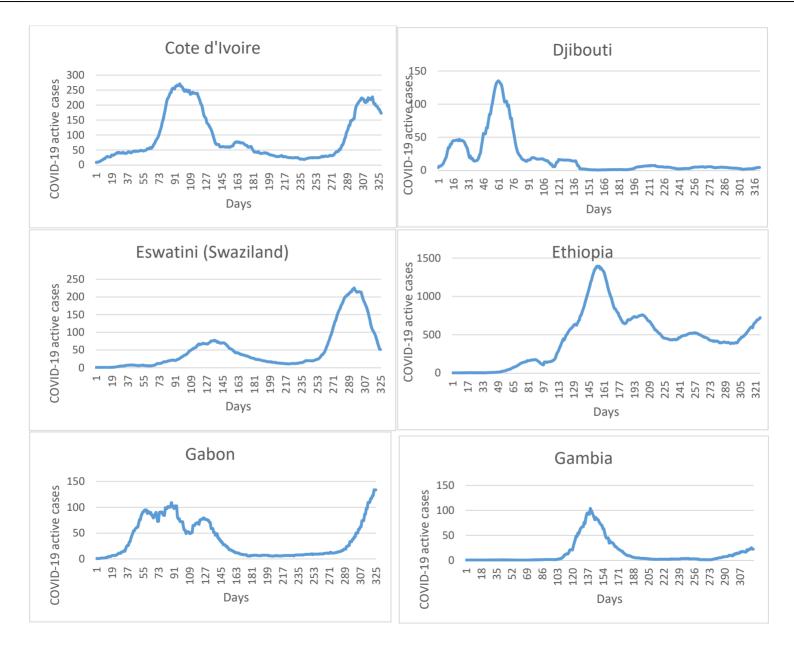
| VARIABLES | MODEL 1 | MODEL 2 | MODEL 3 |
|-----------------------|-----------|----------|------------|
| GDP | 0.256* | 0.0765 | 0.0139*** |
| | (0.131) | (4.226) | (0.00371) |
| TOBACCO | -0.00622 | -0.153 | 0.00165*** |
| | (0.00711) | (0.245) | (0.000209) |
| AGED | 0.0277 | 0.451 | -0.00325** |
| | (0.0481) | (1.521) | (0.00141) |
| GOVERNANCE | | | -0.0106*** |
| | | | (0.00285) |
| TEMPERATURE | | 0.626 | |
| | | (0.479) | |
| DENSITY | 0.145*** | 1.044 | -0.00144 |
| | (0.0501) | (1.687) | (0.00147) |
| 2.LOWER-MIDDLE-INCOME | 0.726* | 6.433 | -0.0380*** |
| | (0.407) | (13.03) | (0.0112) |
| 3.UPPER-MIDDLE-INCOME | 0.687 | 17.04 | -0.0385*** |
| | (0.430) | (14.73) | (0.0121) |
| 2.INCGROUP#c.DENSITY | -0.160* | -1.411 | 0.00714*** |
| | (0.0875) | (2.773) | (0.00241) |
| 7.INCGROUP#c.DENSITY | -0.242*** | -0.616 | 0.00122 |
| | (0.0909) | (3.000) | (0.00274) |
| CONSTANT | -0.878 | -19.11 | 0.899*** |
| | (0.974) | (32.23) | (0.0302) |
| SIGMA | 0.249*** | 7.871*** | 0.00682*** |
| | (0.0265) | (0.839) | (0.000727) |

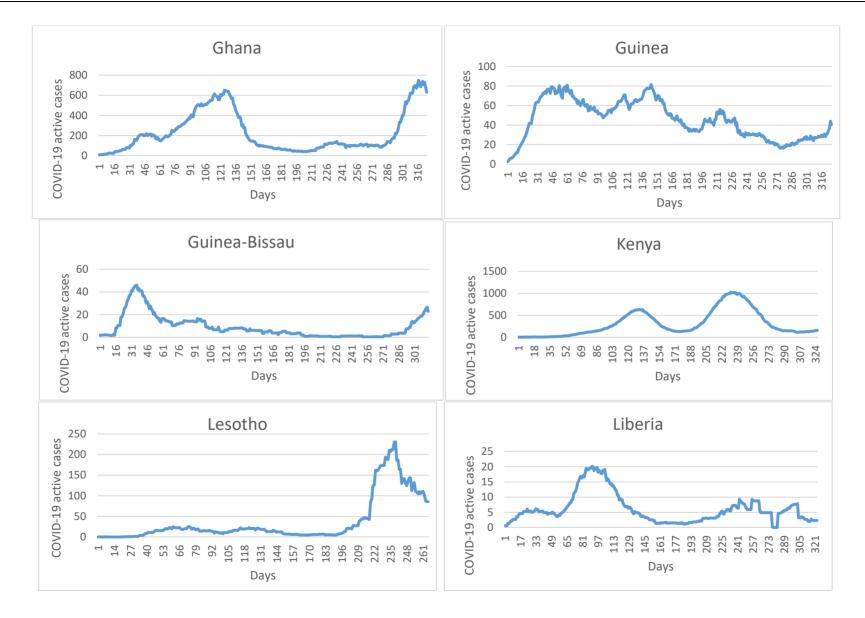
Notes. Standard errors in parentheses. Dependent variables: inefficiency scores (*i. e.* $\theta_m^* > 1$). *** p<0.01, ** p<0.05, * p<0.1

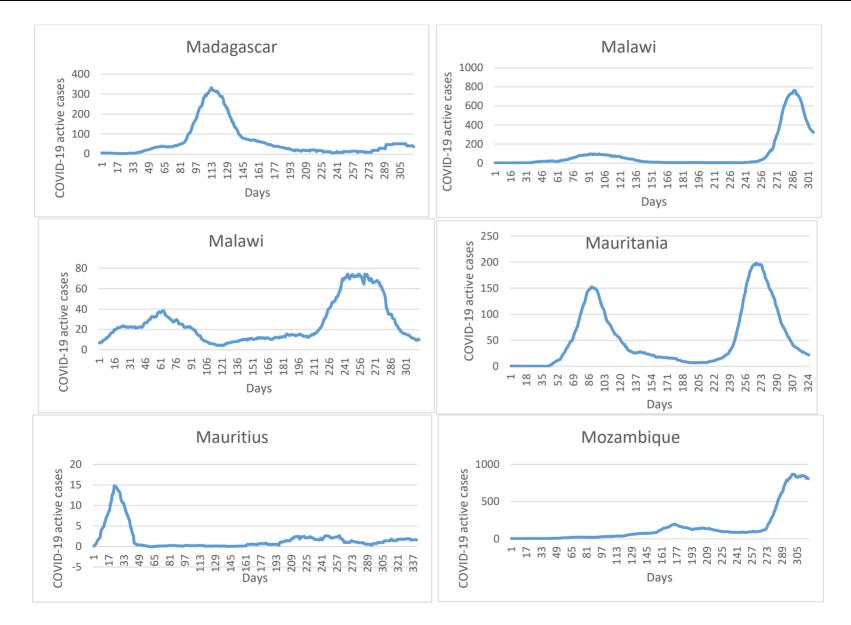


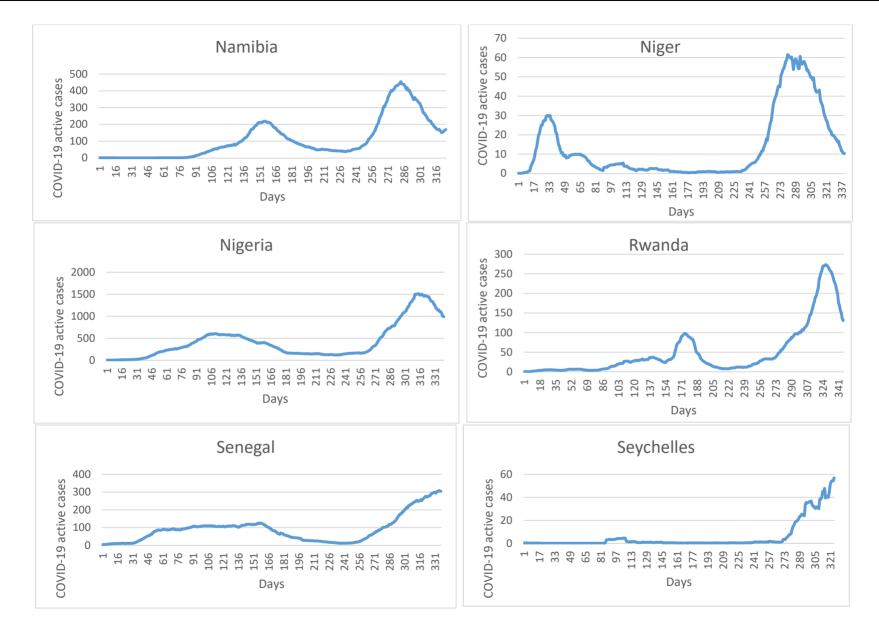
APPENDIX E: Epidemiological Curves for COVID-19 Active Cases

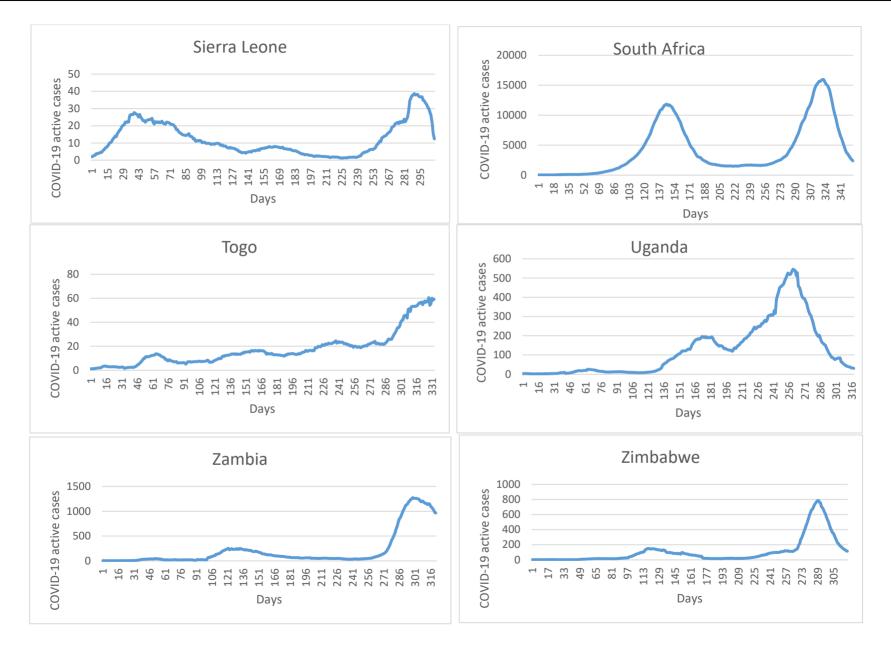












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Perception of Death among Young Adults in Multicultural Peninsular West Malaysia: The Abrahamics and Dharmics

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| Received: January 10, 2022 | Accepted: March 26, 2022 | Online Published: March 31, 2022 |
|----------------------------|--------------------------|----------------------------------|
| doi:10.5539/gjhs.v14n4p149 | URL: https://doi.org | /10.5539/gjhs.v14n4p149 |

Abstract

The topic of death perception is often a matter related to older people. As there is a paucity of studies with the young population, insights into their views would be helpful to healthcare professionals who may be confronted by events of death and dying. This study is aimed at exploring the perception of death among young adults of different religions in a multi-cultural and multi-faith society as in Malaysia. A total of 32 participants representing the main religious groups, i.e., Islam, Christianity, Buddhism and Hinduism were recruited from the Klang Valley area of Peninsular Malaysia. Focus group discussions were undertaken with participants grouped according to their religious identifications. Five themes emerged from the data: (a) Belief in Afterlife, (b) Fear of Own Death, (c) Fear of Others' Death, (d) Preparation towards Death and Afterlife, and (e) Way of Living. In a diverse and polarised society such as in conservative Malaysia, insights into death perceptions of different main groups of people can play a significant role in the provision of health care.

Keywords: Perception of death, young adults, religions, peninsular West Malaysia

1. Introduction

One attribute associated with young people is that of a sense of invincibility as demonstrated by the high morbidity and mortality from trauma-related injuries due to attitudes and risk behaviours (Monneuse et al., 2008). For instance, in the Malaysian context, smoking behaviours are often adopted during adolescence because it gives them a sense of being unique and omnipotent as they seek the attention of peers (Lim et al., 2018). Owing to the addictive effects of tobacco smoking behaviours they tend to continue, leading to increased risk of smoking-related cancer and related mortality (Levitz, Bradley, & Golden, 2004; Gritz et al., 2021). Other examples include the aggressive illegal motorcycle street racing and death-defying stunts in many Malaysian cities with serious underestimation of the risks involved (Wong, 2011). Given the increased risks of mortality involved one question arising is *the perceptions of death* among young people in Malaysia.

2. Background

The topic of death evokes various emotions and thoughts primarily influenced by fear of the unknown (Holcomb, Neimeyer, & Moore, 2007). The experience of death is not something we can determine as we cannot hear from those who have died. People who have encountered near death experiences have reported enhanced perception of light and enhanced cognitive powers (Agrillo, 2011). Such experiences have been described as syncopal hallucinations (Lempert, Bauer & Schmidt, 1994). A study of near-death experience in 344 survivors of cardiac arrest reported 50% of them having awareness of being 'dead' with as many as 56% experiencing positive emotions, 29% observation of celestial landscapes, 24% out of body experience; 32% meeting with deceased person; 13% life review; and most having no fear of death but strong belief in an afterlife (van Lommel, van Wees, Meyers, & Elfferich, 2001). The interpretation of near-death experiences may be related to the social conditioning and beliefs of the experiencer, such as interpreting the experience in relation to their cultural and religious beliefs concerning life after death. Verifying such views remain a challenge.

2.1 The Topic of Death Anxiety in the Multicultural Malaysian Context

In general, the subject of death is mainly avoided from daily conversations (von Blanckenburg et al., 2021), often brushed off or spoken about in jest, even though it is a daily event, for someone, somewhere. It can be a confronting matter for humans tending to be influenced by personal experiences and socio-cultural beliefs (Lehto & Stein, 2009). Considering it to be a matter of certainty at some point in life it is not often discussed, raising the question of people's perception of death. Insights on them could be helpful particularly to healthcare professionals who may be faced with situations of impending death and actual death in the course of their work (Benore & Park, 2004). As anxiety over death and dying tends to be seen as a matter relegated to the older population most studies on the subject have also been on the elderly (Fortner & Neimeyer, 2010) including in East Asia (Wu, Tang, & Kwok, 2002) or particular categories of people, such as Muslims in Malaysia (Kasmo et al., 2015). However, as a multicultural society the lack of studies on the other ethnic groups suggests a gap in knowledge and understanding on the subject of death perceptions of significant segments of the community in Malaysia. Without knowledge and understanding of how people of different backgrounds may perceive the matter, the negative affective state of death anxieties may also be experienced by healthcare professionals posing a challenge to their capacity for functioning with competency in their helping roles (Nia et al., 2016). In the Malaysian context this is important because of the increasingly polarised society as a result of decades of political actions by the Malay-Muslim government which marginalizes people who are not of Malay-Muslim backgrounds (Chin, 2015; Ignatius, 2021). Society has become such that it is not common to see Malay-Muslims socializing with non-Malays. As a result, the non-Muslims have a largely vague and incoherent understanding of Islam (Salam, 2017) for reasons including the practices being rigidly dogmatic in nature and incongruent with rationalities. Furthermore, Islam tends to be inaccurately described and explained for understanding, being manipulated for political and personal gains (Hussin, Nawi, & Mohamad, 2015). Owing to the polarization of the ethnic groups, Muslims also do not have clear insights into others from the other ethnicities. Given the scarcity of literature on the issue in Malaysian society, a study on the perceptions of death of the different groups would be helpful for a clearer sense of perspective.

We often make plans for our future, but ironically, not for death, when death is certain but future uncertain. It may make sense as a mental defense mechanism to deny it due to fear of the unknown, or even fear of the body being annihilated and so not being able to fulfill personal goals (Cicirelli, 1998), but the realities of its inevitability cannot be avoided.

For such an event of certainty, it would be rational for some emphasis towards being comfortable talking about death (von Blankenburg et al., 2021). For instance, it could help facilitate addressing the issue in relation to the closely linked concept of human dignity considered to be of importance in eastern cultures such as through Confucian philosophy (Zhang, 2000). The East Asian belief is that the discussion of death is disrespectful and the mere mention of this term may lead to the event itself. Drawing from the experiences of terminally ill patients in Hong Kong, the *Dignity Model* is applicable (Chochinov, 2001). It suggests that culturally specific views of death can influence the individual's state of acceptance. Carers and family members are often obliged to care for the dying with no clear evidence of how the dying is viewing the final event. Some insights would be helpful, for example, where patients were not anxious about death itself but wanted to be independent and not be a burden to the family (Ho et al., 2013). It could be illustrated by the situation where both a patient and family know of the impending death. Still, the family would not discuss it with the patient for fear of causing distress. Likewise, the patient may be reluctant to open up discussions to protect the family from any distress. Hence, insights of some kind are essential considering the death can significantly impact those left behind. They could serve as facilitators for honest discussions that may help with the grieving process.

2.2 The Elusive Definition of Death

Acceptable definitions of death remain elusive as it appears to have multi-dimensions that may be at odds with one another. In the absence of brain activity, technological advances have enabled cardiopulmonary support to maintain life suggesting the need for a broader definition (Capron & Kass, 1979) to avoid controversies around the issue of criteria for death and organ procurement after the declaration of death (Menikoff, 1998). The standard definition of death under the Uniform Determination of Death Act (1980) (p.3) is the "- total failure of the cardiopulmonary system -" and "- irreversible loss of all brain functions -". The clinical definition of being brain dead is acceptable from the Westernised prism. However, from the Eastern perspective, to the religious groups such as Buddhists, death is inevitable, and one should prepare for this in the way of living. Religion is silent about the soul, but the spirit will transcend to another being based on karma (Prophet & Spadaro, 2004).

Traditional cultural beliefs and factors play a large part in the meaning placed in some communities including talking about death and dying, and the language used around such discussions. For instance, "- passing -" is a more

accepted term for the spiritual belief of Australian aborigines around the life cycle (Queensland Health, 2015). They can determine how people perceive and respond to death. Such insights and understanding can help those taking on the helping role to manage the challenges more sensitively (Benore & Park, 2004). With significant impacts on those left behind there is a need for being comfortable in talking about death especially with loved ones (van der Geest et al., 2015) to lay out plans pragmatically when it should occur.

2.3 Influence of Religions in Malaysian Society

Religious doctrine and religiosity have been influential in shaping people's thoughts on death (Chan & Yap, 2009). From the Hindu perspective the concept of being reborn is prominent. Life does not begin with birth but is lived through many past lives, either as human beings or other living things, and will continue until one's soul, "- atma -" unites (Sharma, 1990). There is positivism in that death leads on to a new life with opportunities to accomplish unfinished business and to lead a better life. For Buddhism, the universe is the product of "- karma -". The aim is avoidance of suffering in the cycle of births and deaths ("samsara") and aspire to nirvana following enlightenment and elimination of karma (Walter, 2001). In Islam, death is inevitable when God (Allah) permits it (Sachedina, 2005) - ("Inshallah" - if Allah wills), as part of the divine plan that should not be resisted (Sheikh, 1998). Therefore, death is a matter to be determined by the Almighty God. With the belief in an afterlife, earthly death is a transition from the present world to the eternal via the day of judgement (Sheikh, 1998; Ross, 2001). For Christianity, death is a detachment of one's soul from the body (Decker, 2007) and emancipation of freedom from life on earth to eternal life with God (Holy Bible, Phil 1:24). Beliefs of such nature would suggest death as something to be looked forward to. While the religions present death in a positive light, perceptions of followers tend to be that of fear. Such a presentation raises questions as to why that may be so. They may include the strengths of beliefs, group effects from the community, personal experiences of seeing friends and relatives die, etc

Notwithstanding the religions' portrayal of death with promising positive outcomes, fear of death remains, possibly influenced by various factors including individual perceptions (von Blankenburg et al., 2021). In attempting to explain the anxiety of death, *Terror Management Theory* (TMT) posits that humans deal with it by diverting towards cultural values and belief systems for their own comfort (Chan & Yap, 2009). They turn to religion as a coping strategy (Vail et al., 2010). Some become more religious and fervent with their belief in God (Norenzayan & Hansen, 2006) to deal with their fears and anxieties through hopes of an afterlife. Whilst religion is a crucial source of belief in an afterlife, Death Apprehension Theory suggests heightened anxieties from the uncertainty of extreme outcomes which could either be eternal life in heaven or eternal life in hell (Ellis, Wahab, & Ratnasingam, 2013). The theory based on a study with college students in the USA, Turkey and Malaysia asserts that fear is positively related to most religious beliefs and practices. It makes the assumption that fear of death is unavoidable due to the perceived association between death, pain and end-of-life pleasures. However, studies on religiosity and fear of death have been mixed. For instance, the survey by Patrick (1979), with Buddhists and Christians reported Christians to be less fearful in confronting death, but the opposite was found to be the case in a more recent study (Chaiwutikornwanich, 2014).

As a multicultural society, Malaysia is comprised of several ethnic groups. West Malaysia is formed of three predominant ethnicities i.e., Malay, Chinese, and Indian, with equally diverse religious heritage and beliefs amongst them. The prominent ones are Islam, Buddhism, Hinduism, and Christianity (Department of Statistics Malaysia, 2015). For perspective, the diversity in East Malaysia on the island of Borneo is far greater than in Peninsular West Malaysia. It would require a far more extensive study to incorporate representation from the whole country as it could be more complex because of a significant and more diverse indigenous population. At present, for the purpose of this study, it is suggested that the diversity with the four prominent religions in peninsular West Malaysia provides a rich field for the study of such nature. The insights gained would be helpful for health professionals who may be confronted with similarities or differences that may exist as findings from other countries with different cultural values may not be applicable. It is also known that the suicide rate in West Malaysia is highest among those below 30 years of age (Maniam et al., 2014). As discussed earlier, most studies on the subject tend to be with the elderly. Given that the highest suicide rate in Malaysia is among the young adults, the need for some studies on them are compelling. In the unfortunate situation of a person in palliative care (which also includes youths), some insights may also be of help to health care professionals in promoting good end-of-life care (Leiter, 2021). With the above background in mind, this study set out to explore the role of religions on the perception of death among young adults in Malaysia.

2.4 Aim of Study

The aim of the study is two-fold, directed at determining:

- 1) What are the perceptions of death among the young adults of different religious backgrounds in Malaysia?
- 2) What are the roles of religious beliefs in influencing death beliefs among the young adults of different religious beliefs?

3. Method

Clearance for conducting the study was obtained from the University Research and Ethics Committee [IMU JC No.: BPS I-1/14(04)2016]. This study was conducted using basic qualitative research design to explore the perception of death among young adults of different religions in West Malaysia. More specifically, the young adults involved in this study are university students and recent graduates from the health professions, namely: nursing, pharmacy, dentistry, medicine and psychology. Their educational level is a helpful criterion for the articulation of their thoughts in response to the questions posed in an interactive manner which would enable clarification of ideas. Focus group discussions (FGD) was adopted as the tool in gathering data from the participants as it is an excellent way for collecting data based on group norms and to discover the issue that is not normally discussed by people in their own daily conversations (Kitzinger, 1994; Macnaghten & Myers, 2004). The approach was adopted instead of interviews to minimize the possibility of embodying the preconceived ideas of the interviewer, thus enabling free discussion among participants from the key points provided (Rice, 1931, p.561 cited in Krueger, 1988, p.18). Instead of individual interviews, having a few participants at a time can be conducive as some young adults need social support to talk with greater confidence (Glesne & Peshkin, 1992).

3.1 Participants and Sampling

A total of 32 participants (17 women and 15 men) for this study were recruited through purposive sampling by snowballing from the Klang Valley area. This sampling method is conducive for gathering data when participants are required for the provision of the most pertinent information (Merriam, 2009). Their ages ranged from 20 to 28 years (mean = 22.3) and all of them reported having been brought up according to their respective religions.

The participants were selected based on a set of inclusion criteria: a) those who are either of Islamic, Christian, Hindu or Buddhist religious affiliation, b) young adults who are of age between 18 to 35 years old, c) those who are able to converse well in English, and, d) those who are not experiencing any physical and/or mental health issues.

The FGDs were held in a meeting room. A total of eight (8) groups were conducted and the homogeneity of each group was maintained according to their religious affiliations, i.e., Muslims (2 groups), Christians (2 groups), Hindus (2 groups), and Buddhists (2 groups). Each group comprised of four participants, as shown in Table 1. To assist with process management, the FGDs were organized on separate days for each religious grouping. The Muslims were undertaken on one day, followed by Christians on the following day, Hindus on the next, and then Buddhists.

| Group | Muslims | Christians | Hindus | Buddhists |
|-------|----------------|----------------|----------------|----------------|
| 1 | 4 participants | | | |
| 2 | 4 participants | | | |
| 3 | | 4 participants | | |
| 4 | | 4 participants | | |
| 5 | | | 4 participants | |
| 6 | | | 4 participants | |
| 7 | | | | 4 participants |
| 8 | | | | 4 participants |

| TT 1 1 1 1 1 0 | | 1.0 |
|--------------------|-----------------|------------------|
| Table 1. Number of | narticinants in | each tocus group |
| | pur norpunto m | each locus group |

The duration of FGDs varied from 40 to 70 minutes, depending on when saturation of data was achieved.

3.2 Procedure

Explanations for the study (including information sheets) were provided to participants and their signed informed consent was obtained prior to commencement. They were also informed that the discussions would be audio recorded to assist in capturing data and reassured of all data being treated with strict confidentiality. Their rights to

withdraw from the FGDs at any time in the process were also reinforced. The FGDs were guided by questions based on the study on Death Apprehension Theory (Ellis, Wahab, & Ratnsingan, 2013) to elicit participants' perspectives of death and understand the role of their religions in influencing and shaping their lives views on death. Debriefing sessions were undertaken at the conclusion of each FGD.

3.3 Data Analysis

The audio recordings of the FGDs were transcribed and analysed using thematic analysis (Braun & Clarke, 2006), in which the data underwent several phases of analysis where codings and re-codings were undertaken to arrive at common major themes. The transcriptions were read several times alongside the audio recordings to get clear familiarity of their content. The initial stage of the coding was done through the identification of the contents considered relevant to the established research questions. Similar codes or those that were found to be within the same categories were then grouped together in searching for potential themes. The themes then underwent further refinement processes before they were finalized, defined, and named accordingly. The most suitable transcripts were then adopted to demonstrate the identified themes.

4. Limitations of Qualitative Research

Focus groups are an established method for data collection in the social sciences. It enables discussions which facilitate generation of collective insights on the topic of interest. Although suitable for the nature and purpose of the current study, there are also limitations which, if not well managed by researchers could stifle the quality of data derived from the group discussions. They include the size and composition of the groups and such aspects as age, gender, personality, ethnicity, and lived experiences (Hopkins, 2007; Moore, McKee, & McLoughlin, 2015). Their impacts on group dynamics could determine the substance of output.

5. Findings

The data analysis extracted several evident key concepts. They comprised of themes seen to be fundamental in explaining the two research questions that this study aimed to address: a) the perception of death among young adults of different religions in Malaysia, and b) the role of religious beliefs in influencing one's thoughts and views of death. The identified themes are classified as (a) Beliefs in the afterlife, (b) Fear of Death, (c) Beginning of Suffering for Others, (d) Preparation towards Death and Afterlife, and (e) The Way of Living.

5.1 Beliefs in the Afterlife

The common perception of death that was shared by participants from the four religions is that they see death as a form of physical cessation (of the body) only, whilst the soul of the dead continues to live on. They acknowledged that this world is a temporary phase for them, and that death acts as a transition platform to the next phase of life.

"To me, death, it's just the ending of your current life... Their soul is still there but... physically, they actually stop functioning." Buddhist FGD 1.

"...It's the loss of function of the human being, which is probably due to you know, losing life... death is not the end of life..." Muslim FGD 1.

"... I would say death, especially here, is like a physical death ... although it's not proven scientifically that we have a spiritual side, I think that is the part that we are referring to that lives on..." Christian FGD 1.

"... Death is like a progression point to whatever comes later on ... so it's like our phase on earth as living beings in this body is over..." Hindu FGD 2.

All the four groups shared similar perceptions of separation between the physical and spiritual being. The primary difference in terms of their concept of afterlife is whether they will be there for eternity either be in heaven or hell, which happens to be the core beliefs among the Muslims and Christians, or they will be reborn or reincarnate in this present world again as mentioned by the Buddhists and Hindus. A difference is that in Hinduism there is a belief in reincarnation with transmigration of the soul, whereas, in Buddhism, they believe in re-birth – soul is not a belief. Examples can be seen from the quotations below.

"... I mean, you would still go to heaven and hell... but that's the end... so, basically, it's embarking on a journey of eternity..." Christians FGD 1.

"... death is like a place for you to wait to go to heaven and hell ... " Muslims FGD 1.

"...the popular Hindu belief - you die then you can incarnate as different sort of living being on this earth..." Hindu FGD 1.

"... according to Buddhist religion, death is just ending of one's life and we do believe we have afterlife but the

only difference between Buddhist and other religions such as Muslim and Christians is we don't have so-called heaven place that we can go to because we are reborn as another living thing..." Buddhist FGD 2.

The distinction is clear between the Abrahamic religions (Islam and Christianity) in terms of the departure from the physical body of the soul to a dual dimension heaven or earth, compared with the Dharmic religions (Hinduism and Buddhism) where there is another form of life on earth. This similar beliefs of the two main religious groupings are consistent with the philosophies based on the shared roots of Islam and Christianity (Abrahamic) on one hand, and Hinduism and Buddhism (Dharmic) on the other.

5.2 Fear of Death

Death is often perceived as something that is terrifying by most groups. This can be seen from two perspectives, one, is the fear of their own death. This was clearly mentioned by the Muslims and the Christians, due to their readiness in having to face death. The other aspect is the uncertainty of the afterlife as well as the idea of it being eternity.

"... it might be scary because even though you know your time is up, but you might be like 'Oh, am I ready to face it'?" Muslim FGD 1.

"I think it's the unfamiliarity of it... It's a huge transition between living in this world and then dying and moving into a different world..." Muslim Group 2.

"Scary... because in a way, you think about it, it's eternity..." Christian FGD 1.

This sense of fear, based on the discussions, might also have the potential to be implanted by society in terms of the ways in which people talk about death and also the media portrayal in their dramatized forms. Such experiences can be easily etched into their memories to evoke their sense of fear to overtake their religious beliefs:

"... yeah, here they focus more to teaching kids to be afraid of death... like this is where you gonna be punished and they do all focus on the punishments... but not on the rewards..." Muslim FGD 2.

"... because it's usually like one sentence of going to heaven and then if you are bad, then you go to hell and hell is a terrible place, you don't wanna be there. That was how I receive it..." Christian FGD 1.

The other perspective of fear was portrayed very clearly among the Buddhists where they fear the loss of their loved ones. While they can readily accept their own death, the death of others is seen as something that is very disturbing to them.

"... Actually, I'm not afraid of death for myself, but I am afraid of death for my family members and the closed ones." Buddhist FGD 2

"I think I'm not afraid of death but if let's say that happens to any of my closed ones, I will be very scared of it." Buddhist FGD 1.

The fear, they believe, are in relation to the loss of attachment and support that would have to be faced after the death of their loved ones.

"Because someone who is close to you are going to leave, means that you are going to lose somebody in your life. Because you are afraid that you will lose the support, that's why you have the fear." Buddhist FGD 2.

Interestingly, there is a clear distinction presented between the Abrahamic group and the Dharmic group. For instance, in both the Muslims and Christians, the focus tends to be on what would happen to the self. On the other hand, for the Dharmic Buddhists, there is a preoccupation about the others rather than themselves. Such insights can make a significant difference in the context of healthcare provisions.

5.3 Beginning of Suffering for Others

Death also left a negative perception on the Hindus whereby they see it as a point where their loved ones will start to suffer once they die.

"When you die, maybe your suffering will end but it would be the beginning of the suffering of the people around you..." Hindu FGD 2.

"...When it comes to their suffering, it's something that you do not know how long or how bad it is going to affect them..." Hindu FGD 2.

Those who are of Hindu religions feel as if they are the ones who are responsible for causing the pain on others and knowing that they would not have the control to make things better for their loved ones concerns them even more. In relation to the point about the Abrahamic and Dharmic groups mentioned in the previous section, this point

about the suffering of others demonstrates a clear distinction of differences in focus between the two main groups.

5.4 Preparation towards Death and Afterlife

In understanding the roles of religions in influencing the thoughts of death among its believers, one of the themes that have been identified was that religions play a role in helping to prepare oneself towards death. This was significant among the Muslims and the Christians. Again, this point reinforces the distinctive difference in emphasis on the self, in the case of the Abrahamic group, and on the outward focus for the others in the Dharmic group.

"It's like am I prepared to face it? – that's the first statement about it. Like am I really prepared for it and how should I prepare for it." Muslim FGD 1.

"I really think it's either heaven or hell for us" Christian FGD1

Again, this point reinforces the distinctive difference in emphasis on the self, in the case of the Abrahamic group, and on the outward focus for the others in the Dharmic group.

5.5 The Way of Living

The Buddhists and Hindus claimed that their religions guided them towards how they should be living their life in this world and did not emphasise so much on the concept of death. The prominent idea of an afterlife served practical meaningful purposes on the here and now of their day-to-day living as they engage with others.

"Hinduism is more of leading your life rather than thinking about what's gonna happen. It's more about the journey..." Hindu FGD 1.

"... we emphasize more on being better beings, better human kind of thing than we talk about death" Buddhist FGD 2.

In living their life, their religions (Buddhism and Hinduism) encourage them to practice good manners and good attitudes to ensure that they will be reborn into better beings in their next life.

"We are trying to do goodness. At the end of the day, we all know we must do some sort of goodness because we are going to die. Yeah... so, we do as much as we can." Hindu FGD 1.

"The moral... of our religion is actually just to tell us... do good things." Buddhist FGD 1.

The emphasis is about living one's life in a way that would be for the good of others with mindfulness rather than being preoccupied by one's own needs.

6. Discussions

The findings highlighted both, the common perceptions of death that young adults of different religions have and the specific perspectives on how individuals from each of the religious groups perceived death. The portrayal is that all the four religious groups believed in the existence of life after death in one form or another, in which death acts as a platform for them to move on to another life. All the groups appear to agree that life on earth is just a temporary phase and that one's soul or being would continue to live on. The distinct difference that was identified in the content of the data was the concept of the afterlife that each religious group has. They fall under the Abrahamic or Dharmic philosophies – based on their respective geographical roots. The Muslims and Christians (Abrahamic) believe in an eternal afterlife where one's soul will either end in heaven or hell, based on God's judgment of their worldly deeds. A different view of the afterlife was shared by the Buddhists and Hindus (Dharmic) where both believed in the notion of reincarnation. Although they were of different ethnicities, their beliefs were influenced by religious teachings.

Although death seems to be regarded as a terrifying event for one to go through in their life, the fear of it does not necessarily incline towards their own death but their fear in losing someone significant as shown by both the Dharmic religious groups. This sentiment did not arise from the Abrahamic groups. Such a distinctive observation between the two main groups is significant in the provision of health care. Understanding of the distinctions could provide guidance to healthcare professions in times when they should be confronted with issues of death and dying. Insights into such distinctions could be significant to the development and maintenance of therapeutic relationships fundamental in healthcare.

What seems like important elements contributing to one's fear of their own death is the whole idea of an eternal afterlife with uncertainties on what is to be expected and the readiness to face it. This was portrayed among the Muslims and the Christians. Although guided by their Holy Book, i.e., the Quran and the Bible, respectively, on the anticipation of the afterlife, the fear element may well be compounded by society as they tend to emphasize more

on the punishments and pain that one would have to go through in the afterlife instead of the blessings rewarded by God.

Apart from this, the matter of fear towards the death of others was highlighted, particularly by the Buddhists. For Buddhists, death is not an absolute end – but it does mean the breaking of all ties that bind us to our present existence. Therefore, the more detached we are from this world and its enticements, the more ready we shall be to die (Walshe, 1978). Interestingly, the Buddhists in this study can accept their death more readily but not those who are close to them due to the humanistic value they place on their relationships. In this regard, death is not the loss of support but a form of farewell to the deceased – a reason why Buddhists have a hard time in letting go of someone who has died. In such a case, one possible buffer for the Buddhists who are mostly of Chinese ethnicity in Malaysia, is the belief in ancestral worship which helps maintain a sense of connection following death (Hsu, O'Connor & Lee, 2009). It provides a sense of peace in the afterlife because a worshipped ancestor would not become a wandering ghost (Liu & van Schalkwyk, 2019). The difficulty in letting go of someone might also be a reason why the participants mentioned that they would tend to invest a lot on health essentials that would help to prolong the lives of their loved ones, possibly due to sociocultural conditioning.

Death is perceived negatively as it is seen to inflict pain on others whom the deceased have left behind. As Buddhists, the Hindus see their own death as a beginning of other's suffering as they are unsure of how others would manage their emotional state and how long it would affect them when they are gone.

In understanding the role of religions in shaping one's view of death, this study also identified evident key findings in which religions can either help prepare oneself towards death and the afterlife, as was prominently seen among the Abrahamic, or to guide oneself in the way of living, as observed by the Dharmic. Essentially, the Dharmic philosophy is about the spreading of goodness in life rather than a concern with death. At the individual level, the concepts of the topic are open to debate as they may not have sufficient knowledge of death and dying. Perhaps preparation for death is not an issue that is addressed adequately in many faiths as discussion of the subject is not necessarily welcome.

6.1 Comparison with Past Reports

The aim of this study was to gain insights on the perception of death among the young adults of different religions in Malaysia as well as to understand the role of religious beliefs in shaping one's idea and view of death. Religions was incorporated in this context of the discussion as it is suggested that they play a significant role in equipping one with the rules and thoughts of death (Beit-Hallahmi, 2012).

The theme of afterlife beliefs was identified by Rosenbalt, Walsh and Jackson (1976) and more recently by Ellis, Wahab and Ratnasingan (2013). They were found to be central to most religions and a significant aspect that influenced perceptions on death. The specific beliefs on the concept of afterlife were also consistent with earlier reports aligned with Buddhists and Hindus being more inclined towards believing in the concept of reincarnation (Sharma, 1990; Walter, 2001), while the Muslims and the Christians held on to their beliefs in having an eternal afterlife (Decker, 2007; DeSpelder & Strickland, 2011; Ross, 2001; Sheikh 1998).

While earlier studies have found that beliefs in the afterlife could be associated with the reduced fear of death (Jorajuria, Forsyth, & Evans, 2003; Lee et al., 2013; Roshani, 2012; Wen, 2010), the findings from this study seems to support the assumptions from Death Apprehension Theory (Ellis, Wahab, & Ratnasingan, 2013), where belief in the afterlife was theorized to be an essential aspect in leading to fear towards one's own death. However, there is no evidence from this study to support two aspects proposed by the theory – beliefs in God and perceived characteristics of God. Instead, it was indicated by the Muslims and the Christians, that their fear of death was imposed by society and religious institutions through their narrative of punishments to be endured in the afterlife. It is reflected by the notion of torture in the afterlife as one of the main reasons for fearfulness (Abdel-Khalek, 2002).

In terms of fear towards the death of others, in general, and without distinct associations with religions, it has been reported that fear of death is highly related to the thought of the loss of loved ones (Mikulincer, Florian, & Hirschberger, 2003). In the case of Buddhists, their fear of death was reported to be due to their inability to free themselves from the cycle of re-birth (Prabhu & Glucklich, 1989; Cheng, 2017).

Death has been described as a pain of loss by traditional Chinese teachings as they often think of death as a form of misfortune (Tang, Wu, & Yan, 2002). However, it is not entirely seen as a suffering for Hindus, possibly due to an emphasis by Hindu literature on embracing death as a natural phenomenon where one will have opportunities for leading a better life during their next life (Sharma, 1990).

In understanding the role of religions in influencing one's view of death, Puolimatka & Solasaari (2006) stated that the answers to the issue of death and guidance on the expectations of the afterlife are offered by all religions. While this was clearly reflected among the Abrahamic religious groups during the focus group discussions, a different theme was highlighted from the Dharmic in which their religions' focus is on the way of living in this world, i.e., in the here and now. It is consistent with the core principles in Buddhism of "Inn" and "Ko", also referred to as cause and effect, which plays a role in guiding their way of living and spreading of goodness (Chen, 2001). Likewise, in Hinduism, it is considered helpful to think of a way of living in practical terms rather than an emphasis on religion, per se (Thomson, 2014).

In relation to patients in hospice care, insights into individual's perceptions can go some way towards providing a buffer from the challenges of anxieties as one is about to die. For instance, instead of the preoccupation with death itself, it is also known that patients who are dying may also be inclined towards consideration of the small pragmatic things like having a special favourite meal with a loved one (Stuart, 2021)

6.2 Limitations and Future Improvement of the Study

One of the limitations of this research is that the participants' *level of religiosity* was not considered. Although previous studies (Harding et al., 2005; Gedik & Bahadir, 2014; Suhail & Akram, 2002; Wen, 2010) have found inconsistent results in the relationship between religiosity and death anxiety, for this qualitative study, the levels of religiosity could have influenced the focal thoughts towards death. It is therefore suggested to be prudent for future studies of such nature to incorporate the matter of religiosity as a key variable. Furthermore, this study did not consider the diversities within the various religious groups. For example, in the case of Christians, there are relatively clear distinctions in relation to life matters such as between the Jehovah Witness, Catholics, Mormons, Evangelicals, non-denominational, etc. Although, the philosophical underpinnings may be on the eternal concept of afterlife (Cohen et al., 2005), there may well be fundamental differences on their perceptions of life after death (Lester et al., 2002). In terms of manageability of data, it may be helpful in such cases of multi-denominational groups within the main religions, for separate studies to be undertaken with more participants.

Perhaps, if presented with a narrative of death as one which is positive such as in terms of peace, tranquillity, and heavenly, the fear of it may not be as intense. As it stands, death is often associated with pain and suffering from illnesses or trauma from accidents and wars. Therefore, the differential presentation of death being associated with suffering may evoke fears of death as opposed to being something to look forward to if perceived as one linked with peace and tranquillity, or even celebrations of joy in being able to transition a better place. It would be good to determine if the subjects have experienced death of others and how it affected them, as many of the issues may also be related to social conditioning and socio-cultural perspectives.

6.3 Implications for Future

Death is inevitable and can happen at any time including when it is least expected. In the case of unexpected tragedies, the traumatic events are highly distressing for all who may be affected. Studies have identified coping mechanisms to be varied (Bonanno, Westphal, & Mancini, 2011). Hence, it would be helpful in situations requiring psychological support, for helpers to be well prepared to provide culturally sensitive and appropriate care. This requires understanding on the perspectives of death and the influence of religion in shaping thoughts, attitudes, and beliefs in a multicultural society such as in Malaysia. They are based on the knowledge that death-specific religious beliefs are important aspects in the loss and bereavement process (Benore & Park, 2004).

7. Conclusion

The findings from this study have highlighted the differences in perception of death among the young adults of different religious backgrounds in Malaysia. It identified two main beliefs groupings i.e. Abrahamic and Dharmic, from the four different groups which comprised of individuals from different ethnicities. It is an indication of the major influence of religions through the narratives taken on board by individuals. The insights could be of help to the healthcare professions, not only in clinical settings but also in instances where their assistance is called upon such as following natural disasters or major incidents.

Acknowledgements

We would like to express our gratitude to all the participants who kindly gave us their time and thoughts on the subject.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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