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# Contents

***Editorial: The effect of Cyriax method on the treatment of Lateral Elbow Tendinopathy***

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Lateral elbow tendinopathy (LET) is the most common chronic disease of the elbow joint [1], affecting almost 1-3% of the general [2, 3]. Its incidence increases with age and is highest in the 35-60 age group [2, 4].

Extensor carpi radialis brevis' tendon is the most common structure affected by LET [5]. There is a continuous cycle of minor injuries and constant attempts to repair the damage, causing in progressive degeneration [6,7]. Consequently, a domino effect of changes occurs in the peripheral nervous system neurons, ultimately resulting to the sensitization of the central nervous system [3, 8].

Treatment for LET includes a wide variety of techniques, due to the complexity of the condition. Scientific evidence on the efficacy of the various techniques is of poor quality [9], which hampers the choice of the right therapeutic plan [10, 11].

The Cyriax method was empirically developed by James Cyriax as a therapeutic approach to connective tissue damage [12]. It is an inseparable combination of deep transverse friction (DTF) and Mill's manipulation [13, 14]. This approach aims to the passive mobilization of soft tissues, preparing them to endure load. The regenerative process is boosted and the mobility of the damaged tissue is restored through pain reduction [12, 14].

Despite the fact that clinical experience supports the use of Cyriax method on LET, the results of systematic reviews show that it is not superior to other approaches indicated for this condition [15-17]. At the same time, there is no consensus on how to apply the method, which leads to a lack of standardization of the relative protocols [12]. In addition, great diversity is observed in the methodological design, the instruments and methods of evaluating the variables (pain, functionality) [12].

The disagreement on DTF procedures and the awareness that physiotherapists' performance may be affected by the lack of understanding of Cyriax's conclusions motivated the development of this thesis: The primary aim is to analyze the application parameters of the Cyriax method, as well as its effect on the symptoms of LET, by documenting how physiotherapists in Greece use the method.

Moreover, and in line with the latest findings [18], a psychometric evaluation of LET will be included in this thesis. Kinesiophobia is an outcome measure that should be considered, as it is affected by LET [18-20].

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**Physical activity and bone mineral density in Greek women: an observational study**

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**Note:** Mrs. Demetriou Andriana and Mrs. Sideri Konstantina participated equally in the research procedures and in the writing of the article.

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**ABSTRACT**

**Purpose:** This observational study aimed to investigate the correlation between physical activity (PA) and bone mineral density (BMD) in Greek women.

**Materials - Methods:** 46 women (aged >45 years) participated and grouped according to their BMD into three groups: Group A (normal BMD), Group B (osteopenia), and Group C (osteoporosis). The evaluation of PA and lower limb endurance (LLE) was carried out through the Greek version of the International Physical Activity Questionnaire-short version (IPAQ-Gr), and 30 seconds sit-to-stand (30STS) test, respectively. Multivariate analysis of variance (MANOVA) and Post-Hoc comparison (Tukey's test) were used for the statistical analysis. The correlations between BMD and the variables: age, height, weight, body mass index, 30STS, and IPAQ-Gr were calculated using the Pearson's *r* correlation coefficient. Statistical significance was set at $p<0.05$.

**Results**: The results showed that PA, as expressed with the IPAQ-Gr, has a weak and positive correlation to BMD (r=.209, p=.163). The best correlation, with a statistically significant difference, was weak and negative and found to be between the age and BMD (r=-.287, p=.05). Post-Hoc comparison demonstrated statistically significant differences in the 30STS between Group A (normal BMD) and Group C (osteoporosis) (p=.01).

**Conclusions**: As expected, BMD was found to be age-related, while statistically significant was the difference between LLE of women with normal BMD in relation to osteoporotic women. PA seemed to have a positive effect on BMD, although no statistically significant difference was found. However, further research needs to be conducted with larger sample size to investigate the relationship between physical activity and BMD.

**Key words**: physical activity, bone mineral density, quantitative ultrasound, Greek version of international physical activity questionnaire-short version, 30 seconds sit-to-stand test

## *Introduction*

Physical activity (PA) is defined as any bodily movement produced by skeletal muscles that requires energy expenditure (Dasso, 2019). Regular exercise has been shown to contribute to the prevention of hypertension, the maintenance of a normal body weight and, in general, to the improvement of the person's quality of life (Dasso, 2019; Pinheiro et al, 2020).

However, PA can be affected by a number of factors, the most important being the increase in age. Older adults appear to have lower participation rates in Physical activity, approximately 40-80% less than young people **(**Suryadinata et al, 2020; Westerterp, 2018). Statistics indicate that, in the United States of America, only 16% of adults aged 65 years or older, follow the guidelines for exercise (aerobics or/and empowerment (Cauley & Giangregorio 2020). In Europe, less than a third of adults perform moderate intensity exercise (at least 150 minutes) or vigorous intensity exercise (at least 75 minutes) per week, as it is clearly recommended by the World Health Organization (Cauley & Giangregorio 2020; Warburton & Bredin 2017).

In parallel, osteoporosis is defined as a systemic skeletal disease, characterized by low BMD and microarchitectural deterioration of bone tissue, resulting in reduced mechanical strength of the bones and an increased risk of fractures. **(**Compston et al, 2019)**.** Epidemiological studies report that osteoporosis is a silent chronic disease of global scope. Specifically, in the United States between 2005 and 2010, it was estimated that 10.2 million older adults suffered from osteoporosis while 43.4 million older adults had osteopenia. (Cooper & Ferrari 2019). In 2019 in Europe it was estimated that 25.5 million women and 6.5 million men suffered from osteoporosis **(**Willers et al, 2022). Regarding the epidemiological data of osteoporosis among the Greek population, it is estimated that in 2019, approximately 684,000 people were affected, of which 80% were women **(**Willers et al, 2022).

PA can stimulate bone growth and maintain or even improve bone mass through the mechanical effects of gravity, and from concentric muscle contraction (Muir et al, 2013; Pinheiro et al, 2020; Tong et al, 2019). This adaption of osteocyte metabolism results in long-term changes in the macro- and micro architecture of bones, their shape and structure (Lombardi et al, 2019). Through this mechanism, PA promotes the formation of osteitis tissue, which could effectively prevent and treat osteoporosis, without the impact of the side

effects of anti-osteoporotic medication, with low economic cost and high personalization (Tong et al, 2019; Troy et al, 2018).

In recent years, due to longer life expectancy, the rapid increase in the population of older adults has brought about a number of health problems that need intervention, including osteoporosis (Tong et al, 2019). Adequate PA seems to have an effect on both the prevention and treatment of osteoporosis, delaying the loss of BMD and muscle mass. The association of PA with osteoporosis is still a current field of research (Tolomio et al, 2008).

The purpose of this observational study is to investigate the association of PA with BMD in Greek women. The results may provide important evidence which through this correlation, a need may arise to create programs to inform and give targeted guidelines for the prevention of osteoporosis. Furthermore, a wider awareness of the findings in the Greek population would facilitate objective comparisons between studies of different ethnic origins and could contribute to future meta-analyses.

## *Material- Methods*

### *Study design*

The present observational study was carried out through the voluntary action of the OSTEOSAF group in the works of the “Petalouda" Skeletal Health Association and in which the authors of this article participated. The research protocol of the study was approved by the Research Ethics and Ethics Committee of the University of West Attica (No. Prot.: 19725-28/02/2023).

### *Population*

Women over 45 years of age participated in the research. The participants were recruited by the “Petalouda" Skeletal Health Association. The main inclusion criterion of the study was the measurement of the BMD of the participants. People who faced serious neurological problems, dementia, had balance disorders and in general any condition likely to affect their performance in the objective tests were excluded from the research. On the day of the measurements, the subjects who accepted their participation in the study gave their written consent in accordance with the principles of the Declaration of Helsinki and its subsequent amendments (World Medical Association- Declaration of Helsinki, 2013) and their demographical and clinical characteristics were recorded.

### *Variables/ Evaluation Procedures*

In the present study, measurement of BMD, evaluation of PA and lower limb endurance (LLE) were carried out.

The measurement of BMD was carried out with the method of calcaneal quantitative ultrasound (QUS) (Chin & Ima-Nirwana, 2013; Hans et al, 2022). The Greek version of the self-reported International Physical Activity Questionnaire- short version (IPAQ-Gr) was used to evaluate the PA of the participants (Papathanasiou et al, 2009). The lower limb endurance (LLE) was measured through the 30 seconds sit-to stand (30STS) test (Gürses et al, 2020; Stasi et al, 2021; Yee et al, 2021). Details of the measurements and evaluation procedures are described in the Appendix.

The participants were divided into three groups according to their BMD. Group A consist of women whose BMD was within the normal range (T-score >-1SD). Women whose BMD was on the borderline of osteopenia (T-score <-1 to >-2.5 SD) and women who had osteoporosis (T-score <-2.5 SD) were included in group B and group C, respectively. The examiner did not know to which of these groups each participant belonged to.

### *Statistical Analysis*

Statistical analysis was performed using IBM® SPSS® software package version 28 (IBM Corporation, Somers, NY, USA). Tests were two-tailed and statistical significance was set at $p<0.05$.

Data were expressed for continuous variables as mean±standard deviation (SD). The Kolmogorov-Smirnov test examined the normal distribution of the parameters.

The effect of the independent variables (age, height, weight, BMI, 30STS, IPAQ-Gr - Vigorous, IPAQ-Gr - Moderate, IPAQ-Gr - Walking, IPAQ-Gr - Total) on the dependent BMD was examined using the multivariate analysis model (MANOVA), and for pairwise comparisons Tukey's HSD test was used. Furthermore, a multinomial logistic regression was performed using the fit model method to assess the effect of the independent variables on the variable under consideration (BMD)

Correlations between the BMD and the continuous response variables were calculated using the Pearson's correlation coefficient (r). Pearson's correlation coefficient (r) is the most common way to calculate a linear correlation. Specifically, it is a number between -1 and 1

that measures how strong the correlation is between two variables, but also shows its direction (Turney,2022).

## *Results*

### *Study population*

Initially, 60 individuals were selected, of which 14 were excluded. Specifically, four were male, three had not undergone BMD measurement, and seven had comorbid neurological conditions. Finally, 46 women were included in the survey. Eleven women had normal BMD and were assigned to group A; 20 women had osteopenia and were included in group B, and 15 were osteoporotic and formed group C. The demographic and clinical characteristics are presented in Table 1.

**Table 1. Demographic and Clinical Characteristics of Participants**

| | Group A (N=11) | Group B (N=20) | Group C (N=15) | Total sample size (N=46) |
|---|---|---|---|---|
| Age (years) | 67.5(±8.4) | 66.8(±6.4) | 72.5(±8.1) | 68.8(±7.7) |
| Height (cm) | 163.9(±6.5) | 160.2(±5.5) | 159.5(±8.1) | 160.8(±6.8) |
| Weight (Kg) | 76.8(±11.5) | 67.9(±13.3) | 67.4(±11.2) | 69.8(±12.6) |
| Body Mass Index ($Kg/m^2$) | 28.6(±3.9) | 26.3(±4.4) | 26.4(±3.4) | 26.9(±4.0) |
| Bone Mineral Density (T-score) | -0.62(±-0.38) | -1.9(±-0.26) | -3.1(±0.75) | -5.62(±1.39) |
| 30sec sit-to-stand (repetitions) | 12.4(±1.4) | 10.8(±3.0) | 9.2(±2.6) | 10.7(±2.8) |
| IPAQ-Gr - Vigorous ($MET.min.wk^{-1}$) | 174.5(±443.7) | 382.0(±572.2) | 320.0(±123.9) | 218.2(±459.0) |
| IPAQ-Gr - Moderate ($MET.min.wk^{-1}$) | 932.7(±1428.2) | 754.8(±874.6) | 568.0(±696.1) | 736.4(±972.6) |
| IPAQ-Gr - Walking ($MET.min.wk^{-1}$) | 652.5(±437.5) | 842.3(±578.1) | 755.7(±677.8) | 768.6(±576.5) |
| IPAQ-Gr - Total ($MET.min.wk^{-1}$) | 1759.7(±1238.2) | 1979.1(±1494.5) | 1355.7(±792.9) | 1723.7(±1246.5) |

**Table 1. Demographic and Clinical Characteristics of Participants**

| | Group A (N=11) | Group B (N=20) | Group C (N=15) | Total sample size (N=46) |
|---|---|---|---|---|

Group A: Normal Bone Mineral Density, Group B: Osteopenia, Group C: Osteoporosis

IPAQ-Gr: Greek version of International Physical Activity Questionnaire-short version

### *Measurements*

The mean (±SD) of the measurements of the BMD (T-score), 30STS test (repetitions), and IPAQ-Gr (MET.min.wk-1) of the three groups are presented in Table 1. Post-hoc comparison using Tukey's test revealed statistically significant differences in mean 30STS repetitions between Group A and Group C (Mean difference, p=0.01). The comparisons of each variable between the three groups are presented in Table 2.

**Table 2. Multiple comparisons (pairwise) between study's groups**

| Variables | Pairs of Groups | Mean Difference | Standard Deviation | Significance (p-value) |
|---|---|---|---|---|
| | Group A - Group B | .74 | 2.8 | .96 |
| Age (years) | Group A - Group C | - 4.7 | 2.9 | .22 |
| | Group B - Group C | - 5.7 | 2.5 | .07 |
| | Group A - Group B | 3.6 | 2.5 | .32 |
| Height (cm) | Group A - Group C | 4.3 | 2.6 | .24 |
| | Group B - Group C | .71 | 2.3 | .94 |
| | Group A - Group B | 8.9 | 4.6 | .14 |
| Weight (Kg) | Group A - Group C | 9.4 | 4.8 | .14 |
| | Group B - Group C | .50 | 4.2 | .992 |
| | Group A - Group B | 2.2 | 1.5 | .30 |
| BMI ($Kg/m^2$) | Group A - Group C | 2.1 | 1.5 | .36 |
| | Group B - Group C | - .07 | 1.3 | .99 |
| | Group A - Group B | 1.6 | .98 | .24 |
| **30sec sit-to-stand (repetitions)** | **Group A - Group C** | **3.1** | **1.0** | **.01** |
| | Group B - Group C | 1.5 | .89 | .193 |
| | Group A - Group B | -207.4 | 165.9 | .84 |
| IPAQ-Gr - Vigorous ($MET.min.wk^{-1}$) | Group A - Group C | 142.5 | 175.5 | .69 |
| | Group B - Group C | 350.0 | 151.0 | .43 |
| | Group A - Group B | 179.9 | 369.7 | .88 |
| IPAQ-Gr - Moderate ($MET.min.wk^{-1}$) | Group A - Group C | 364.7 | 390.9 | .62 |
| | Group B - Group C | 186.8 | 336.4 | .88 |
| | Group A - Group B | - 189.8 | 219.4 | .66 |

**Table 2. Multiple comparisons (pairwise) between study's groups**

| Variables | Pairs of Groups | Mean Difference | Standard Deviation | Significance (p-value) |
|---|---|---|---|---|
| IPAQ-Gr - Walking (MET.min.wk$^{-1}$) | Group A - Group C | -103.2 | 232.0 | .89 |
| | Group B - Group C | 350.0 | 151.0 | .64 |
| IPAQ-Gr - Total (MET.min.wk$^{-1}$) | Group A - Group B | - 219.3 | 467.0 | .88 |
| | Group A - Group C | 404.0 | 493.9 | .69 |
| | Group B - Group C | 623.4 | 425.0 | .31 |

Group A*:* Normal Bone Mineral Density, Group B: Osteopenia, Ομάδα C: Osteoporosis
IPAQ-Gr: Greek Version of International Physical Activity Questionnaire–short version
*Note.* Tukey HSD, Mean Difference sig. 5%

The multivariate logistic regression between BMD and the variables (age, height, weight, BMI, IPAQ-Gr - Vigorous Physical Activity, IPAQ-Gr - Moderate Physical Activity, IPAQ-Gr - Walking and IPAQ-Gr - Total) did not show a statistically significant difference (p=0.91), so the variables mentioned above did not affect the participants' BMD.

Finally, pearson's correlation coefficient (r) was calculated between BMD and each independent variable. The best correlation, with a statistically significant difference, was weak and negative and was found to be between age and BMD (r= -.287, p=.05). Characterized as weak, positive, and without statistical significance were the correlations between BMD and the variables: height, weight, BMI, 30STS, IPAQ-Gr (Table 3).

**Table 3.** Correlations between Variables

| | **Variables** | **Correlation Coefficient Pearson's *r*** | **Significance (*p*-value)** |
|---|---|---|---|
| Bone Mineral Density | **Age (years)** | **-.287** | **.05** |
| | Height (cm) | .103 | .496 |
| | Weight (Kg) | .188 | .210 |
| | Body Mass Index (Kg/m$^2$) | .168 | .266 |
| | 30 sec sit-to-stand test (repetitions) | .266 | .074 |
| | IPAQ-Gr - Vigorous (MET.min.wk$^{-1}$) | .178 | .236 |
| | IPAQ-Gr - Moderate (MET.min.wk$^{-1}$) | .160 | .288 |

**Table 3.** Correlations between Variables

| Variables | | Correlation Coefficient Pearson's *r* | Significance (*p*-value) |
|---|---|---|---|
| | IPAQ-Gr - Walking (MET.min.wk$^{-1}$) | .040 | .792 |
| | IPAQ-Gr - Total (MET.min.wk$^{-1}$) | .209 | .163 |

IPAQ-Gr: Greek Version of International Physical Activity Questionnaire–short version

## *Discussion*

This research examined the correlation between PA and BMD in Greek women. The results showed that the BMD has a weak and positive correlation with the 30STS test and PA, as expressed by the self-completion questionnaire IPAQ-Gr.

The best and most statistically significant correlation was between age and BMD. More specifically, this correlation was characterized as negative, meaning BMD decreases with increasing age. This finding is consistent with the results of other studies, where it is reported that with increasing age, there is an increase in the proportion of women with osteoporosis and, thus, a decrease in BMD. According to a systematic review, it is reported that the rate of loss of BMD each year increases progressively with age, by 0.6 % and 1.1 % for the age groups 60-69 and 70-79 years, respectively (Gómez-Cabello et al., 2012). In the United States, it has been found that the percentage of women with osteoporosis in the age group 50-64 years was 13.1%, while in the age group of 65 and older, this percentage rose to 27.1% (Sarafrazi, 2021). The percentage mentioned above is in line with the percentage found in the present study, where 32.6% of the participants had osteoporosis. It has also been reported that in Austria, in the age group 70-74 years, 33% of women have osteoporosis. (Boschitsch et al, 2017). The fact that osteoporosis is age-dependent is confirmed by international literature, and indeed, it can be seen from the present research work that in Greece, similar rates of osteoporosis are observed as those in Europe and America (Sarafrazi, 2021; Boschitsch et al, 2017).

The sample of women in this study had a BMI exceeding the upper limit of normal (24.9 kg/m$^2$), classifying them as overweight. Although no statistically significant difference was found between the groups, it was observed that the BMI of group A was higher by about 7.8% compared to groups B and C. This finding may be justified by the fact that there is a

correlation between high BMI and better BMD. In particular, it has been found that there is a positive correlation between BMI and BMD in older adults, and specifically, a one-point increase in BMI was associated with a 0.0082 g/cm2 increase in total BMD (Lloyd et al., 2014). These findings are supported by other studies reporting that lower BMI is a risk factor for the development of lower BMD and also that the prevalence of osteoporosis was lower in obese women compared to non-obese women (Fawzy et al, 2011; Hssan et al, 2020).

In the 30STS test, a statistically significant difference was observed between groups A and C, demonstrating that the reduction in BMD is associated with LLE, as expressed by the number of the 30STS test repetitions. However, the correlation between the two variables was found to be weak and positive. During the literature search, studies were found that studied women of a similar age group to those in the present study. Specifically, it has been found that women in the age range 65-69 years, without reporting their T-score, performed on the 30STS test an average of 13.5 (±SD=3.5) repetitions (Rikli & Jones, 1999). It has also been reported that women over 60, whose BMD status was not reported, performed an average of 12.7 (±SD=3.6) repetitions (Jones et al, 1999). The number of repetitions of these studies is consistent with the number of repetitions of the 30STS performed by the women in group A of the present study. It should be noted that, during the literature review, no study was found that directly correlated 30STS test repetitions with T-score.

No studies were found examining physical activity in women with osteoporosis using the IPAQ-Gr during the literature review. Thus, a comparison of our results cannot be made. The measurement of PA using the IPAQ-Gr did not show a statistically significant difference between the groups. However, it can be seen that group B performed more vigorous PA and walking compared to the other groups, while group A performed more moderate PA. The finding that, osteopenic women were more active than the others may be due to their intention to remain active, knowing that their BMD has started to decrease.

Participants in group C were older than the other groups and performed less PA (more walking). This result may be due to the older age of group C participants, as it has been reported that after 60 years, increasing age results in a decrease in PA, which can reach 40-80% at older ages (Gómez-Cabello et al, 2012; Westerterp, 2018; Suryadinata et al, 2020). Also, studies report that after 52 years, vigorous and moderate PA gradually decreases more, as observed in group C participants (Ayabe et al, 2009).

This research study has advantages and disadvantages. In terms of advantages, this study had a homogeneous sample, as no statistically significant differences were observed between the characteristics of the three groups, except for age. Another advantage is that the recording of PA was subjective as the participants conducted it and reflected their perception of their level of PA. When conducting the 30STS objective test, the assessors did not know which of the three groups the participants belonged to, ensuring the measurements' objectivity. Finally, adequate statistical analysis gives the present study another advantage. However, the study has several disadvantages, including the relatively small sample size, which may be the reason that no statistically significant difference was found. Another disadvantage is the non-recording of any coexisting musculoskeletal conditions, which may have influenced the participants' PA levels. Also, no follow-up measurement was performed to investigate any difference in the levels of PA and BMD over time.

## *Conclusion*

This study investigated the correlation between PA and BMD in Greek women. The results showed a weak but statistically significant correlation between age and BMD and a significant difference in the 30STS test between women with normal BMD and osteoporotic women. As assessed by the IPAQ-Gr questionnaire, PA appeared to have a positive effect on BMD, although no statistically significant difference was found. However, further research is recommended with more participants to ascertain the correlations between BMD and PA as expressed by the IPAQ-Gr. Furthermore, a broader awareness of the findings in the Greek population would facilitate objective comparisons.

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adults. *European Review of Aging and Physical Activity*, *18* (1). https://doi.org/10.1186/s11556-020-00255-5

**Appendix. Evaluation Tools and Procedures**

| | |
|---|---|
| **Quantitative Ultrasound** | Bone density was measured using Quantitative Ultrasound (QUS) which offers portable and accurate technology to measure bone density in the heel. Quantitative ultrasound does not use ionizing radiation and is less expensive than the Dual-Energy X-Ray Absorptiometry (DEXA) (Chin & Ima-Nirwana, 2013; Hans et al., 2022). The Achilles InSight machine from General Electric was used to measure bone density in the heel bone of the participants in this study. |
| **Greek version of the International Physical Activity Questionnaire-short version** | The self-completed Greek version of the International Physical Activity Questionnaire-short version (IPAQ-Gr) is a scale to assess a person's physical activity (PA) in the last week. It consists of 7 questions, of which, the first 6 questions relate to the number of days (frequency) and the number of minutes per day (duration) of participation in PA. Specifically, the first two questions relate to vigorous PA, the 3rd and 4th to moderate PA, while the 5th and 6th include the recording of walking for more than 10 minutes. Finally, the 7th question records the amount of time the person spends sitting, an average normal day in the previous week. The scale scores are initially calculated separately for each category, excluding question 7, which is not included. For the calculation, the frequency and duration of each category is multiplied together with a value of METs set for each category: 8.0 for vigorous PA, 4.0 for moderate PA and 3.3 for walking. Specifically, the score for vigorous PA is equal to 8*(days of vigorous PA) *(minutes of vigorous PA during the day), the score for moderate PA is equal to 4.0*(days of moderate PA)*(minutes of moderate PA during the day), and finally, the score for walking is equal to 3.3*(days of walking)*(minutes of walking during the day). Then, to calculate the total score, the three categories are added together, (Total PA score = Vigorous PA score + Moderate PA score + Walking PA score), and depending on the result, the person's PA is classified as low, moderate or high. Interpreting the scores, when the individual has a total score <600MET.min.wk1 then they are considered to be performing generally low PA, whereas when the vigorous PA is ≥480 MET.min.wk-1 or the total score is ≥600 MET.min. wk-1, the individual is considered to be performing moderate PA. Finally, when the vigorous PA score is ≥1500MET.min.wk-1 or the total score ≥3000 MET.min.wk-1, the individual is considered to be performing high PA (Papathanasiou et al., 2009). |
| **30 seconds Sit-to-stand Test** | The 30STS is a test to assess strength and functionality, as it appears to be influenced by lower limb strength, balance and endurance (Gürses et al, 2020; Yee et al, 2021). The test is performed as follows: the participant sits in the middle of a chair, approximately 43 cm without arms, which is fixed to the wall for safety reasons, with arms ideally crossed at chest height, and back in a straight posture. Participants' feet must be on the floor. The aim of the test is for the participant to stand up from the chair, with knees fully extended, and to sit back down in the chair as many times as possible within the 30-second period. Before the start, the test is explained and demonstrated and then the participant is given the opportunity to perform 1-2 test lifts. The outcome of this test is the number of repetitions performed by the subject (Gürses et al, 2020; Stasi et al, 2021; Yee et al, 2021). In cases where the risers are performed incorrectly, they are not considered in the total score, and in the last second, the riser, if performed up to the standing position, is counted in the total number of repetitions (Jones et al., 1999) |

# The official Greek version of the National Institutes of Health - Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies

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## ABSTRACT

**Purpose:** The aim of this study was the official translation into Greek of the "National Institutes of Health - Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies" (NIH-QATOCCs) proposed by the American National Institutes of Health.

**Materials - Method:** Official permission for translating the original NIH-QATOCCsS questionnaire and its guidance was given by the American National Heart, Lung, and Blood Institute (NHLBI). The adaptation of NIH-QATOCCsS into Greek followed Brislin's classic back-translation model, which included: (a) back-translation method, (b) bilingual technique, (c) committee approach, and (d) pretest procedure.

**Results:** After completing all the required procedures, the final Greek version of the NIH-QATOCCsS was approved by the present study's authors.

**Conclusions:** The NIH-QATOCCsS is a detailed tool, easy to use, with clear guidance, and its Greek translation is available for scientists and students writing in Greek, systematic reviews that include observational cohort or cross-sectional studies.

**Key words:** Observational study, Methodological quality, Assessment, Systematic review

## *Introduction*

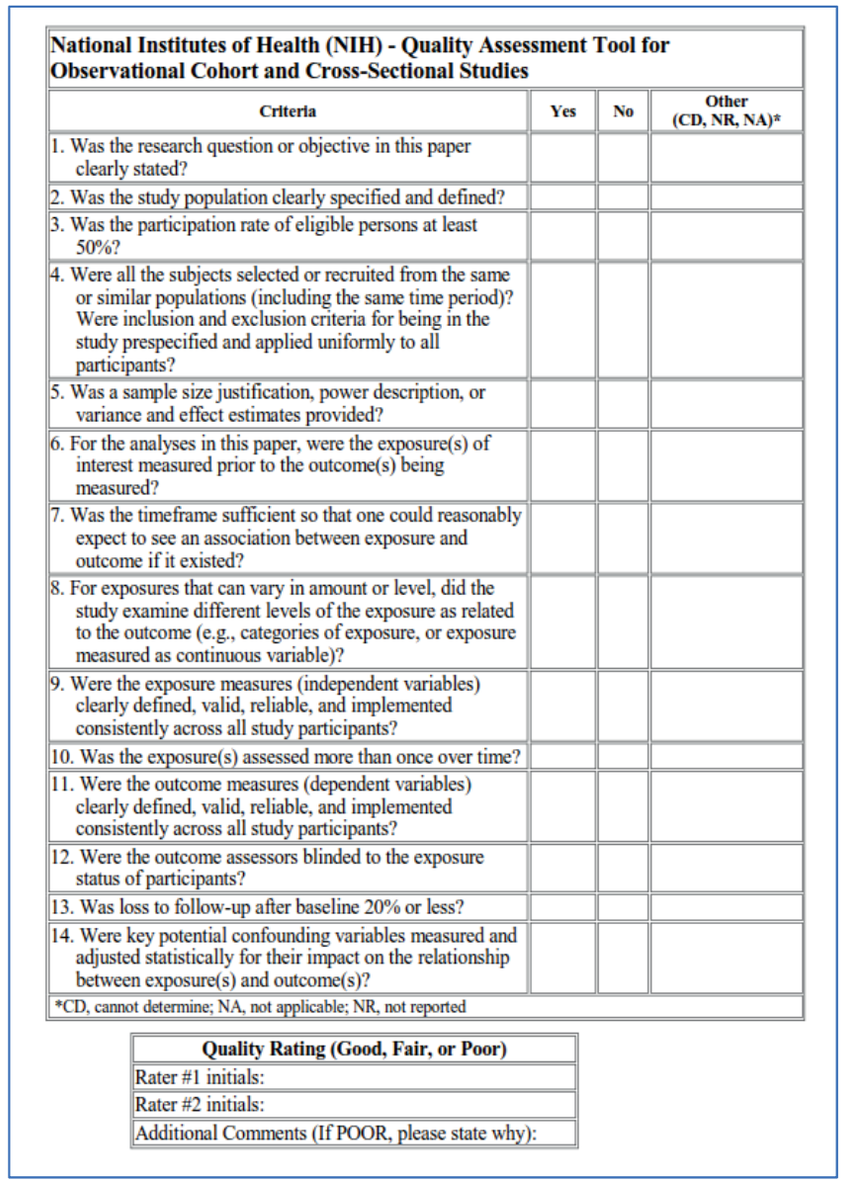
In the health sciences, systematic reviews are valuable for acquiring and exchanging knowledge as they summarize and analyze findings from individual studies (Drukker et al, 2021). The evaluation of the methodological quality of the included studies is considered necessary for the assessment of the internal validity of a study (Drukker et al, 2021). Various methodological quality assessment tools are available for non- or randomized controlled trials, case studies, and observational studies (Drukker et al, 2021). However, they are written in English, and a possible misunderstanding of the tool's questions by a non-native English author poses a risk of misinterpretation. Generally, direct translation of an instrument from one language to another does not guarantee content equivalence of the translated scale (Brislin, 1970; Sechrest & Fay, 1972). Researchers agree that the back-translation of an instrument is essential for its validation (Brislin, 1970; Jones et al., 2001).

The purpose of this study was the official translation into Greek of the “National Institutes of Health - Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies” (NIH-QATOCCsS) of the American National Institutes of Health.

## *Materials – Method*

### *National Institutes of Health - Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies*

The NIH - QATOCCsS contains 14 questions that assess the internal validity and risk of potential bias of the parameters: sample selection, information, measurements, or confounding factors on the effects of exposures on the outcomes/results of the included studies (Figure 1). The methodological evaluation is carried out by two assessors, and the possible answers to each question are: "Yes", "No", or "Other" (Not specified/ Not applicable/ Not mentioned). After the 14 questions are answered, the assessor rates the quality of the research as "Good" ("Yes" to 11–14 out of the 14 questions), "Moderate" ("Yes" to 5–10 out of the 14 questions), or "Poor "("Yes" to 0–4 out of the 14 questions). If a study is rated as "Poor" the reviewers explain why (NHLBI, 2021; Bagias et al, 2021).



**National Institutes of Health (NIH) - Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies**

| Criteria | Yes | No | Other (CD, NR, NA)* |
|---|---|---|---|
| 1. Was the research question or objective in this paper clearly stated? | | | |
| 2. Was the study population clearly specified and defined? | | | |
| 3. Was the participation rate of eligible persons at least 50%? | | | |
| 4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants? | | | |
| 5. Was a sample size justification, power description, or variance and effect estimates provided? | | | |
| 6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured? | | | |
| 7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed? | | | |
| 8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)? | | | |
| 9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants? | | | |
| 10. Was the exposure(s) assessed more than once over time? | | | |
| 11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants? | | | |
| 12. Were the outcome assessors blinded to the exposure status of participants? | | | |
| 13. Was loss to follow-up after baseline 20% or less? | | | |
| 14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)? | | | |

*CD, cannot determine; NA, not applicable; NR, not reported

| Quality Rating (Good, Fair, or Poor) |
|---|
| Rater #1 initials: |
| Rater #2 initials: |
| Additional Comments (If POOR, please state why): |

**Figure 1.** The original NIH - Quality Assessment Tool questionnaire for Observational Cohort and Cross-Sectional Studies.

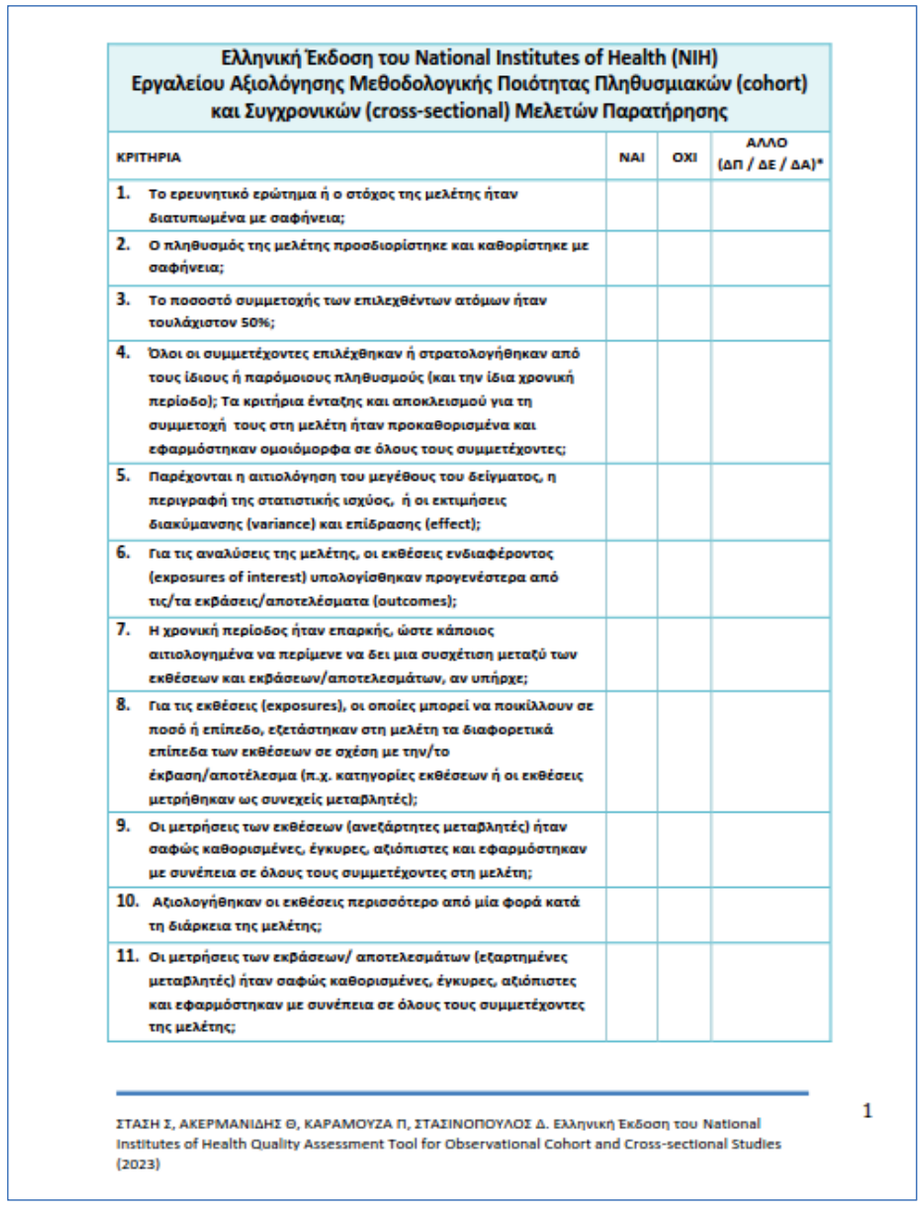
### *Translation Procedures*

Official permission for translating the original NIH- QATOCCsS questionnaire and its guidances was given by the American National Heart, Lung, and Blood Institute (NHLBI).

The adaptation of NIH- QATOCCsS into Greek followed the guidelines proposed by Brislin's classic back-translation model (Brislin, 1970; Brislin, 1976) and Jones et al. (2001). Brislin (1970) offered four techniques for maintaining the equivalence between the original and translated measures: (a) back-translation method, (b) bilingual technique, (c) committee approach, and (d) pretest procedure.

According to the aforementioned model, a bilingual non-medical specialist blindly translated the questionnaire and the guidance of the NIH- QATOCCsS from English to

Greek; a second bilingual translator independently back-translated the Greek documents back to English. Next, the two English versions of the instrument (original and back-translated versions) were compared for concept equivalence. Technical and linguistic adaptations were agreed upon in a consensus meeting. During the “committee approach” phase, a team of experts consisting of physiotherapists and three bilingual non-medical specialists took care of all the required procedures. Finally, according to Brislin's pretest procedure, a comprehension test of the NIH- QATOCCsS's Greek version was carried out by a group of health scientists (N=15) unfamiliar with the English version.



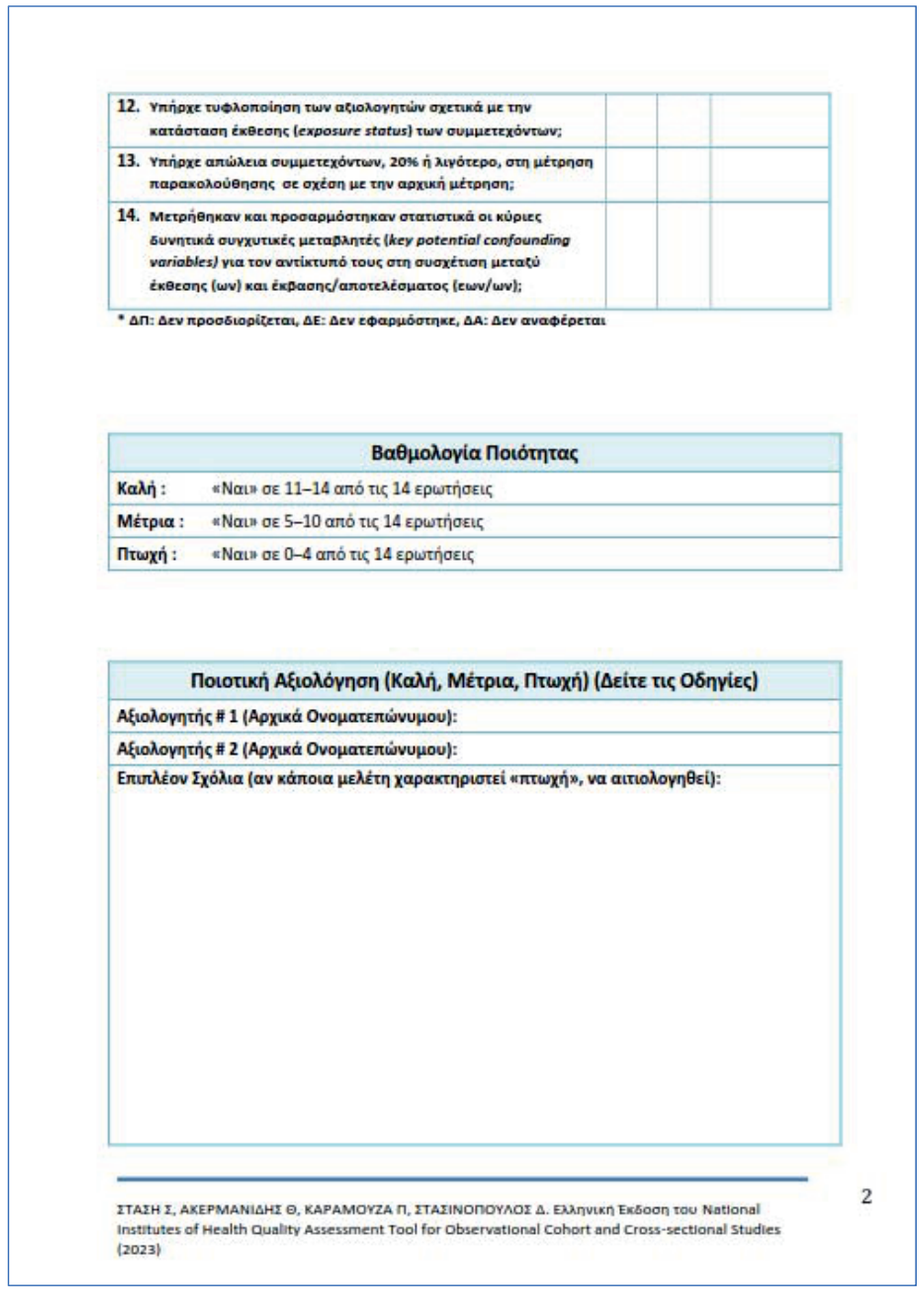
**Ελληνική Έκδοση του National Institutes of Health (NIH) Εργαλείου Αξιολόγησης Μεθοδολογικής Ποιότητας Πληθυσμιακών (cohort) και Συγχρονικών (cross-sectional) Μελετών Παρατήρησης**

| ΚΡΙΤΗΡΙΑ | ΝΑΙ | ΟΧΙ | ΑΛΛΟ (ΔΠ / ΔΕ / ΔΑ)* |
|---|---|---|---|
| 1. Το ερευνητικό ερώτημα ή ο στόχος της μελέτης ήταν διατυπωμένα με σαφήνεια; | | | |
| 2. Ο πληθυσμός της μελέτης προσδιορίστηκε και καθορίστηκε με σαφήνεια; | | | |
| 3. Το ποσοστό συμμετοχής των επιλεχθέντων ατόμων ήταν τουλάχιστον 50%; | | | |
| 4. Όλοι οι συμμετέχοντες επιλέχθηκαν ή στρατολογήθηκαν από τους ίδιους ή παρόμοιους πληθυσμούς (και την ίδια χρονική περίοδο); Τα κριτήρια ένταξης και αποκλεισμού για τη συμμετοχή τους στη μελέτη ήταν προκαθορισμένα και εφαρμόστηκαν ομοιόμορφα σε όλους τους συμμετέχοντες; | | | |
| 5. Παρέχονται η αιτιολόγηση του μεγέθους του δείγματος, η περιγραφή της στατιστικής ισχύος, ή οι εκτιμήσεις διακύμανσης (variance) και επίδρασης (effect); | | | |
| 6. Για τις αναλύσεις της μελέτης, οι εκθέσεις ενδιαφέροντος (exposures of interest) υπολογίσθηκαν προγενέστερα από τις/τα εκβάσεις/αποτελέσματα (outcomes); | | | |
| 7. Η χρονική περίοδος ήταν επαρκής, ώστε κάποιος αιτιολογημένα να περίμενε να δει μια συσχέτιση μεταξύ των εκθέσεων και εκβάσεων/αποτελεσμάτων, αν υπήρχε; | | | |
| 8. Για τις εκθέσεις (exposures), οι οποίες μπορεί να ποικίλλουν σε ποσό ή επίπεδο, εξετάστηκαν στη μελέτη τα διαφορετικά επίπεδα των εκθέσεων σε σχέση με την/το έκβαση/αποτέλεσμα (π.χ. κατηγορίες εκθέσεων ή οι εκθέσεις μετρήθηκαν ως συνεχείς μεταβλητές); | | | |
| 9. Οι μετρήσεις των εκθέσεων (ανεξάρτητες μεταβλητές) ήταν σαφώς καθορισμένες, έγκυρες, αξιόπιστες και εφαρμόστηκαν με συνέπεια σε όλους τους συμμετέχοντες στη μελέτη; | | | |
| 10. Αξιολογήθηκαν οι εκθέσεις περισσότερο από μία φορά κατά τη διάρκεια της μελέτης; | | | |
| 11. Οι μετρήσεις των εκβάσεων/ αποτελεσμάτων (εξαρτημένες μεταβλητές) ήταν σαφώς καθορισμένες, έγκυρες, αξιόπιστες και εφαρμόστηκαν με συνέπεια σε όλους τους συμμετέχοντες της μελέτης; | | | |

ΣΤΑΣΗ Σ, ΑΚΕΡΜΑΝΙΔΗΣ Θ, ΚΑΡΑΜΟΥΖΑ Π, ΣΤΑΣΙΝΟΠΟΥΛΟΣ Δ. Ελληνική Έκδοση του National Institutes of Health Quality Assessment Tool for Observational Cohort and Cross-sectional Studies (2023)

1

**Figure 2:** The 1st page of the Greek questionnaire of the NIH - Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies.



| | | | |
|---|---|---|---|
| 12. Υπήρχε τυφλοποίηση των αξιολογητών σχετικά με την κατάσταση έκθεσης (*exposure status*) των συμμετεχόντων; | | | |
| 13. Υπήρχε απώλεια συμμετεχόντων, 20% ή λιγότερο, στη μέτρηση παρακολούθησης σε σχέση με την αρχική μέτρηση; | | | |
| 14. Μετρήθηκαν και προσαρμόστηκαν στατιστικά οι κύριες δυνητικά συγχυτικές μεταβλητές (*key potential confounding variables*) για τον αντίκτυπό τους στη συσχέτιση μεταξύ έκθεσης (ων) και έκβασης/αποτελέσματος (εων/ων); | | | |

* ΔΠ: Δεν προσδιορίζεται, ΔΕ: Δεν εφαρμόστηκε, ΔΑ: Δεν αναφέρεται

| Βαθμολογία Ποιότητας | |
|---|---|
| **Καλή :** | «Ναι» σε 11–14 από τις 14 ερωτήσεις |
| **Μέτρια :** | «Ναι» σε 5–10 από τις 14 ερωτήσεις |
| **Πτωχή :** | «Ναι» σε 0–4 από τις 14 ερωτήσεις |

| Ποιοτική Αξιολόγηση (Καλή, Μέτρια, Πτωχή) (Δείτε τις Οδηγίες) |
|---|
| **Αξιολογητής # 1 (Αρχικά Ονοματεπώνυμου):** |
| **Αξιολογητής # 2 (Αρχικά Ονοματεπώνυμου):** |
| **Επιπλέον Σχόλια (αν κάποια μελέτη χαρακτηριστεί «πτωχή», να αιτιολογηθεί):** |

2

ΣΤΑΣΗ Σ, ΑΚΕΡΜΑΝΙΔΗΣ Θ, ΚΑΡΑΜΟΥΖΑ Π, ΣΤΑΣΙΝΟΠΟΥΛΟΣ Δ. Ελληνική Εκδοση του National Institutes of Health Quality Assessment Tool for Observational Cohort and Cross-sectional Studies (2023)

**Figure 3:** The 2nd page of the Greek questionnaire of the NIH - Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies.

## *Results*

During Brislin's "committee approach" phase, the phrase "exposure of interest" was translated as "exposure to the factors under study" and the word "outcome" as "outcomes/results". The vast majority of health scientists involved to the Greek questionnaire's comprehension test understood these phrases. The final Greek version of the NIH- QATOCCsS is presented in Figures 2 & 3.

The detailed guidance for assessing the quality of observational cohort and cross-sectional studies is documented below. It is organized by question number.

### *Question 1. Research question*

Did the authors describe their goal in conducting this research? Is it easy to understand what they were looking to find? This issue is important for any scientific paper of any type. Higher-quality scientific research explicitly defines a research question (NHLBI, 2021).

### *Questions 2 and 3. Study population*

Did the authors describe the group of people from which the study participants were selected or recruited, using demographics, location, and time period? If you were to conduct this study again, would you know who to recruit, from where, and from what time period? Is the cohort population free of the outcomes of interest at the time they were recruited?

An example would be men over 40 years old with type 2 diabetes who began seeking medical care at Phoenix Good Samaritan Hospital between January 1, 1990 and December 31, 1994. In this example, the population is clearly described as: (1) who (men over 40 years old with type 2 diabetes); (2) where (Phoenix Good Samaritan Hospital); and (3) when (between January 1, 1990 and December 31, 1994). Another example is women ages 34 to 59 years of age in 1980 who were in the nursing profession and had no known coronary disease, stroke, cancer, hypercholesterolemia, or diabetes, and were recruited from the 11 most populous States, with contact information obtained from State nursing boards.

In cohort studies, it is crucial that the population at baseline is free of the outcome of interest. For example, the nurses' population above would be an appropriate group in which to study incident coronary disease. This information is usually found either in descriptions of population recruitment, definitions of variables, or inclusion/exclusion criteria.

Reviewer may need to look at prior papers on methods in order to make the assessment for this question. Those papers are usually in the reference list. If fewer than 50% of eligible persons participated in the study, then there is concern that the study population does not adequately represent the target population. This increases the risk of bias (NHLBI, 2021).

### *Question 4. Groups recruited from the same population and uniform eligibility criteria*

Were the inclusion and exclusion criteria developed prior to recruitment or selection of the study population? Were the same underlying criteria used for all of the subjects involved? This issue is related to the description of the study population, above, and you may find the information for both of these questions in the same section of the paper.

Most cohort studies begin with the selection of the cohort; participants in this cohort are then measured or evaluated to determine their exposure status. However, some cohort studies may recruit or select exposed participants in a different time or place than unexposed participants, especially retrospective cohort studies–which is when data are obtained from the

past (retrospectively), but the analysis examines exposures prior to outcomes. For example, one research question could be whether diabetic men with clinical depression are at higher risk for cardiovascular disease than those without clinical depression. So, diabetic men with depression might be selected from a mental health clinic, while diabetic men without depression might be selected from an internal medicine or endocrinology clinic. This study recruits groups from different clinic populations, so this example would get a "no."

However, the women nurses described in the question above were selected based on the same inclusion/exclusion criteria, so that example would get a "yes" (NHLBI, 2021).

### *Question 5. Sample size justification*

Did the authors present their reasons for selecting or recruiting the number of people included or analyzed? Do they note or discuss the statistical power of the study? This question is about whether or not the study had enough participants to detect an association if one truly existed.

A paragraph in the article's methods section may explain the sample size needed to detect a hypothesized difference in outcomes. You may also find a discussion of power in the discussion section (such as the study had 85 percent power to detect a 20 percent increase in the rate of an outcome of interest, with a 2-sided alpha of 0.05). Sometimes estimates of variance and/or estimates of effect size are given, instead of sample size calculations. In any of these cases, the answer would be "yes."

However, observational cohort studies often do not report anything about power or sample sizes because the analyses are exploratory in nature. In this case, the answer would be "no." This is not a "fatal flaw." It just may indicate that attention was not paid to whether the study was sufficiently sized to answer a prespecified question–i.e., it may have been an exploratory, hypothesis-generating study (NHLBI, 2021).

### *Question 6. Exposure assessed prior to outcome measurement*

This question is important because, in order to determine whether an exposure causes an outcome, the exposure must come before the outcome.

For some prospective cohort studies, the investigator enrolls the cohort and then determines the exposure status of various members of the cohort (large epidemiological studies like Framingham used this approach). However, for other cohort studies, the cohort is selected based on its exposure status, as in the example above of depressed diabetic men (the exposure being depression). Other examples include a cohort identified by its exposure to fluoridated drinking water and then compared to a cohort living in an area without fluoridated water, or a cohort of military personnel exposed to combat in the Gulf War compared to a cohort of military personnel not deployed in a combat zone.

With either of these types of cohort studies, the cohort is followed forward in time (i.e., prospectively) to assess the outcomes that occurred in the exposed members compared to nonexposed members of the cohort. Therefore, you begin the study in the present by looking at groups that were exposed (or not) to some biological or behavioral factor, intervention, etc., and then you follow them forward in time to examine outcomes. If a cohort study is conducted properly, the answer to this question should be "yes," since the exposure status of members of the cohort was determined at the beginning of the study before the outcomes occurred.

For retrospective cohort studies, the same principle applies. The difference is that, rather than identifying a cohort in the present and following them forward in time, the investigators go back in time (i.e., retrospectively) and select a cohort based on their exposure status in the past and then follow them forward to assess the outcomes that occurred in the exposed and nonexposed cohort members. Because in retrospective cohort studies the exposure and outcomes may have already occurred (it depends on how long they follow the cohort), it is important to make sure that the exposure preceded the outcome.

Sometimes cross-sectional studies are conducted (or cross-sectional analyses of cohort-study data), where the exposures and outcomes are measured during the same timeframe. As a result, cross-sectional analyses provide weaker evidence than regular cohort studies regarding a potential causal relationship between exposures and outcomes. For cross-sectional analyses, the answer to Question 6 should be “no” (NHLBI, 2021).

### *Question 7. Sufficient timeframe to see an effect*

Did the study allow enough time for a sufficient number of outcomes to occur or be observed, or enough time for an exposure to have a biological effect on an outcome? In the examples given above, if clinical depression has a biological effect on increasing risk for CVD, such an effect may take years. In the other example, if higher dietary sodium increases BP, a short timeframe may be sufficient to assess its association with BP, but a longer timeframe would be needed to examine its association with heart attacks.

The issue of timeframe is important to enable meaningful analysis of the relationships between exposures and outcomes to be conducted. This often requires at least several years, especially when looking at health outcomes, but it depends on the research question and outcomes being examined.

Cross-sectional analyses allow no time to see an effect, since the exposures and outcomes are assessed at the same time, so those would get a "no" response (NHLBI, 2021).

### *Question 8. Different levels of the exposure of interest*

If the exposure can be defined as a range (examples: drug dosage, amount of physical activity, amount of sodium consumed), were multiple categories of that exposure assessed? (for example, for drugs: not on the medication, on a low dose, medium dose, high dose; for dietary sodium, higher than average U.S. consumption, lower than recommended consumption, between the two). Sometimes discrete categories of exposure are not used, but instead exposures are measured as continuous variables (for example, mg/day of dietary sodium or BP values).

In any case, studying different levels of exposure (where possible) enables investigators to assess trends or dose-response relationships between exposures and outcomes–e.g., the higher the exposure, the greater the rate of the health outcome. The presence of trends or dose-response relationships lends credibility to the hypothesis of causality between exposure and outcome.

For some exposures, however, this question may not be applicable (e.g., the exposure may be a dichotomous variable like living in a rural setting versus an urban setting, or vaccinated/not vaccinated with a one-time vaccine). If there are only two possible exposures (yes/no), then this question should be given an "NA," and it should not count negatively towards the quality rating (NHLBI, 2021).

### *Question 9. Exposure measures and assessment*

Were the exposure measures defined in detail? Were the tools or methods used to measure exposure accurate and reliable–for example, have they been validated or are they objective? This issue is important as it influences confidence in the reported exposures. When exposures are measured with less accuracy or validity, it is harder to see an association between exposure and outcome even if one exists. Also as important is whether the exposures were assessed in the same manner within groups and between groups; if not, bias may result.

For example, retrospective self-report of dietary salt intake is not as valid and reliable as prospectively using a standardized dietary log plus testing participants' urine for sodium content. Another example is measurement of BP, where there may be quite a difference between usual care, where clinicians measure BP however it is done in their practice setting (which can vary considerably), and use of trained BP assessors using standardized equipment (e.g., the same BP device which has been tested and calibrated) and a standardized protocol (e.g., patient is seated for 5 minutes with feet flat on the floor, BP is taken twice in each arm, and all four measurements are averaged). In each of these cases, the former would get a "no" and the latter a “yes”.

Here is a final example that illustrates the point about why it is important to assess exposures consistently across all groups: If people with higher BP (exposed cohort) are seen by their providers more frequently than those without elevated BP (nonexposed group), it also increases the chances of detecting and documenting changes in health outcomes, including CVD-related events. Therefore, it may lead to the conclusion that higher BP leads to more CVD events. This may be true, but it could also be due to the fact that the subjects with higher BP were seen more often; thus, more CVD-related events were detected and documented simply because they had more encounters with the health care system. Thus, it could bias the results and lead to an erroneous conclusion (NHLBI, 2021).

***Question 10. Repeated exposure assessment***

Was the exposure for each person measured more than once during the course of the study period? Multiple measurements with the same result increase our confidence that the exposure status was correctly classified. Also, multiple measurements enable investigators to look at changes in exposure over time, for example, people who ate high dietary sodium throughout the followup period, compared to those who started out high and then reduced their intake, compared to those who ate low sodium throughout. Once again, this may not be applicable in all cases. In many older studies, exposure was measured only at baseline. However, multiple exposure measurements do result in a stronger study design (NHLBI, 2021).

***Question 11. Outcome measures***

Were the outcomes defined in detail? Were the tools or methods for measuring outcomes accurate and reliable–for example, have they been validated or are they objective? This issue is important because it influences confidence in the validity of study results. Also important is whether the outcomes were assessed in the same manner within groups and between groups.

An example of an outcome measure that is objective, accurate, and reliable is death–the outcome measured with more accuracy than any other. But even with a measure as objective as death, there can be differences in the accuracy and reliability of how death was assessed by the investigators. Did they base it on an autopsy report, death certificate, death registry, or report from a family member? Another example is a study of whether dietary fat intake is related to blood cholesterol level (cholesterol level being the outcome), and the cholesterol level is measured from fasting blood samples that are all sent to the same laboratory. These examples would get a "yes." An example of a "no" would be self-report by

subjects that they had a heart attack, or self-report of how much they weigh (if body weight is the outcome of interest).

Similar to the example in Question 9, results may be biased if one group (e.g., people with high BP) is seen more frequently than another group (people with normal BP) because more frequent encounters with the health care system increases the chances of outcomes being detected and documented (NHLBI, 2021).

### *Question 12. Blinding of outcome assessors*

Blinding means that outcome assessors did not know whether the participant was exposed or unexposed. It is also sometimes called “masking”. The objective is to look for evidence in the article that the person(s) assessing the outcome(s) for the study (for example, examining medical records to determine the outcomes that occurred in the exposed and comparison groups) is masked to the exposure status of the participant. Sometimes the person measuring the exposure is the same person conducting the outcome assessment. In this case, the outcome assessor would most likely not be blinded to exposure status because they also took measurements of exposures. If so, make a note of that in the comments section.

As the reviewer assesses this criterion, he/she thinks about whether it is likely that the person(s) doing the outcome assessment would know (or be able to figure out) the exposure status of the study participants. If the answer is no, then blinding is adequate. An example of adequate blinding of the outcome assessors is to create a separate committee, whose members were not involved in the care of the patient and had no information about the study participants' exposure status. The committee would then be provided with copies of participants' medical records, which had been stripped of any potential exposure information or personally identifiable information. The committee would then review the records for prespecified outcomes according to the study protocol. If blinding was not possible, which is sometimes the case, mark "NA" and explain the potential for bias (NHLBI, 2021).

### *Question 13. Followup rate*

Higher overall followup rates are always better than lower followup rates, even though higher rates are expected in shorter studies, whereas lower overall followup rates are often seen in studies of longer duration. Usually, an acceptable overall followup rate is considered 80 percent or more of participants whose exposures were measured at baseline. However, this is just a general guideline. For example, a 6-month cohort study examining the relationship between dietary sodium intake and BP level may have over 90 percent followup, but a 20-year cohort study examining effects of sodium intake on stroke may have only a 65 percent followup rate (NHLBI, 2021).

### *Question 14. Statistical analyses*

Were key potential confounding variables measured and adjusted for, such as by statistical adjustment for baseline differences? Logistic regression or other regression methods are often used to account for the influence of variables not of interest.

This is a key issue in cohort studies, because statistical analyses need to control for potential confounders, in contrast to an RCT, where the randomization process controls for potential confounders. All key factors that may be associated both with the exposure of interest and the outcome–that are not of interest to the research question–should be controlled for in the analyses. For example, in a study of the relationship between cardiorespiratory fitness and CVD events (heart attacks and strokes), the study should control for age, BP, blood cholesterol, and body weight, because all of these factors are associated both with low fitness and with CVD events. Well-done cohort studies control for multiple potential confounders (NHLBI, 2021).

## Discussion

The questions in the form of NIH-QATOCCsS are designed to help reviewers focus on the key concepts for evaluating the internal validity of a study. They are not intended to create a list that tally up to arrive at a summary judgment of quality.

Internal validity for cohort studies is the extent to which the results reported in the study can truly be attributed to the exposure being evaluated and not to flaws in the design or conduct of the study–in other words, the ability of the study to draw associative conclusions about the effects of the exposures being studied on outcomes. Any such flaws can increase the risk of bias.

Critical appraisal involves considering the risk of potential for selection bias, information bias, measurement bias, or confounding (the mixture of exposures that one cannot tease out from each other). Examples of confounding include co-interventions, differences at baseline in patient characteristics, and other issues throughout the questions above. A high risk of bias translates to a rating of poor quality. A low risk of bias translates to a rating of good quality (thus, the greater the risk of bias, the lower the quality rating of the study).

In addition, the more attention in the study design to issues that can help determine whether there is a causal relationship between the exposure and outcome, the higher the quality of the study. These include exposures occurring prior to outcomes, evaluation of a dose-response gradient, accuracy of measurement of both exposure and outcome, sufficient

timeframe to see an effect, and appropriate control for confounding–all concepts reflected in the tool.

Generally, when a reviewer evaluates a study, he/she will not see a "fatal flaw," but he/she will find some risk of bias. By focusing on the concepts underlying the questions in the quality assessment tool, the reviewer should ask himself about the potential for bias in the study that are critically appraising. For any box where reviewer check "no" he/she should ask, "What is the potential risk of bias resulting from this flaw in study design or execution?" That is, does this factor cause to doubt the results that are reported in the study or doubt the ability of the study to assess an association between exposure and outcome accurately?

The best approach is the reviewer to think about the questions in the tool and how each one tells something about the potential for bias in a study. The more the reviewer is familiarized with the key concepts, the more comfortable he/she will be with critical appraisal. Examples of studies rated good, fair, and poor are useful, but each study must be assessed on its own based on the details that are reported and consideration of the concepts for minimizing bias (NHLBI, 2021).

All these guidances are essential for determining the overall quality rating of observational cohort and cross-sectional studies.

## Conclusions

The purpose of the present study was the official translation into Greek of the NIH-QATOCCsS proposed by the American National Institutes of Health. The tool is detailed, easy to use, with clear guidance, and its Greek translation is available for scientists and students writing in Greek, systematic reviews that include observational cohort or cross-sectional studies.

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