Associations between hand grip strength indicators and body composition: a cross-sectional study

Associações entre indicadores da força de preensão da mão e composição corporal: um estudo transversal

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Abstract

Introduction

Hand grip strength (HGS) is an important marker of muscle strength associated with health outcomes. New dynamometers provide a vast array of information regarding the measurement of force over time, providing potential data to explore new indicators.

Aim

This exploratory analysis aims to construct a HGS indicator, and to study its association with muscle mass and other parameters of nutritional status.

Methods

A convenience sample of adults was recruited. HGS was measured with a GripWise® digital dynamometer and a new indicator, Hand-Grip Maintenance Difficulty Index (HGMDI) was created. Sociodemographic, anthropometric, and functional data were collected. Body composition was estimated by dual energy X-ray absorptiometry.

Results

A total of 179 participants were included, 66.5% women, median (Md) age 33 years, and Md HGDMI 0.78 KgF/s. Women revealed lower HGDMI than men (Md = 0.70 vs. 1.05 KgF/s, respectively). In multivariable analysis, an increase in ALM was associated with higher quartiles of HGDMI (OR=1.53; 95%CI=1.07–2.19), independently of age, sex, and physical activity. Height was associated with higher HGMDI (OR=1.07; 95%CI=1.02–1.13).

Conclusion

In summary, HGMDI can provide valuable insights of force maintenance, highlighting the impact of muscle fiber composition and factors like hand grip strength and appendicular lean mass. However, further research is necessary to deepen our understanding of the biological associations underlying this indicator, as well as the implications of the muscle characteristics and the influence of the type of exercise practiced.

Keys: Hand Grip Strength; Muscle Mass; Strength Assessment; Force Maintenance.

Resumo

Introdução

A Força de Preensão da Mão (FPM) é um importante marcador de força muscular associado a desfechos de saúde. Novos dinamómetros fornecem uma vasta gama de informações da medição da força ao longo do tempo, providenciado potenciais dados para explorar novos indicadores.

Objetivo

Esta análise exploratória tem o objetivo de construir um indicador de FPM, e estudar sua associação com a massa muscular e outros parâmetros do estado nutricional.

Métodos

Uma amostra de conveniência de adultos foi recrutada. A FPM foi medida com um dinamômetro digital GripWise® e um novo indicador, *Hand-Grip Maintenance Difficulty Index* (HGMDI) foi criado. Foram coletados dados sociodemográficos, antropométricos e funcionais. A composição corporal foi estimada por absorciometria de raios X de dupla energia.

Resultados

Um total de 179 participantes foram incluídos, 66,5% mulheres, mediana (Md) de idade de 33 anos e Md de HGMDI de 0,78 KgF/s. As mulheres revelaram menor HGMDI do que os homens (Md = 0,70 vs. 1,05 KgF/s, respectivamente). Na análise multivariada, um aumento no ALM foi associado a quartis mais altos de HGDMI

(OR=1,53;IC95%=1,07–2,19), independentemente de idade, sexo e atividade física. A altura associou-se a um maior HGMDI (OR=1,07;IC95%=1,02–1,13).

Conclusão

O HGMDI pode fornecer informações valiosas da manutenção da força, destacando o impacto da composição da fibra muscular e fatores como FPM e massa magra apendicular. Entretanto, mais pesquisas são necessárias para aprofundar a compreensão das associações biológicas desse indicador, bem como as implicações das características musculares e a influência do tipo de exercício praticado.

Palavras-chave: Avaliação da Força. Manutenção da Força. Força de Preensão da Mão. Indicador.

List of Abbreviations and Acronyms

ALM – Appendicular Lean Mass

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

HGMDI – Hand Grip Maintenance Difficulty Index

HGS – Hand Grip Strength

Summary

Introduction

Muscle mass and muscle functionality are crucial for physical, metabolic, and homeostatic roles in human body[1]. Physiological deficits in both muscular and nervous systems can lead to muscle weakness. This is often related to age, that in addition to generating discomfort from the mobility disability, have been associated to mortality and to other unhealthy outcomes, such as chronic cardiometabolic diseases and neural morbidities[2, 3]. Thereby the determination of muscle strength can be relevant to prevent or delay adverse consequences related to health status.

Hand Grip Strength (HGS) is a non-invasive marker of muscle strength, assessed by a hand grip dynamometer, and has been suggested as an important biomarker of health status and a predictor of outcomes related to nutritional status, such as undernutrition[4, 5]. Furthermore, it has been demonstrated as a valuable diagnostic tool for identifying sarcopenia and for classifying physical frailty[6, 7].

Low HGS is a relevant method to identify increased functional limitations, risk of longer hospitalizations, poor health-related quality of life and mortality[8]. Moreover, measures of HGS can conveniently be included in routine health assessments in clinical and epidemiological settings as it is a quick, simple, and inexpensive way to assess a marker of adverse health outcomes[2, 8].

Nevertheless, the assessment of HGS exhibits a wide range of parameters, protocols, and devices utilized across various studies, resulting in significant

diversity[9], although it is noteworthy that the diagnostic criterion still predominantly relies on measuring maximum force.

Some investigations with small samples explored different parameters derived from the force-time profile, such as the "time to reach maximum force" [10], the duration to achieve specific levels of peak force like 50%, 70%, or 90% [11, 12], the time taken to decrease from peak force to 80%, 70%, and 60% of peak force[13] and the analysis of the area under the force-time curve[10, 11]. Additionally, the studies differ on the test durations, spanning from two seconds[14], to five seconds [10], seven seconds [15], fifteen seconds[16], and even up to sixty seconds[17].

Considering the vast array of possibilities, further exploration of HGS assessment is warranted to enhance the comprehensiveness of potential indicators.

Aim

This exploratory analysis aims to construct a new HGS indicator, and to study its association with muscle mass and other parameters of nutritional status.

Methods

This study was developed within the “NutriFunction - New aspects of muscle function related to nutritional outcomes”, and “NUTRIC – Nutrition and functional status in heart failure”, ongoing at the Faculty of Nutrition and Food Sciences of the University of Porto (FCNAUP), Portugal.

Sample

A cross-sectional study was conducted at FCNAUP, with a convenience sample of subjects of both sexes aged 18 and over.

Exclusion criteria were being pregnant, having edema, using diuretics, and using pacemaker or any other implantable devices. Participants were required to fast and to abstain from physical activity for at least 8 hours prior to the examination.

After signing the informed consent form, information on age, physical activity, self-perception of health status and education were self-reported.

Anthropometric measures

Anthropometric data were collected using the procedures recommended by the International Society of Kinanthropometry (ISAK)[18]. Measurements of weight, height, waist circumference and right-hand length were taken. Body Mass Index (BMI) was calculated using the standard formula [weight (Kg) / height $(m)^2$].

Dual Energy X-Ray Absorptiometry

Body composition was estimated by Whole Body DEXA, using a Hologic Horizon Wi densitometer. Total Appendicular Lean Mass (ALM) was calculated in kg/m^2, and the body fat was estimated in percentual.

Physical activity and performance variables

Physical activity was assessed using the International Physical Activity Questionnaire – Short Form (IPAQ-SF)[19], validated for the Portuguese population. Activity levels were categorized as "Inactive", "Minimally Active" and "Active". Sitting time was also registered.

Gait speed was measured as the time spent to walk a course of 4.6m at a normal gait, in m/s[7].

Hand Grip Strength (HGS)

The participants' HGS profile was evaluated using a GripWise® dynamometer, which interacts with a software application. The validity of this device was assessed against the gold-standard Jamar dynamometer[20]. HGS was measured according to the American Society of Hand Therapists protocol[21]. Hand dominance information was self-reported. HGS measurements consisted in three trials in each hand, in which continuous force was made with a time duration of 15 seconds.

The GripWise® system allows the recording in a database of the force *vs.* time profile for each participant during a time interval, providing a real-time graphical representation and a "comma-separated values" (.csv) file containing 100 HGS measured values per second for each of the six measures. These data were imported into Microsoft Excel® for analysis.

Hand-Grip Maintenance Difficulty Index (HGMDI)

A total of 191 subjects were evaluated and the force-time values of 179 participants (119 females and 60 males) were taken in consideration, with 12 subjects having been excluded due to incomplete HGS data. The characteristics of this HGS digital device allowed the study to create a new potential indicator of force *vs.* time profile that was not only related to the maximum force of the HGS.

Therefore, the Hand-Grip Maintenance Difficulty Index (HGMDI) was created using Microsoft Excel® to assess the difficulty of the subjects maintaining the force after the peak of force. Figure 1 shows a typical behavior of HGS in a 15s measure and the proposed descriptors from the force-time curve used to calculate the new indicator. The trial was chosen taking in consideration the measure that contained the highest value of the maximum force applied to the device.

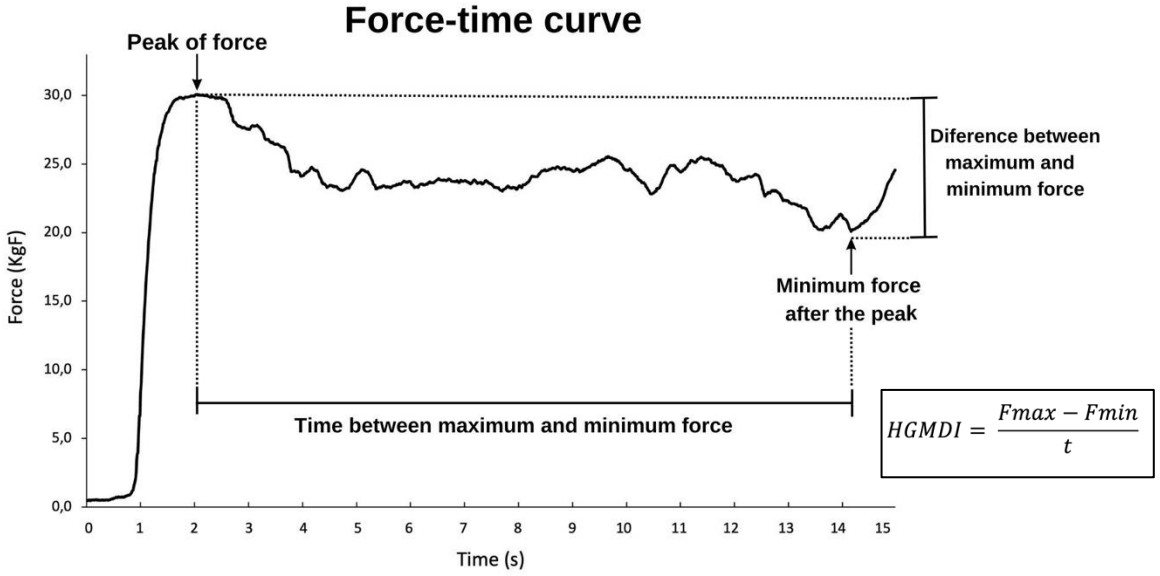

Figure 1. Proposed descriptors in a typical HGS force-time curve and how they were used to calculate the HGMDI, emphasizing the peak force in the 15s test (F_{max}), the minimum force after reaching the maximum force (F_{min}) and the time it takes to reach the minimum force after the maximum force has been applied (t).

Statistical analysis

Descriptive analysis was conducted on tertiles of HGMDI as a dependent variable. Normality tests were performed on continuous variables and one-way ANOVA or Kruskal-Wallis tests were performed on variables with normal or non-normal distribution, respectively. Values for continuous variables were depicted in medians (Md) and inter-quartile ranges (IQR). Chi-square or Fisher exact tests were conducted to assert differences on categorical variables.

A proportional odds model was constructed using ordinal logistic regression regarding the association of ALM with HGMDI quartiles, adjusted for age, sex, standing height and physical activity level (active vs. minimally active and inactive). Unadjusted values were also reported. The test of parallel lines was used to assert the proportional odds assumption of the ordinal regression analysis. Multivariable results are presented in proportional odds ratios (OR) and 95% confidence intervals (95%CI).

SPSS statistics V.27 (IBM) was used to conduct statistical analysis. A significance of $p < 0.05$ was assumed for all results.

Ethics

All procedures were conducted in accordance with the Declaration of Helsinki. Every participant signed an informed consent. The NutriFunction (Annex I) and NUTRIC (Annex II) studies were approved by the Ethics Committee of FCNAUP (references 71/2022 and 115/2022, respectively).

Results

A total of 179 participants were included in this study (66.5% women, median age 33 years old, IQR = 23 years). The subjects had a HGMDI median of 0.78 KgF/s (IQR = 0.42 KgF/s; min = 0.23 KgF/s, max: 2.98 KgF/s). Women revealed a much lower HGMDI than men (Md = 0.70 KgF/s vs. 1.05 KgF/s, respectively; $p < 0.001$).

Characteristics of the studied sample regarding HGMDI tertiles are presented on Table 1, stratified by sex. Older age and slower gait were associated with lower HGMDI only in women. Higher HGS was associated with higher HGMDI in both sexes ($p < 0.05$).

Table 1. Baseline characteristics by Hand Grip Maintenance Difficulty Index (HGMDI) tertiles

	Women *(n = 119)*				Men *(n = 60)*			
	Lowest tertile *(n = 40)*	Middle tertile *(n = 38)*	Highest tertile *(n = 41)*	p-value	Lowest tertile *(n = 20)*	Middle tertile *(n = 20)*	Highest tertile *(n = 20)*	p-value
HGMDI (KgF/s)	0.50 (0.16)	0.70 (0.10)	0.92 (0.24)	<0.001	0.72 (0.27)	1.04 (0.14)	1.63 (0.61)	<0.001
Age (years)	45 (17.00)	31 (29.00)	24 (14.00)	<0.001	35 (24.00)	31 (19.00)	34 (20.00)	0.711
Education (years)	17 (2.00)	17 (3.25)	16 (2.50)	0.289	17 (2.00)	17 (3.75)	16 (5.00)	0.097
Height (cm)	162.00 (5,88)	161.60 (6.93)	163.10 (7.10)	0.133	173.30 (10.45)	175.35 (9.05)	176.05 (6.25)	0.229
Weight (Kg)	57.00 (11.30)	55.70 (8.53)	57.00 (11.95)	0.446	69.20 (15.60)	77.30 (17.80)	77.45 (23.32)	0.076
Body Mass Index (Kg/m^2)	21.83 (3.84)	21.21 (3.58)	21.20 (3.93)	0.904	23.62 (3.87)	25.38 (4.10)	25.13 (5.91)	0.228
Waist Circumference (cm)	70.60 (12.63)	68.65 (8.17)	71.2 (10.80)	0.913	80.6 (8.90)	85.4 (9.98)	89.35 (24.35)	0.245
Body fat (%)	30.40 (12.00)	29.46 (9.89)	29.54 (6.44)	0.508	20.67 (7.11)	23.20 (9.15)	28.84 (11.69)	0.177
Hand Length (cm)	17.80 (1.23)	18.30 (1.07)	18.10 (1.15)	0.270	19.20 (1.30)	19.90 (1.08)	19.75 (1.58)	0.094
Maximum Hand Grip Strength (Kgf)	22.03 (5.66)	24.14 (4.25)	24.92 (7.07)	0.031	37.15 (11.98)	40.75 (10.73)	44.90 (13.15)	0.005
Gait Speed (m/s)	1.40 (0.44)	1.57 (0.35)	1.42 (0.42)	0.041	1.38 (0.42)	1.35 (0.64)	1.45 (0.62)	0.709
Sitting Time (hours/day)	6.00 (4.25)	7.00 (2.25)	7.00 (5.50)	0.756	6.00 (3.75)	6.00 (3.38)	6.50 (4.75)	0.995
Appendicular Lean Mass (Kg/m^2)	5.96 (0.80)	5.96 (0.67)	6.24 (1.11)	0.278	7.99 (1.08)	8.24 (1.66)	8.40 (1.95)	0.458

(Continued)

Table 1. Continued

	Women *(n = 119)*				Men *(n = 60)*			
	Lowest tertile *(n = 40)*	Middle tertile *(n = 38)*	Highest tertile *(n = 41)*	p-value	Lowest tertile *(n = 40)*	Middle tertile *(n = 38)*	Highest tertile *(n = 41)*	p-value
Body Fat (%)	30.40 (12.00)	29.46 (9.89)	28.54 (6.44)	0.508	20.67 (7.11)	23.20 (9.15)	23.84 (11.69)	0.177
Physical-Activity level, n (%)								
Inactive	6 (15.00)	5 (13.20)	6 (14.60)		2 (10.00)	5 (25.00)	0 (0.00)	
Minimally active	15 (37.50)	18 (47.40)	10 (24.40)	0.302	8 (40.00)	7 (35.50)	8 (40.00)	0.197
Active	19 (47.50)	15 (39.50)	25 (61.00)		10 (50.00)	8 (40.00)	12 (60.00)	
Self-perception of health status, n (%)								
Very good	14 (35.00)	10 (26.30)	15 (36.60)		8 (40.00)	5 (25.00)	9 (45.00)	
Good	18 (45.00)	16 (42.10)	23 (56.10)		10 (50.00)	10 (50.00)	9 (45.00)	
Not good or bad	6 (15.00)	12 (31.60)	3 (7.30)	0.065	2 (10.00)	5 (25.00)	1 (5.00)	0.401
Bad	2 (5.00)	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	1 (5.00)	
Very bad	0 (0.00)	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	0 (0.00)	

All results depict medians and inter-quartile ranges, except when indicated otherwise.

Regarding the multivariable analysis (Table 2), an increase in ALM was associated with higher quartiles of HGMDI (OR = 1.53; 95% CI = 1.07 – 2.19), independently of age, sex, and physical activity level. For each cm increase in height, the probability of being allocated in a higher HGMDI increased by 7% (OR = 1.07; 95% CI = 1.02 – 1.13).

Table 2. Results from the ordinal regression regarding HGMDI quartiles

	Unadjusted model		Adjusted model	
	OR	95% CI	OR	95% CI
ALM	2.28	1.78 – 2.90	1.53	1.07 – 2.19
Age	0.97	0.95 – 0.99	0.97	0.95 – 2.19
Sex				
Women	1		1	
Men	0.13	0.07 – 0.24	0.57	0.20 – 1.59
Height	1.14	1.09 – 1.18	1.07	1.02 – 1.13
Physical activity				
Inactive and minimally active	1		1	
Active	1.45	0.85 – 2.45	0.68	0.38 – 1.18

HGMDI = Hand Grip Maintenance Difficulty Index. ALM = Appendicular Lean Mass. OR = proportional Odds Ratio. 95% CI = 95% Confidence Intervals. Test of parallel lines: $p > 0.05$.

Discussion

This exploratory analysis reveals an interesting association between ALM and the ability to sustain maximum force, regardless of age, sex, and physical activity level. Individuals with higher appendicular lean mass exhibited a greater probability of experiencing difficulties in maintaining maximum force.

The skeletal muscle exhibits a remarkable diversity of fiber types, characterized by distinct morphological, biochemical, and functional attributes[22]. This diversity enables the distinct activation of muscle fibers to accomplish different functional tasks and force generation [23].

There are two major fiber types, slow-twitch (Type I) and fast-twitch (Type II), that determine the four distinct types of skeletal muscle fibers. Further subdivision of the Type II fiber are the subtypes IIA, IIB, and IIX[24].

Slow-twitch (Type I) muscle fibers are characterized by low glycolytic activity, resistance to fatigue, reliance on oxidative metabolism for energy production, and the ability to sustain contractions over extended periods with relatively low force generation[25]. On the other hand, fast-twitch (Type II) muscle fibers exhibit high glycolytic activity, faster contraction times, the capacity for short bursts of anaerobic activity, but are more prone to fatigue compared to Type I fibers[25].

Resistance exercise is characterized by low-frequency, high-intensity contractions against external resistance to promote muscle bulk, and stimulates the increase of satellite cells, predominantly Type II muscle fibers[24]. This observation suggests that the subjects in our sample may have been more inclined to the practice of resistance exercise, given its recognized influence on lean muscle mass.

Moreover, we observed a bivariate discrepancy in HGMDI between women and men, that indicated that women faced less difficulty in sustaining the maximum force than men. This could lead to the hypothesis that HGMDI is able to identify pertinent biological differences between sexes concerning muscle fiber composition.

A study of the vastus lateralis muscle composition in young men and women revealed gender discrepancies in muscle fiber composition[26]. Specifically, women exhibited larger Type I fibers, while men displayed larger Type IIB fibers[26].

Therefore, this new indicator could speculatively be reflecting the biological comportment of muscle fiber composition, suggesting a higher abundance of Type I fibers in women and a higher proportion of Type II fibers in men within the studied subjects.

A review explored the physiological changes that occur in adipose tissue with aging, and how these changes contribute to the harmful effects on skeletal muscle, known as lipotoxicity[27]. The authors studied the impact on contractility of different types of muscle fibers and revealed that the decline in satellite cell content and muscle atrophy associated with aging is more pronounced in Type II fibers compared to Type I fibers.

Building upon this, our findings suggest that older women experienced less difficulty in maintaining maximum force. This could be explained by the fact that these individuals may have a lower proportion of Type II fibers and that the new indicator used in the study may indeed reflect the biological composition of the muscle.

In multivariable analysis, sex was not associated with HGMDI and this loss in association could possibly be related to the effect of muscle quantity estimated by ALM. This may signify that the interplay between muscle quantity, quality and strength may be complex and warranting further study.

Additionally, this study reveals intriguing findings regarding the relationship between HGS and the ability to sustain force. Surprisingly, higher HGS values were found to be linked with increased difficulty in maintaining force after its peak, regardless of the sex.

In a previous study which was also centered on HGS indicators, albeit rather diverse from the HGMDI, different patterns of force endurance were identified in a sample of 94 individuals, with those who had higher average force during the time of the trial having a slower rate of force decay[9]. The present study further elucidates the relation between maximum force and endurance.

While the mechanisms underlying this relationship are still elusive, this observation led us to hypothesize that subjects with greater HGS may exhibit a higher prevalence of Type II muscle fibers. Consequently, while they may demonstrate higher HGS, their muscles were more prone to fatigue quickly.

This exploratory analysis had limitations, including a small sample size, uneven distribution of participants across genders and the sample was highly homogeneous, raising concerns about its ability to accurately represent the community. Additionally, the cross-sectional approach used in this study had limitations including susceptibility to bias and confounding variables, and the inability to establish causal relationships or track individual trajectories over time.

Therefore, further research is necessary to obtain a more comprehensive understanding of the new indicator.

Conclusion

In summary, HGMDI can provide valuable insights of force maintenance, highlighting the impact of muscle fiber composition and factors like hand grip strength and appendicular lean mass. However, further research is necessary to deepen our understanding of the biological associations underlying this indicator,

as well as the implications of the muscle characteristics and the influence of the type of exercise practiced.

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Annex I – Statement of the ethics committee of the Nutrifunction project

U.PORTO

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-I3ID, FCS

Outras instituições como lares, instituições locais de saúde e hospitais

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Relator: Rita Negrão

Âmbito do Projeto submetido: Projeto de investigação

Duração do estudo: É referido que o estudo poderá ser iniciado se e quanto 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 clinico, 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
Rita Negrão	Sara SP Rodrigues
Profª. Doutora Rita Negrão	Profª. Doutora Sara Rodrigues

Annex II – Statement of the ethics committee of the NUTRIC project

U.PORTO

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|.
Nome: |Rui Valdiviesso|; Email: | ruivaldiviesso@fcna.up.pt|; Função: |Coordenador Executivo|.
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:

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 ambulatório, 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 µSv), considerado significativamente menor que a da exposição aquando da realização de uma radiografia de tórax (20 µSv), 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 registros clínicos. Todos os dados relativos ao estado nutricional e funcional serão recolhidos por nutricionistas e bolseiros 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 µSv), which is considered significantly less than exposure of a chest X-ray (20 µSv), 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*
Rita Negrão	Sara SP Rodrigues
Profª. Doutora Rita Negrão	Profª. Doutora Sara Rodrigues