

**Associações entre o Teste
Yubi-Wakka e composição corporal:
um estudo transversal**
***Associations between the Yubi-Wakka
test and body composition: a
cross-sectional study***

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Abstract

We aim to study the association between the results of the YW test and appendicular lean mass (ALM) evaluated by Dual Energy X-ray Absorptiometry (DXA) and to explore the impact of using a dichotomous YW on the model's predictive validity. In this cross-sectional study developed with a sample of 187 community-dwelling adults aged 18 years old or over we studied the association between the independent variables and the results of the YW test performed by binary and ordinal logistic regression models. For each unity increase in ALM, the multivariate binary logistic regression showed a decrease probability of being allocated to the “adjusted” and “smaller calf” group (OR=0.30; 95% CI= 0.18-0.50). The ordinal logistic regression showed an increased probability in transitioning to a higher YW category for each unity increase in ALM (pOR=4.10; 95% CI= 2.65-6.35). In the adjusted ordinal logistic regression model being male is associated with an increased probability of transitioning to higher categories of the YW test. Our logistic regression models also importantly show that our result variables are independent from age. The results shown in both logistic regressions, using the dichotomic YW test in the binary and the trichotomic YT test in the ordinal logistic regression, were similar, therefore, using either classification seems to have no significant impact on the results. Resorting to a reference standard method (DXA) for evaluating muscle mass we confirmed the YW test as an accurate method of evaluating ALM. In the future, we aim to evaluate the YW test as a method of self-screening sarcopenia.

Keywords: Yubi-Wakka, anthropometry, screening, appendicular lean mass, DXA.

Resumo

Neste estudo, pretendemos estudar a associação entre os resultados do teste YW e a massa magra apendicular (ALM) avaliada por Absorciometria de raios-X de dupla energia (DXA) e explorar o impacto do uso de um YW dicotômico na validade preditiva do modelo. Neste estudo transversal desenvolvido com uma amostra de 187 adultos da comunidade, com 18 anos ou mais, avaliámos a associação entre as variáveis independentes e os resultados do teste YW com recurso a modelos de regressão logística binária e ordinal. Por cada aumento unitário de ALM, a regressão logística binária multivariada mostrou uma probabilidade decrescente de ser alocado ao grupo de perna “ajustada” e “menor” (OR=0.30; IC 95%= 0.18-0.50). A regressão logística ordinal mostrou uma probabilidade aumentada na transição para uma categoria de YW superior por cada aumento unitário de ALM (pOR=4.10; 95% CI= 2.65-6.35). No modelo de regressão logística ordinal ajustado, ser do sexo masculino está associado a uma maior probabilidade de transição para categorias superiores do teste YW. Os modelos de regressão logística mostram, ainda, que as variáveis de resultado são independentes da idade. Os resultados apresentados em ambas as regressões logísticas, usando o teste dicotômico YW na regressão binária e o teste tricotômico YW na regressão logística ordinal, foram semelhantes, portanto, o uso de qualquer uma das categorizações parece não ter um impacto significativo nos resultados. Recorrendo a um método de referência padrão (DXA) para a avaliação da massa muscular confirmámos o teste YW como um método válido na avaliação da ALM. No futuro, pretendemos avaliar o teste YW como método de autorraastreio de sarcopenia.

Palavras-chave: Yubi-Wakka, antropometria, autorraastreio, ALM, DXA.

List of abbreviations and acronyms

ACC - “Adjusted calf” category

ALM - Appendicular lean mass

BCC - “Bigger calf” category

BLR - Binary logistic regression

BMI - Body Mass Index

CC - Calf circumference

CP - Calf perimeter

DXA - Dual Energy X-ray Absorptiometry

ERDF - European Regional Development Fund

EWGSOP2 - European Working Group on Sarcopenia in Older People

FCNAUP - Faculty of Nutrition and Food Sciences of the University of Porto

Hand length - HL

ISAK - International Society for the Advancement of Kinanthropometry

NF - New aspects of muscle function related to nutritional outcomes study

NutrIC - Nutrition and functional status in heart failure study

OLR - Ordinal logistic regression

SCC - “Smaller calf” category

TFM - Total Fat Mass

YW - Yubi-Wakka

Summary

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Introduction

In 2017, Tanaka et al.⁽¹⁾ developed the “Yubi-Wakka” test (YW) as a practical and accessible method of self-screening sarcopenia, validating it in the Japanese population. Since then, studies have emerged analyzing its effectiveness in the evaluation of body composition abnormalities⁽²⁻¹⁰⁾. The association between the YW test and appendicular lean mass (ALM) has been evaluated using bioimpedance^(1, 4, 7, 8, 10, 11). However, using a reference standard method such as the Dual Energy X-ray Absorptiometry (DXA) to evaluate ALM⁽¹²⁾ in an adult community-dwelling population, remains to be studied.

Over the last few years, multiple studies have emerged regarding the trichotomic YW test: “smaller calf” category (SCC), “adjusted calf” category (ACC), and “bigger calf” category (BCC). Nonetheless, some of these studies use the BCC as a control group and merge the other two categories to indicate a risk group, while applying a binary logistic regression^(2-4, 8). Other studies use a multivariate logistic regression to analyze the association between the reference group (BCC) and the other two categories (ACC and SCC)^(3, 5, 7, 10, 11). To our knowledge, the use of the dichotomic and trichotomic categorization has not yet been compared as to understand the potential impact of using a different number of categories on the model’s predictive validity regarding the same variables that have a direct implication in the YW test results.

Objectives

We aim to study the association between the results of the YW test and ALM evaluated by DXA, as well as clarify the association between the results of the YW

test and body composition measurements, namely hand length (HL) and total fat mass (TFM) also evaluated by DXA. We also aim to explore the impact of using a dichotomous rather than a trichotomic YW on the model's predictive validity.

Methodology

Study oversight, sample and data collection

This cross-sectional study was developed within the “NutriFunction - New aspects of muscle function related to nutritional outcomes” (NF), and “NutriIC - Nutrition and functional status in heart failure” (NutriIC), ongoing at the Faculty of Nutrition and Food Sciences of the University of Porto (FCNAUP), Portugal. The participants' data was obtained through the application of a questionnaire for socio-demographic, lifestyle, anthropometrics, body composition, physical activity, cognitive performance, health status, drug therapy, food supplements, status and risk of undernutrition and functional status characterization. Bioimpedance and DXA exams were also carried out. The information concerning this study was widespread throughout the community using physical and digital promotional material, as well as the University of Porto dynamic e-mail. The inclusion criteria for the study were not being hospitalized/institutionalized and being aged 18 years old or over.

Yubi-Wakka test

For the self-application of the YW test, each participant was in a sitting position with legs flexed at 90° and their thumbs joined behind their right leg. Circling their leg with their index fingers as to create a finger-ring, the participants were asked to check if their calf was smaller, adjusted, or bigger than the finger-ring formed.

Anthropometric measurements and measurement error study

Weight (Kg), height (cm), hand length (cm), calf perimeter (cm), maximum right hand grip strength (KgF), maximum left hand grip strength (KgF) and ½ finger-ring length (cm) were measured by trained interviewers. The ½ finger-ring length was measured using a circular measuring tape which participants were asked to involve with their thumb and index finger. The body mass index (BMI) was calculated and used to define BMI classes⁽¹³⁾. The calf circumference (CC) was calculated from calf perimeter (CP) and calf skinfold according to a formula (Calf Circumference (cm) = Calf perimeter (cm) - π * Calf skinfold thickness (mm)) derived from the mid-arm muscle circumference formula from World Health Organization, 1966⁽¹⁴⁾. A measurement error study was carried out prior to the beginning of data collection to ensure precise and exact anthropometric measurements.

DXA items

A Hologic Horizon Wi densitometer was used to quantify the right leg lean mass (Kg), total lean mass (Kg), TFM (%), and ALM (Kg/m²).

Sarcopenia

Sarcopenia, defined as low muscle strength and low muscle quality/quantity by the European Working Group on Sarcopenia in Older People, 2018 (EWGSOP2)⁽¹⁵⁾, was identified based on their recommended criteria.

Ethical considerations

The NF (Annex I and II) and NutrIC (Annex III) studies were approved by the Ethics Committee of FCNAUP (reference 71/2022, addendum to the reference

71/2022 and 115/2022, respectively). This study was carried out in accordance with the Declaration of Helsinki, 2013.

Statistical analysis

The normality of the variables was assessed by the values of skewness and kurtosis. The characteristics of the participants were compared using the Chi-square test for categorical variables and the ANOVA test and the Kruskal-Wallis test for continuous variables with and without normal distribution, respectively. The association between the independent variables and the results of the YW test (dependent variable), was performed by two exploratory regression models:

- (1) to analyze the association between the variables and the dichotomic YW test, a binary logistic regression was conducted. The robustness of the model was assessed by the Hosmer and Lemeshow test. Results were presented in odds ratios (OR) and 95% CI;
- (2) to study the association between the variables and the trichotomic YW test, an ordinal logistic regression was conducted, using a multivariate model of proportional odds. The assumption of the proportional odds across dependent categories was assessed using the test of parallel lines. Results were presented in proportional odds ratios (pOR) and their respective 95% confidence intervals (95% CI).

Participants with visible peripheral edema were not excluded from the sample, instead a sensitivity analysis was conducted and determined the predictive validity of both models (binary and ordinal logistic regressions) did not change with the exclusion of edema.

We considered $p \leq 0.05$ statistically significant. SPSS V29.0 software was used for statistical analysis.

Results

Baseline participants characteristics

Table 1 summarizes the characteristics of the 187 participants enrolled in this cross-sectional study by YW categories.

Table 1 Characteristics by *Yubi-Wakka* categories.

	Smaller calf (n=39)	Adjusted calf (n=77)	Bigger calf (n=71)	p-value
Sex [n (%)]				
Women	26(66.7)	47(61.0)	51 (71.8)	0.381
Men	13 (33.3)	30 (39.0)	20 (28.2)	
Age [years; μ(sd)]	34.3(15.5)	36.5(14.4)	38.1(14.4)	0.420
Education level [n (%)]				
None/ Basic education/Secondary education	12(30.8)	13(16.9)	16(22.5)	0.506**
Post-secondary education	2(5.1)	4(5.2)	5(7.0)	
Higher education	25(64.1)	60(77.9)	50(70.4)	
Smoking habits [n (%)]				
Nonsmoker	29(74.4)	53(68.8)	48(67.6)	0.971**
Current smoker	3(7.7)	8(10.4)	7(9.9)	
Former smoker	7(17.9)	16(20.8)	16(22.5)	
Alcoholic habits [n(%)]				
Nondrinker	10 (25.6)	18(23.4)	11(15.5)	0.354
Drinker	29(74.4)	59(76.6)	60(84.5)	

*IPAQ - International Physical Activity Questionnaire.

**Fisher's exact test.

Table 1 Continued.

	Smaller calf (n=39)	Adjusted calf (n=77)	Bigger calf (n=71)	p-value
Chronic diseases [n (%)]				
None	19(48.7)	24(31.2)	29(40.8)	0.163
At least one	20(51.3)	53(68.8)	42(59.2)	
Risk of undernutrition [n (%)]				
Low risk	24(61.5)	72(93.5)	65(91.5)	<0.001
Moderate or high risk	15(38.5)	5(6.5)	6(8.5)	
Sarcopenia [n (%)]				
Diagnosed	5(12.8)	3(5.2)	3(4.2)	0.228**
Healthy	34(87.2)	74(94.8)	68(95.8)	
Level of physical activity* [n (%)]				
Inactive or minimally active	20(51.3)	39(50.6)	35(49.3)	0.977
HEPA active	19(48.7)	38(49.4)	36(50.7)	
Body mass index class [n (%)]				
Low weight or normal weight	36(92.3)	64(83.1)	39(54.9)	<0.001
Overweight or obesity	3(7.7)	13(16.9)	32(45.1)	

*IPAQ - International Physical Activity Questionnaire.

**Fisher's exact test.

Table 2 summarizes the characteristics of the participants by sex and YW categories. The results show significant differences between the risk of undernutrition ($p<0.001$), body mass index ($p<0.001$), body mass index class ($p<0.001$), calf perimeter ($p<0.001$), calf circumference ($p=0.010$), right leg lean mass ($p=0.023$) and ALM ($p=0.003$) and YW categories.

Table 2 Characteristics by sex and Yubi-Wakka categories.

	Women (n=124)				Men (n=63)			
	Smaller calf (n=26)	Adjusted calf (n=47)	Bigger calf (n=51)	p-value	Smaller calf (n=13)	Adjusted calf (n=30)	Bigger calf (n=20)	p-value
Weight [Kg; Md (Q ₁ -Q ₃)]	51.4(49.8-56.9)	56.1(53.1-61.5)	60.7(55.8-70.1)	<0.001	73.3(66.8-76.0)	73.4(66.8-82.4)	84.5(67.0-95.2)	0.089
Height [cm; μ (sd)]	163.4(4.9)	163.4(5.3)	161.7(5.6)	0.229	174.8(4.8)	174.5(6.8)	173.8(9.5)	0.908
Body mass index [Kg/m ² ; μ (sd)]	19.9(1.3)	21.6(1.8)	24.1(3.7)	<0.001	22.9(2.0)	24.7(2.8)	25.1(3.4)	<0.001
Hand length [cm; μ (sd)]	18.3(0.7)	18.1(0.8)	17.9(0.9)	0.115	19.6(0.7)	19.6(1.1)	19.4(1.0)	0.768
Calf perimeter [cm; μ (sd)]	32.5(1.8)	34.2(1.8)	36.7(2.7)	<0.001	35.1(2.7)	37.2(2.1)	39.5(2.5)	<0.001
Calf circumference [cm; μ (sd)]	28.8(2.0)	29.6(2.0)	31.0(2.3)	<0.001	32.5(2.9)	34.2(2.3)	35.8(2.5)	0.010
Right leg lean mass [Kg; μ (sd)]	5.8(0.6)	6.4(1.1)	6.5(1.0)	0.010	8.3(1.3)	9.4(1.4)	9.8(1.7)	0.023
Total lean mass [Kg; Md (Q ₁ -Q ₃)]	3.6(3.4-3.8)	3.8(3.6-4.0)	3.8(3.5-4.2)	0.068	5.0(4.7-5.7)	5.6(5.1-6.0)	6.0(5.0-6.6)	0.069
Total fat mass [%; Md (Q ₁ -Q ₃)]	26.2(3.4)	28.1(6.7)	32.7(7.5)	<0.001	21.6(6.0)	20.8(6.0)	23.7(6.1)	0.248
Appendicular lean mass [Kg/m ² ; μ (sd)]	5.7(0.5)	6.1(0.6)	6.4(0.8)	<0.001	7.5(1.0)	8.3(0.9)	8.7(1.1)	0.003
Maximum right hand grip strenght [KgF; μ (sd)]	22.4(5.9)	24.1(5.4)	23.5(4.5)	0.424	39.6(7.1)	35.6(6.4)	39.1(10.2)	0.458
Maximum left hand grip strenght [KgF; μ (sd)]	39.6(7.1)	35.6(6.4)	39.1(10.2)	0.183	20.6(4.7)	21.6(4.7)	21.3(3.8)	0.640

Table 3 represents a sub-analysis of 67 participants regarding the ½ finger-ring length.

Table 3 Sub-analysis of ½ finger-ring length by sex and *Yubi-Wakka* categories.

	Women (n=42)				Men (n=25)			
	Smaller calf (n=9)	Adjusted calf (n=14)	Bigger calf (n=19)	p-value	Smaller calf (n=3)	Adjusted calf (n=12)	Bigger calf (n=10)	p-value
½ finger-ring length [μ (sd)]	16.6(0.7)	15.9(0.8)	15.4(1.0)	0.008	17.3(0.6)	16.9(1.2)	17.5(0.8)	0.348

Binary logistic regression

For the binary logistic regression, the participants from the BCC were used as the control group and the other two YW categories were merged as the risk group (SCC and ACC). The results of the binary logistic regression are presented in Table 4.

Each centimeter increase in HL is associated with a 91% probability increase of being allocated to the risk group (OR=1.91; 95% CI= 1.25-2.90). Each kilogram per square meter increase in ALM is associated with a 70% decrease probability of being allocated to the risk group (OR=0.30; 95% CI= 0.18-0.50). For each 1% increase in TFM there is a 12% probability decrease of being allocated to the risk group (OR=0.88; 95% CI= 0.82-0.93). Both HL and TFM have a significant association in the unadjusted and adjusted model. The association between HL is stronger in the adjusted model.

Table 4 Results from the binary logistic regression regarding *Yubi-Wakka* categories (“bigger calf” versus “adjusted” and “smaller” calf).

	Unadjusted model		Adjusted model	
	Odds Ratio	95% CI	Odds Ratio	95% CI
Sex				
Women	1.00	(Referent)	1.00	(Referent)
Men	1.50	0.79-2.85	3.37	0.84-13.56
Age	0.99	0.97-1.01	0.99	0.96-1.01
Level of physical activity				
Inactive or minimally active	1.00	(Referent)	1.00	(Referent)
Active	0.94	0.52-1.70	1.30	0.63-2.57
Hand length	1.39	1.05-1.83	1.91	1.25-2.90
Appendicular lean mass	0.83	0.66-1.04	0.30	0.18-0.50
Total fat mass	0.91	0.87-0.95	0.88	0.82-0.93

OR = proportional Odds Ratio. 95% CI = 95% Confidence Intervals. Test of Hosmer and Lemeshow: $p > 0.05$.

Ordinal logistic regression

The results of the ordinal logistic regression are presented in Table 5. Each centimeter increase in HL is associated with a 57% probability decrease in transitioning from a lower to a higher YW category ($pOR=0.53$; 95% CI= 0.37-0.75). Each kilogram per square meter increase in ALM is associated with a 310% probability increase in transitioning from a lower to a higher YW category ($pOR=4.10$; 95% CI= 2.65-6.35). For each 1% increase in TFM there is a 12% probability of increase in transitioning from a lower to a higher YW category

(pOR=1.12; 95% CI= 1.07-1.18). All the 3 measurements (HL, ALM, and TFM) have a significant association both in the unadjusted and adjusted model, stronger in the adjusted model. In the adjusted model, men have 3.42 higher odds than women in transitioning from a lower to a higher YW category.

Table 5 Results from the ordinal regression regarding *Yubi-Wakka* categories.

	Unadjusted model		Adjusted model	
	Odds Ratio	95% CI	Odds Ratio	95% CI
Sex				
Women	1.00	(Referent)	1.00	(Referent)
Men	1.28	0.73-2.25	4.42	1.45-13.42
Age	1.01	0.99-1.03	1.02	0.99-1.04
Level of physical activity				
Inactive or minimally active	1.00	(Referent)	1.00	(Referent)
Active	0.94	0.55-1.61	1.24	0.69-2.23
Hand length	0.78	0.62-0.99	0.53	0.37-0.75
Appendicular lean mass	1.32	1.07-1.63	4.10	2.65-6.35
Total fat mass	1.08	1.04-1.12	1.12	1.07-1.18

pOR = proportional Odds Ratio. 95% CI = 95% Confidence Intervals. Test of parallel lines: $p > 0.05$.

Sensitivity analysis

A sensitivity analysis was conducted to assess the effect of the presence of peripheral edema on the predictive validity of the model. Differences between regression estimates of the binary logistic regression (with and without edema) varied between 0.00 and 0.01, with a mean difference of 0.004. Differences between regression estimates of the ordinal logistic regression (with and without

edema) varied between 0.00 and 0.03, with a mean difference of 0.01. The predictive validity of both models did not change with the exclusion of edema.

Discussion

In the present study we conducted an exploratory analysis of body composition measurements associated with the YW test. Previous studies have confirmed the YW test as a useful method for screening sarcopenia in community dwelling middle aged and older adults both in Japanese and Chinese populations (1, 3, 7-10). Some of these studies^(3, 10) have already mentioned the need for using more reliable methods of evaluating body composition than bioimpedance or computed tomography. To the best of our knowledge, this study is the first to analyze the association between ALM and the YW test, using a reference standard method for evaluating muscle mass (DXA)⁽¹²⁾. As previously evaluated by bioimpedance and reported by Watanabe *et al.* 2021⁽¹⁰⁾, there is a significant association between the YW test and ALM. As shown by our results, we confirmed an increased probability in being allocated to the BCC and transitioning to higher YW categories with each unity increase in ALM (Kg/m²), respectively in the binary and ordinal logistic regressions.

We did not evaluate the YW test performance as a screening method for sarcopenia due to low sarcopenic frequency in the studied sample. Instead, one of our objectives was to analyze the association between the YW test and the ALM measured by DXA. Moreover, this study enabled the comparison of body composition measurements such as the finger-ring length which are essential for understanding the anatomic differences which impact the YW test results in the Japanese and Portuguese populations. According to Tanaka *et al.* 2018⁽¹⁾, the

mean ($\pm$ standard deviation) of finger-ring length for Japanese women was 32.6($\pm$ 1.8) cm and 31.0($\pm$ 1.6) cm for Japanese men. Our results show a mean finger-ring length for women of approximately 34 cm and 37 cm for men. However, one of the advantages of the YW test is precisely its ability to use each participant's hands as their own personal calf measurer thus reflecting the adjustment of the method to the participant's hand size which in turn represent their differences in physical size. Our logistic regression models also importantly show that our result variables are independent from age. The same was previously mentioned by Tanaka et al. 2018⁽¹⁾ who said that the finger-ring length does not change with age, which is an advantage of the YW test. However, sex seems to affect the allocated category of the YW test in the adjusted ordinal logistic regression model. In this model being male is associated with an increased probability of transitioning to higher categories of the YW test. Watanabe et al. 2021⁽¹⁰⁾ found similar results showing the calf perimeter as a screening tool for low muscle mass to be less sensitive in women than in men, which he believes is due to larger fat volumes in women's legs. It is important to notice the high athlete proportion of participants from the studied sample which may help explain this finding. In response to our other objective, we compared the studied variables using the dichotomic and trichotomic categorization of the YW test. The results shown in both logistic regressions, using the dichotomic YW test in the binary and the trichotomic YT test in the ordinal logistic regression, were similar, apart from variable sex for the adjusted model of the ordinal logistic regression. Therefore, using either classification seems to have no significant impact on the results.

In this study we followed the EWGSOP2⁽¹⁵⁾ and International Society for the Advancement of Kinanthropometry (ISAK)⁽¹⁶⁾ criteria which enables the results to

be compared with those from future research. Although the YW test is self-administrated and self-reported, our staff further confirmed the YW test results given by the participants, therefore any systematic error due to self-reporting was eliminated.

Tanaka et al.⁽¹⁾ developed the YW test to be performed on the non-dominant leg, however, we carried out this measurement on the right leg in order to follow the ISAK guidelines⁽¹⁶⁾ and thus be able to have comparable data from the same limb to other anthropometric measurements. In future studies, a more heterogeneous sample is required for a more robust analysis by adding additional research settings such as long-term care institutions and hospitals. It should be noted that most of our sample were women. Consequently, there may be bias due to sex-specific effect, hence the need in the future for sampling methods to attempt to even the gender ratio or allowing a stratified analysis for sex.

Also seeing that study participation was voluntary, participants would be more health-conscious than the general population, leading to a self-selection bias. There is a need for studies with larger samples, with even gender ratio and even sarcopenic participation to further confirm the association between the YW test and body composition measurements firstly here described.

Conclusion

Seeing as ALM is one of the criteria in diagnosing sarcopenia, in this cross-sectional study we took a step back and resorting to a reference standard method for measuring muscle mass (DXA) we confirmed the YW test as an accurate method of measuring ALM independently of age and level of physical activity. In

the future, we aim to assemble a wider sample with more even sex and sarcopenic participation ratios, to evaluate the YW test as a method of self-screening sarcopenia.

Financial disclosure

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Annexes

Annex I - Rapport of the FCNAUP Ethics Committee on the investigation project NutriFunction



FACULDADE DE CIÊNCIAS DA NUTRIÇÃO E ALIMENTAÇÃO
UNIVERSIDADE DO PORTO

COMISSÃO DE ÉTICA

PARECER Nº 71/2022/CEFCNAUP/2022

Título do Projeto:

Nutrifunction | New aspects of muscle function related to nutritional outcomes

Submetido por:

Teresa Amaral

Instituições envolvidas no estudo:

Faculdade de Ciências da Nutrição e Alimentação

Universidade Fernando Pessoa – Porto: FP-131D, FCS

Outras instituições como lares, instituições locais de saúde e hospitais

Relator: Rita Negrão

Âmbito do Projeto submetido: Projeto de investigação

Duração do estudo: É referido que o estudo poderá ser iniciado se e quando obtiver Parecer positivo da Comissão de Ética da FCNAUP e que tem uma duração prevista de dois anos.

Objetivo do estudo

Identificar outras características para além da força preensora da mão (*Handgrip strength*, HGF) máxima, que possam ser utilizadas como indicadores clínicos.

Desenvolver indicadores de perfis da HGF com base numa população de adultos saudáveis e estudar os critérios e validade preditiva no diagnóstico de desnutrição e sarcopenia, e também de fragilidade, tanto em adultos saudáveis como em hospitalizados.

Pertinência e conceção do estudo

A realização do estudo está justificada e os aspetos metodológicos estão bem descritos.

A HGF é um marcador da função muscular do membro superior e da força geral e é reconhecido que o comprometimento da força muscular pode ocorrer quatro décadas antes de mudanças na estrutura e composição muscular. De acordo com isto, a HGF máxima tem sido amplamente utilizada na triagem, diagnóstico e monitorização de diversas situações e patologias, relacionadas com o comprometimento funcional e nutricional. Embora o valor da HGF máxima seja um indicador largamente utilizado, recentemente têm sido realizadas tentativas de identificação de outros indicadores da função muscular, que possam descrever melhor a função e força muscular geral.

O estudo apresentado é um estudo multicêntrico que inclui participantes da comunidade e doentes hospitalares. Será recrutada uma amostra de conveniência de 500 indivíduos saudáveis com idade superior ou igual a 18 anos da comunidade, através de instituições locais de saúde e lares. Em ambiente hospitalar, prevê-se o recrutamento de uma amostra de 800 pacientes com idade superior ou igual a 18 anos.

Serão recolhidos dados demográficos, de estilo de vida, antropométricos e de composição corporal, de atividade física (versão abreviada do Questionário Internacional de Atividade Física (IPAQ-SF) validado para a população portuguesa), sobre o padrão alimentar (*14-Item Mediterranean Diet Assessment Tool based on PREDIMED trial*), de qualidade de vida (questionário WHOQOL-BREF) e da performance cognitiva (versão portuguesa do *Mini Mental State Examination*, MMSE). Também serão recolhidas informações sobre o estado de saúde, a terapia medicamentosa e os suplementos alimentares. Serão ainda recolhidas algumas informações dos arquivos clínicos dos doentes hospitalares, nomeadamente parâmetros inflamatórios, quando disponíveis, e estimados os custos de hospitalização. O estado e risco de desnutrição será avaliado por recurso a ferramentas já estabelecidas (MUST, MNA-SF, NRS 2002, GLIM). O estado funcional será avaliado por meio da força preensora da mão, da extensão do joelho e da velocidade da marcha em todos os participantes, sempre que possível. Serão identificadas situações de sarcopenia e fenótipos de fragilidade.

Benefícios/riscos

Não estão previstos riscos associados à participação neste estudo. Os participantes têm o benefício de poderem ter acesso aos resultados do seu estado funcional e nutricional e os

médicos que os acompanham serão informados de qualquer anomalia relativa aos valores obtidos para os parâmetros analisados.

Respeito pela liberdade e autonomia do sujeito da investigação

Na informação ao participante e no consentimento informado estão garantidos o respeito pela liberdade e autonomia do sujeito, referindo que a participação no estudo é voluntária e que a desistência é possível a qualquer momento.

Confidencialidade dos dados

O anonimato é garantido na recolha, armazenamento e publicação dos dados. A confidencialidade será assegurada pela anonimização dos dados recolhidos, sendo a ligação do identificador com a identidade dos participantes registada em caderno de papel mantido em armário fechado ou num banco de dados informatizado sem conexão com a internet, acessível apenas ao investigador principal. As informações relativas à identificação dos participantes serão destruídas dois anos após a conclusão do estudo. A confidencialidade dos dados é garantida pelo investigador na informação ao participante.

Obtenção do consentimento informado

Os participantes serão informados de todos os procedimentos e prestarão consentimento informado para participar no estudo, por escrito. No documento de informação ao participante é referida a possibilidade de recolha de dados do arquivo clínico, no caso dos doentes hospitalizados, e é dada garantia de que estes dados serão armazenados de forma segura e anónima. Os documentos de informação ao participante e de consentimento informado respeitam as normas éticas. Quando não for possível ao participante prestar o consentimento informado, é referido que este será pedido ao seu tutor legal.

Elo de ligação

Não está definido elo de ligação com a Universidade Fernando Pessoa, embora vários elementos desta instituição façam parte da equipa de investigação do projeto.

Autorizações necessárias

Estão previstas.

Estando prevista a participação de doentes de lares e hospitais, e o acesso a dados de arquivos clínicos dos doentes, não são mencionados os lares e hospitais em que este estudo irá decorrer, porque ainda não foram formalizadas as colaborações. No projeto é referido que serão pedidas as autorizações necessárias às instituições "The necessary authorizations from each institutions administration board, will be obtained" sendo também referido que serão pedidos pareceres das comissões de ética das instituições, sempre que necessárias "This protocol will be further submitted to local Ethics Committees, if requested".

Indemnização por danos:

Não aplicável.

Continuação do tratamento/Seguimento de problemas identificados:

Não está previsto um acompanhamento ou seguimento dos participantes, mas é referido que os participantes podem ter acesso aos resultados do seu estado funcional e nutricional e que os médicos que os acompanham serão informados de qualquer anomalia relativa aos valores obtidos para os parâmetros analisados.

Curriculum do investigador e equipa:

Foram enviados em conjunto com o requerimento e demonstram grande experiência prévia e capacidade adequada ao desenvolvimento do estudo em questão.

Conclusão

Do exposto, considera-se que o projeto de investigação se mostra cientificamente justificado e sem limitações do ponto de vista ético, pelo que a Comissão dá parecer favorável à sua realização.

Pedimos que nos seja enviado um relatório final do projeto, após a conclusão do mesmo.

Faculdade de Ciências da Nutrição e Alimentação da Universidade do Porto,
21 de fevereiro de 2022

O Relator	A Presidente
	
Profª. Doutora Rita Negrão	Profª. Doutora Sara Rodrigues

Annex II - Addendum to the Rapport of the FCNAUP Ethics Committee on the investigation project NF



COMISSÃO DE ÉTICA

Adenda ao Parecer / Addendum to the Rapport

Parecer número / Rapport number: | 71/2022/CEFCNAUP |

Título do projeto / Project Title

NutriFunction | New aspects of muscle function related to nutritional outcomes

Parecer / Rapport

☒ Favorável / Favourable ☐ Desfavorável / Not Favourable

Comentários e recomendações / Comments and recommendations:

Foi submetido um pedido de apreciação de uma alteração ao projeto *NutriFunction*, cujo parecer favorável (Parecer 71/2022) foi emitido a 21 de fevereiro de 2022 por esta Comissão.

// A request for consideration of an amendment to the *NutriFunction* project was submitted, whose favorable opinion (Rapport 71/2022) was issued on February 21, 2022 by this Committee

O pedido de adenda tem por base a utilização de um densitómetro por absorciometria bifotónica de raio-x (DXA), recentemente adquirido, e que permite obter mais e melhor informação no que diz respeito à avaliação da composição corporal dos participantes no estudo. Foi enviada à Comissão de Ética da FCNAUP toda a documentação atualizada com a inclusão deste novo procedimento, a descrição do projeto, a identificação do risco de realização da DXA, a atualização da informação ao participante e o termo de consentimento informado.

O risco potencial da exposição dos participantes à DXA é o risco de exposição a doses muito baixas de radiação (1 a 10 μ Sv), considerada significativamente menor que a da exposição aquando da realização de uma radiografia de tórax (20 μ Sv), não sendo por isso considerado significativamente prejudicial.

É ainda garantido, pelos investigadores, que, durante este procedimento, serão aplicadas práticas de aquisição de imagem que tornam desnecessária a repetição da aquisição, evitando que os participantes sejam expostos a doses de radiação mais elevadas. O exame completo dura cerca de oito minutos.

Desta forma, considera-se que o risco potencial a que os participantes do estudo se submetem, ao serem expostos a esta metodologia de avaliação da composição corporal por DXA, é superado pelos benefícios do conhecimento gerado com esta avaliação e este projeto.

// The addendum request is based on the use of a recently acquired biphoton x-ray absorptiometry (DXA) densitometer, which allows obtaining more and better information with regard to the assessment of the body composition of the participants in the study. All the documentation updated with the inclusion of this new procedure, the description of the project, the identification of the risk of performing the DXA, the update of the information to the participant and the informed consent form were sent to the Ethics Committee of Faculdade de Ciências da Nutrição e Alimentação da Universidade do Porto.

The potential risk of exposure of participants to DXA is the risk of exposure to very low doses of radiation (1 to 10 μ Sv), considered significantly lower than the exposure for performing a chest X-ray (20 μ Sv), which is not considered significantly harmful.

It is also guaranteed by the researchers that, during this procedure, image acquisition practices will be applied that make it unnecessary to repeat the acquisition, preventing participants from being exposed to higher radiation doses. The DXA evaluation takes about eight minutes.

So, it is considered that the potential risk for participants submitted to DXA evaluation is overcome by the benefits of the knowledge generated with this evaluation and this project.

Conclusão

Pelo exposto, e dado que a análise dos documentos apresentados permitiu verificar que a alteração ao projeto inicial se mostra bem fundamentada e que as questões éticas se mantêm salvas, sendo os participantes informados do risco da realização deste novo procedimento, mantém-se assim o parecer positivo emitido inicialmente no Parecer 71/2022.

A Comissão de Ética solicita o envio do relatório de projeto, após a sua conclusão.

//Conclusion

Taken the above information in consideration, and given that the analysis of all presented documents, made it possible to verify that the amendment to the initial project is well founded and that ethical issues remain safeguarded, with participants informed of the risk of carrying out this new procedure, the opinion is maintained positive, as initially issued in Rapport 71/2022.

The Ethics Commission requests the sending of the project report, after its conclusion.

Faculdade de Ciências da Nutrição e Alimentação da Universidade do Porto, Portugal
13/12/2022

A Relatora / The rapporteur	A Presidente / The President
	
Profª. Doutora Rita Negrão	Profª. Doutora Sara Rodrigues

Annex III - Rapport of the FCNAUP Ethics Committee on the investigation project NutrIC



FACULDADE DE CIÊNCIAS DA NUTRIÇÃO E ALIMENTAÇÃO
UNIVERSIDADE DO PORTO

COMISSÃO DE ÉTICA

Parecer / Rapport

Parecer número / Rapport number: | 115/2022/CEFCNAUP |

Título do projeto / Project Title

NUTRIC – Nutrição e Funcionalidade na Insuficiência Cardíaca

Investigador(es) responsável(eis) / Principal investigator and other researchers

Nome: | Nuno Borges |; Email: | nunoborges@fcna.up.pt |; Função: | Investigador Principal (IP) |.

Nome: | Teresa Amaral |; Email: | tamaral@fcna.up.pt |; Função: | Co-IP |.

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Nome: | Rui Baptista |; Email: | ruibaptista@gmail.com |; Função: | Investigador |.

Parecer / Rapport

☒ Favorável / Favourable ☐ Desfavorável / Not Favourable

Comentários e recomendações / Comments and recommendations:

O projeto

O projeto NUTRIC integra-se autonomamente no projeto “HEALTH-UNORTE” [referência NORTE-01-0145-FEDER-000039].

A Insuficiência Cardíaca (IC) é uma doença crónica que afeta 4% da população adulta portuguesa com um aumento projetado de 33% até 2060, sendo responsável por cerca de 2% das despesas diretas com a saúde nos países desenvolvidos. Está associada a comorbidades do estado nutricional, como a sarcopenia e a fragilidade, e a patologias como a diabetes, a obesidade e a hipertensão arterial. 42% dos pacientes com IC apresentam diminuição da força muscular e da força de preensão da mão (FPM), que é considerado um bioindicador do envelhecimento e marcador do estado nutricional.

// The project

The NUTRIC project is autonomously integrated in the “HEALTH-UNORTE” project [reference NORTE-01-0145-FEDER-000039].

Heart Failure (HF) is a chronic disease that affects 4% of the Portuguese adult population with a projected increase of 33% by 2060, accounting for about 2% of direct health expenditures in developed countries. It is associated with comorbidities of nutritional status, such as sarcopenia and frailty, and pathologies such as diabetes, obesity and high blood pressure. 42% of patients with HF have decreased muscle strength and hand grip strength (HGS), which is considered a bioindicator of aging and a marker of nutritional status.

O objetivo do projeto é:

1. Avaliar a força de preensão da mão (FPM), a composição corporal (através de DXA e/ou análise de impedância bioelétrica), o desempenho físico, a aptidão cardiorrespiratória (CRF), a fragilidade, a sarcopenia e a desnutrição em pacientes com insuficiência cardíaca (IC), a fim de desenvolver novos parâmetros relacionados com a FPM, para melhorar a monitorização e o diagnóstico da IC;
2. Desenvolver indicadores de perfil de FPM, estratificados por composição corporal, em voluntários saudáveis.

// The NUTRIC project aims:

Comissão de Ética da FCNAUP.

1/3

1. To assess hand grip strength (HGS), body composition (through DXA and/or bioelectrical impedance analysis), physical performance, cardiorespiratory fitness (CRF), frailty, sarcopenia and undernutrition in heart failure (HF) patients, in order to develop new parameters related to HGS, to improve monitoring and diagnosis of HF;
2. To develop HGS profile indicators, stratified by body composition, in healthy volunteers.

O projeto está bem fundamentado e a metodologia é adequada.

O projeto NUTRIC é um estudo transversal multicêntrico, que envolve a FCNAUP e hospitais terciários, ainda não identificados, onde os doentes com insuficiência cardíaca realizam as consultas, tratamentos e onde alguns poderão estar internados. Os doentes de IC serão recrutados em ambiente ambulatorio, sendo também utilizada uma amostra de conveniência de doentes internados com IC. Os participantes terão que ter idade igual ou superior a 18 anos. Será ainda recrutada uma amostra de conveniência composta por indivíduos adultos saudáveis. Os potenciais participantes serão contactados pelo entrevistador, que fornecerá informações sobre os objetivos e metodologia do estudo e os convidará a participar.

O estudo pressupõe a resposta a questionários, através de uma entrevista que terá a duração de cerca de 15 minutos, para avaliação das características sociodemográficas, de estilo de vida, desempenho cognitivo, estado de saúde e estado nutricional e funcional.

Serão recolhidos ainda dados antropométricos e realizada a avaliação da composição corporal por DXA e por impedância bioelétrica de multifrequência (BIA). Os participantes interessados serão convidados a realizar densitometria no Laboratório de Composição Corporal da FCNAUP. Será realizada a avaliação funcional por medição da força de preensão da mão e da velocidade de marcha. Aos indivíduos residentes na comunidade serão aplicados os seguintes questionários de avaliação nutricional: *Malnutrition Universal Screening Tool* (MUST) e Mini-Avaliação Nutricional - *Short Form*® (MNA-SF®); bem como questionários de atividade física: *International Physical Activity Questionnaire – Short Form*. Aos indivíduos hospitalizados serão aplicados outros questionários de avaliação nutricional: *Nutritional Risk Screening* (NRS 2002) e *Global Leadership Initiative on Malnutrition* (GLIM). Serão recolhidos dados clínicos dos doentes, obtidos através do médico cardiologista ou por transcrição do registo clínico, sobretudo resultados de avaliação cardíaca, inflamatória e bioquímica.

//The project is well supported and the methodology is adequate.

The NUTRIC project is a multicenter cross-sectional study, involving FCNAUP and tertiary hospitals, as yet unidentified, where patients with heart failure undergo consultations, treatments and where some may be hospitalized. HF patients will be recruited in an outpatient setting, and a convenience sample of hospitalized patients with HF will also be used. Participants must be 18 years of age or older. A convenience sample composed of healthy adult individuals will also be recruited. Potential participants will be contacted by the interviewer, who will provide information about the objectives and methodology of the study and invite them to participate.

*The study presupposes the response to questionnaires, through an interview that will last about 15 minutes, to assess sociodemographic characteristics, lifestyle, cognitive performance, health status and nutritional and functional status. Anthropometric data will also be collected and body composition will be assessed using DXA and multifrequency bioelectrical impedance (BIA). Interested participants will be invited to perform densitometry at the FCNAUP Body Composition Laboratory. Functional assessment will be performed by measuring hand grip strength and gait speed. Individuals residing in the community will be given the following nutritional assessment questionnaires: *Malnutrition Universal Screening Tool* (MUST) and *Nutritional Mini-Assessment - Short Form*® (MNA-SF®); as well as physical activity questionnaires: *International Physical Activity Questionnaire – Short Form*. Other nutritional assessment questionnaires will be applied to hospitalized individuals: *Nutritional Risk Screening* (NRS 2002) and *Global Leadership Initiative on Malnutrition* (GLIM). Clinical data of the patients will be collected, obtained through the cardiologist or by transcription of the clinical record, mainly results of cardiac, inflammatory and biochemical evaluation.*

O curriculum dos investigadores é adequado à realização do estudo.

//The researchers' curriculum is adequate to carry out the study.

O projeto terminará a 30 de setembro de 2023.

//Work will end on 30th September 2023.

Questões éticas envolvidas

Não estão previstos benefícios nem riscos para os participantes deste estudo.

Os participantes terão acesso aos seus resultados e serão informados de qualquer problema que seja detetado durante a investigação.

O único risco potencial é o da exposição dos participantes à DXA (1 a 10 μ Sv), considerado significativamente menor que a da exposição aquando da realização de uma radiografia de tórax (20 μ Sv), não sendo por isso considerado significativamente prejudicial. É ainda garantido que serão aplicadas práticas de aquisição de imagem que evitam que os participantes sejam expostos a doses de radiação mais elevadas. Desta forma, considera-se que o risco potencial a que os participantes do estudo se submetem, ao serem expostos a esta metodologia de avaliação da composição corporal por DXA, é superado pelos benefícios do conhecimento gerado com esta avaliação e este projeto.

Os dados relativos ao estado clínico dos participantes serão recolhidos por cardiologistas. Quando necessário, apenas o pessoal autorizado, como enfermeiros de serviço, cardiologistas ou pessoal administrativo, consultarão os registos clínicos. Todos os dados relativos ao estado nutricional e funcional serão recolhidos por nutricionistas e bolsiros de investigação ou estudantes de licenciatura que integrem a equipa de investigação.

Está prevista a informação ao participante e o preenchimento do consentimento informado, pelos participantes no estudo, sendo expressamente referida a possibilidade de consulta dos registos clínicos dos participantes para recolha de informações relacionadas com o seu estado de saúde, decorrente da insuficiência cardíaca. No consentimento informado é expressamente pedida a autorização para esta consulta.

A liberdade, a autonomia, a pseudo-anonimização (através de codificação) e a confidencialidade estão salvaguardados na informação prestada ao participante e no termo de consentimento informado.

Estão previstos os pedidos de parecer a comissões de ética institucionais, sempre que necessário.

// Ethical issues

No benefits or risks are anticipated for participants in this study.

Participants will have access to their results and will be informed of any problems that are detected during the investigation.

The only potential risk is the exposition of participants to DXA (1 to 10 μ Sv), which is considered significantly less than exposure of a chest X-ray (20 μ Sv), and therefore not considered to be significantly harmful. It is also guaranteed that image acquisition practices applied will prevent participants from being exposed to higher radiation doses. Thus, it is considered that the potential risk of participants exposed to DXA, is outweighed by the benefits of the knowledge generated with this evaluation and this project.

Data regarding the clinical status of participants will be collected by cardiologists. When necessary, only authorized personnel, such as duty nurses, cardiologists or administrative personnel, will consult the clinical records. All data relating to nutritional and functional status will be collected by nutritionists and research fellows or undergraduate students who are part of the research team.

Information to the participant and the completion of the informed consent by the participants in the study is foreseen, with express reference to the possibility of consulting the clinical records of the participants to collect information related to their state of health, resulting from heart failure. The informed consent expressly requests authorization for this consultation. Freedom, autonomy, pseudo-anonymization (through codification) and confidentiality are safeguarded in the information provided to the participant and in the informed consent form.

A Rapport of the institutional ethics committee of each involved institution is foreseen, whenever necessary.

Conclusão

Do exposto, considera-se que o estudo está cientificamente sustentado e cumpre os pressupostos éticos, pelo que obtém o parecer positivo desta Comissão de Ética.

//Conclusion

From the above, it is considered that the study is scientifically supported and complies with ethical assumptions, and thus a favorable opinion is decided by this Ethics Committee.

Faculdade de Ciências da Nutrição e Alimentação da Universidade do Porto, Porto, Portugal
22/12/2022

O Relator / The rapporteur	A Presidente / The President
 Profª. Doutora Rita Negrão	 Profª. Doutora Sara Rodrigues

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