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#### **RESEARCH PAPER**



# Validation of the Lithuanian version of sarcopenia-specific quality of life questionnaire (SarQoL<sup>®</sup>)

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#### **Key summary points**

Aim To translate and culturally adapt the SarQoL<sup>®</sup> questionnaire into Lithuanian language and investigate its main psychometric properties.

**Findings** The total score of the SarQoL<sup>®</sup> questionnaire was significantly lower for sarcopenic subjects compared to non-sarcopenic subjects. Cronbach's alpha coefficient was 0.95. The SarQoL<sup>®</sup> questionnaire revealed good construct validity and test–retest reliability.

Message Lithuanian version of the SarQoL<sup>®</sup> can be used to assess quality of life in sarcopenic population.

#### Abstract

**Purpose** The aim of this study was to translate and culturally adapt the SarQoL<sup>®</sup> questionnaire into Lithuanian and investigate its main psychometric properties.

**Methods** A cross-sectional study was performed on community-dwelling Lithuanian people aged  $\geq 60$  years. The revised criteria of the European Working Group on Sarcopenia in Older People were used. A forward–backward methodology was used for the translation, with a pre-test of the final version of the Lithuanian SarQoL<sup>®</sup> questionnaire. Adjusted logistic regression analysis was used to compare sarcopenic and non-sarcopenic subjects. Internal consistency was determined using Cronbach's alpha coefficient. The correlation of total score of the SarQoL<sup>®</sup> and each domain of the Short-form General Health Survey (SF-36) and EuroQol-5D (EQ-5D) questionnaires was measured using Spearman's correlations. Test–retest reliability was measured by the intraclass correlation coefficient.

**Results** The study was performed on 176 subjects. Fifty-eight subjects were diagnosed with sarcopenia. After adjustment for confounders, the total score of the SarQoL<sup>®</sup> questionnaire was significantly lower for sarcopenic subjects compared to non-sarcopenic subjects ( $50.32 \pm 8.58 \text{ vs } 73.75 \pm 13.51$ , p < 0.001). Cronbach's alpha coefficient was 0.95. Neither floor nor ceiling effects were found. The SarQoL<sup>®</sup> questionnaire revealed good correlation with similar domains of the SF-36 and EQ-5D questionnaires for convergent validity and weak correlations with different domains for divergent validity, confirming its construct validity. An excellent agreement between test and retest was found with an ICC of 0.976 (95% CI 0.959–0.986). **Conclusions** Lithuanian version of the SarQoL<sup>®</sup> is valid, reliable and consistent and could be used to assess quality of life in sarcopenic population.

Keywords Sarcopenia · Quality of life · SarQoL<sup>®</sup> · Translation · Validation

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# Introduction

Sarcopenia is a geriatric syndrome, characterized by the loss of both skeletal muscle mass and function (strength or performance) [1]. A meta-analysis and systematic review published in 2017 by Shafiee et al. [2] revealed that the prevalence of sarcopenia in the world could be around 10% in healthy adults aged  $\geq 60$  years. Sarcopenia is associated

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with unfavorable outcomes such as falls, functional decline, increased hospitalization and death [3, 4]. The European Working Group on Sarcopenia in Older People (EWGSOP) published its sarcopenia definition in 2010 [1]. In 2018, the revised definition and diagnostic criteria of sarcopenia were accepted via consensus: it was concluded by EWGSOP2, that low muscle strength is a key characteristic of sarcopenia, additional detection of low muscle mass defines sarcopenia, and both those symptoms together with low physical performance describes severe sarcopenia [5].

Quality of life is a subjective topic. Usually, assessment is carried out with well-constructed questionnaires. Evaluation of quality of life is important for healthcare providers to understand the burden of the disease in people with a specific condition [6]. Quality of life instruments should prioritize potential problems, facilitate communication and, in some cases, monitor changes in disease course or evaluate response to specific treatment. Using the appropriate quality of life questionnaire in everyday practice assures that treatment and evaluation focuses on the person rather than on the illness [7]. Until recently, the influence of sarcopenia on quality of life was poorly understood. To explore sarcopenia and its impact on quality of life, investigators [8, 9] have had to use generic questionnaires-EuroQol-5D (EQ-5D) and Short-form General Health Survey (SF-36) [10, 11]. That is why, in 2015 Beaudart et al. [12] developed sarcopenia-specific quality of life questionnaire-the Sarcopenia Quality of Life (SarQoL®) questionnaire. This questionnaire consists of 55 items which covers 7 domains of health-related dysfunction: Physical and mental health, Locomotion, Body composition, Functionality, Activities of daily living, Leisure activities, and Fears [12]. Translation of this questionnaire into Lithuanian was important to for two reasons. First of all, an international questionnaire would be accessible to Lithuanian patients. Second, it would be possible to analyze and compare the results of the SarQoL<sup>®</sup> questionnaire between different countries. That is why the aim of this study was to translate and cross-culturally adapt the Lithuanian version of SarQoL<sup>®</sup> questionnaire and to explore its principal psychometric properties.

# Methods

### **Study population**

This cross-sectional study was conducted at the National Osteoporosis Centre, an outpatient clinic in Vilnius, Lithuania. Inclusion criteria were: age 60 years or more; community-dwelling ambulatory women and men whose mother tongue is Lithuanian. The exclusion criteria were: moderate cognitive impairment—with score <21/30 on the mini-mental state examination (MMSE) [13]; score above

5 on Geriatric depression scale 15 (GDS-15) which was suggestive of depressive symptoms [14]; acute illness; diseases with advanced organ failure, e.g., heart, lung, liver, kidney, brain; and malignancy. All subjects were measured for height and weight. The short physical performance battery (SPPB), dynamometry and body composition measurement were performed. The number of concomitant illnesses and medications were collected from medical records. At baseline, all subjects completed the SarQoL<sup>®</sup>, as well as the SF-36 and the EQ-5D questionnaires. After 2 weeks, only sarcopenic subjects were asked to complete the SarQoL<sup>®</sup> again.

#### Assessment of sarcopenia

The criteria for diagnosis of sarcopenia, proposed in 2018 by the European Working Group on Sarcopenia in Older People (EWGSOP2) were used in this research: low muscle strength and low muscle mass [5]. Additionally, low physical performance was used to assess severe sarcopenia. Muscle mass was measured by dual-energy X-ray absorptiometry (iDXA, GE Lunar, USA). A skeletal muscle mass index was calculated by dividing appendicular skeletal muscle mass by the subjects' height squared. The proposed cutoffs of 7 kg/  $m^2$  for men and 6 kg/m<sup>2</sup> for women were used [15]. Muscle strength was assessed by handgrip strength. A hydraulic dynamometer (JAMAR, Patterson Medical, UK) was used for this purpose, and the assessments were made in accordance with the Southampton protocol [16]. The cutoffs of 27 kg for men and 16 kg for women were used as the diagnostic criteria of sarcopenia [17]. Both devices—DXA machine and hand dynamometer-were calibrated according to the manufacturer's instructions. Physical performance was evaluated by short physical performance battery (SPPB) composed of three tests: balance, 4-m gait speed and chair stand. A total of 12 points can be earned. The cutoff of 8 points or less was used to diagnose severe sarcopenia [18].

#### Lithuanian translation of the SarQoL<sup>®</sup>

The translation was performed in accordance with the guidelines proposed by Beaton et al. [19]. First of all, a primary translation from French to Lithuanian was made by two bilingual independent translators whose mother tongue was Lithuanian. The two translations were fused and made into one version. Then the backward translation to French was done by two bilingual independent translators who had French as their native language and who were blinded to the original version of questionnaire. After that, an expert committee (consisting of a geriatrician, a linguist, and two methodologists) compared the backward translations with the original French questionnaire and decided on a second version of the translated questionnaire. The pre-test of the

second version of the SarQoL<sup>®</sup> was carried out by submitting the questionnaire to 16 sarcopenic subjects. Subjects were asked about any problems they had with questionnaire: question wording, questionnaire layout, and word order. This was done to guarantee good understanding of the questionnaire. After that, the final version of questionnaire was created.

#### **Psychometric performance analyses**

To determine questions relations to each other and intention to measure the same concept, the internal consistency of questionnaire was evaluated. The discriminative power of the questionnaire reveals whether it can establish significant differences between different groups, e.g., healthy and ill subjects. Floor and ceiling effects are considered to be present when a high percentage (15%) of the study population has the lowest (0) or the highest (100) score for the Total SarQoL<sup>®</sup> score. Construct validity was assessed using convergent validity and divergent validity, and carried out only with sarcopenic persons. This evaluates the questionnaire's ability to measure what it is intended to measure. Convergent validity explores associations between domains of questionnaires that should be similar. On the opposite, divergent validity explores associations between domains of questionnaires that should be different. For convergent validity, we hypothesized that good correlations will be found between the overall score of the SarQoL® and similar domains of the SF-36 (physical functioning, role limitation due to physical problems, vitality) and EQ-5D (utility score). For divergent validity, we considered that weak correlations will be found between the overall score of the SarQoL® and different domains of the SF-36 (mental health, role limitation due to emotional problems) and EQ-5D (self-care, anxiety/depression) questionnaires. To analyze the test-retest reliability, after 2 weeks sarcopenic subjects were asked to fill in the questionnaire again. The retest was performed only in subjects without changes in their general health over this 2-week period. Self-declared information about changes in general health (acute illness, hospitalization, etc.) was accepted. The intraclass correlation coefficient (ICC) was used to evaluate the test-retest reliability. This analysis serves to assess consistency of response in same subject over period of time.

#### Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics Windows software version 18 (IBM, New York). Normality of data was examined by Shapiro–Wilk test. Data with normal distribution was expressed as mean and standard deviation. Data that were not normally distributed was reported as median and 25th–75th percentile. Nominal data were reported as frequencies (number, percentage). Differences between sarcopenic and non-sarcopenic subjects in univariate analysis were analyzed using Mann–Whitney U test. Internal consistency was determined using Cronbach's alpha coefficient. A value between 0.7 and 0.9 was indicative of high level of internal consistency. The impact of deleting one domain at a time on the internal consistency was also tested. Logistic regression analysis was used to compare sarcopenic and non-sarcopenic subjects. The regression model was adjusted for clinical parameters which were significantly different between groups in clinical characteristics. The correlation of each domain with the overall score of the SarQoL<sup>®</sup> and between the SarQoL<sup>®</sup> and SF-36, EQ-5D questionnaires for convergent and divergent validity were measured using Spearman's correlations. Correlations above 0.81 were considered as excellent, between 0.8 and 0.61-as very good, between 0.6 and 0.41-as good, between 0.4 and 0.21—as acceptable, and less than 0.2—as insufficient [10]. An intraclass correlation coefficient over 0.7 was considered to show suitable reliability for the whole questionnaire and for the individual domains of the SarQoL<sup>®</sup> [7]. Level of significance (p value) of < 0.05 was considered as statistically significant.

# Results

SarQoL<sup>®</sup> questionnaire was translated without any major problems. Discussion was about structure of some questions, word order, and exact meaning of few words. All differences were resolved by consensus within the expert committee. A pre-test version was filled in by 16 subjects. After interviewing subjects no changes to the questionnaire were deemed necessary. A total of 207 people, who previously volunteered in other of our studies, were invited by phone to participate in this study. Twenty-two declined the offer, 6 subjects were excluded because their mother tongue was not Lithuanian. One subject was excluded due to acute illness and 2 due to advanced chronic diseases. Subjects were invited to study center for further evaluation. A total of 176 subjects participated in this study: 105 women (59.7%) and 71 men (40.3%). The median age of subjects was 78.2 (74.1–82.6) years. According to EWGSOP2 criteria, sarcopenia was present in 58 persons, of which 47 (81.03%) had severe sarcopenia. Basic descriptive characteristics of study population are shown in Table 1.

In our study, sarcopenic subjects were significantly older, scored lower on the MMSE, had more chronic illnesses, and were taking more medications than non-sarcopenic individuals. Although sarcopenic subjects scored lower on the MMSE, these values are in range of no cognitive impairment and the difference between the two groups was not clinically significant. Table 1Basic descriptivecharacteristics of studypopulation (median, 25th–75thpercentile)

Characteristic	All subjects $(n = 176)$	No sarcopenia $(n = 118)$	Sarcopenia $(n = 58)$	p value
Age, years	78.2 (74.1–82.6)	76.6 (73.4–81.25)	80.5 (74.9-85.7)	0.001
Sex				
Male (%)	71 (40.3)	38 (32.2)	33 (56.9)	0.002
Female (%)	105 (59.7)	80 (67.8)	25 (43.1)	0.002
Height (cm)	172 (168–175)	171 (166.75–175)	172 (169–176.25)	0.114
Weight (kg)	69 (64.25–73.3)	69 (64–76)	70 (65–73)	0.458
BMI (kg/m <sup>2</sup> )	23.38 (21.91–25.22)	23.66 (21.94–26.42)	23.37 (21.47–24.39)	0.108
MMSE, score	29 (28-30)	29 (28–30)	28 (27–29)	< 0.001
GDS-15, score	4 (3–5)	4 (3–5)	4 (3–5)	0.086
Number of comorbidities	2 (1-3)	1.5 (1–2)	3 (2–3)	< 0.001
Number of medications	3 (2–4)	2 (1–3)	4 (3–5)	< 0.001
SMI (aSM/m <sup>2</sup> )	6.54 (5.37–7.6)	7.32 (6.41–7.89)	5.11 (4.71–5.71)	< 0.001
Male	6.88 (5.36-7.61)	7.59 (7.39–7.86)	5.27 (5.11-6.49)	< 0.001
Female	6.52 (5.38-7.58)	7.03 (6.22–7.9)	5.07 (4.58-5.39)	< 0.001
Handgrip strength (kg)	21 (16-25.75)	22 (18-27.25)	15 (12.75–21)	< 0.001
Male	23 (18–27)	27 (22–29)	20 (15-23)	< 0.001
Female	19 (15–22.5)	21 (18–23)	12 (12–15)	< 0.001
SPPB, score	8 (6–10)	9 (7–10)	3 (1–8)	< 0.001

Calculated using Mann-Whitney U test when comparing non-sarcopenic and sarcopenic subjects

*BMI* body mass index, *MMSE* mini-mental state examination, *GDS-15* geriatric depression scale-15, *SMI* skeletal mass index, *aSM* appendicular skeletal mass, *SPPB* short physical performance battery

#### **Psychometric property analyses**

Internal consistency: Cronbach's alpha for Lithuanian version of the SarQoL<sup>®</sup> questionnaire was 0.95. When the domains of the questionnaire were eliminated one at a time, the Cronbach's alpha values varied between 0.94 (for Physical and mental health, Locomotion or Functionality domains) and 0.96 (for Leisure activities), as seen in Table 2. Furthermore, associations between the total score of the SarQoL<sup>®</sup> and individual domains are also shown in Table 2.

All SarQoL<sup>®</sup> domains showed a significant positive correlation with the total score, ranging from very good

(in Leisure activities) to excellent (in Functionality and Activities of daily living).

The discriminative power of the SarQoL<sup>®</sup> questionnaire can be seen in Table 3.

Non-sarcopenic subjects reported better global quality of life compared to sarcopenic ones  $[73.75 \pm 13.51 \text{ vs} 50.32 \pm 8.58; \text{OR} = 0.913 (0.876-0.951); p < 0.001]$ . This shows that the Lithuanian SarQoL<sup>®</sup> questionnaire has good discriminative power. Also, sarcopenic subjects had significantly lower quality of life scores for all domains of the questionnaire.

Table 2 Correlations between the total score and individual domains of the SarQoL<sup>®</sup> questionnaire, Cronbach's alpha when deleting one domain at a time, and intraclass coefficient correlation (ICC) in sarcopenic subjects

Domains	Total score of the SarQoL <sup>®</sup> , $r$ (n = 176)	p value	Cronbach's alpha $(n=176)$	ICC (95% CI) ( <i>n</i> =54)
D1 Physical and mental health	0.901	< 0.001	0.94	0.939 (0.898–0.964)
D2 Locomotion	0.893	< 0.001	0.94	0.957 (0.927-0.975)
D3 Body composition	0.836	< 0.001	0.95	0.956 (0.925-0.973)
D4 Functionality	0.959	< 0.001	0.94	0.969 (0.947-0.982)
D5 Activities of daily living	0.950	< 0.001	0.95	0.987 (0.978-0.993)
D6 Leisure activities	0.713	< 0.001	0.96	0.854 (0.761-0.913)
D7 Fears	0.791	< 0.001	0.95	0.875 (0.793-0.926)
Total score	-	-	-	0.976 (0.959–0.986)

Calculated using Spearman's correlation, r correlation coefficient, CI confidence interval

SarQoL <sup>®</sup> domains	No sarcopenia $(n=118)$	Sarcopenia ( $n = 58$ )	Odds ratio	95% Confidence interval	p value
D1 Physical and mental health	$67.75 \pm 14.63$	$42.57 \pm 10.14$	0.926	0.892–0.962	< 0.001
D2 Locomotion	$69.11 \pm 16.27$	$41.52 \pm 11.67$	0.934	0.903-0.965	< 0.001
D3 Body composition	$64.44 \pm 13.88$	$42.88 \pm 12.16$	0.943	0.909-0.979	0.002
D4 Functionality	$79.29 \pm 14.49$	$55.58 \pm 9.5$	0.925	0.89-0.961	< 0.001
D5 Activities of daily living	$79.19 \pm 15.39$	$57.44 \pm 11.73$	0.94	0.91-0.971	< 0.001
D6 Leisure activities	$45.36 \pm 12.42$	$28.66 \pm 11.97$	0.94	0.906-0.976	0.001
D7 Fears	$80.29 \pm 15.45$	$62.93 \pm 12.38$	0.963	0.931-0.997	0.034
Total score	$73.75 \pm 13.51$	$50.32 \pm 8.58$	0.913	0.876–0.951	< 0.001

Table 3 Discriminative power of the SarQoL<sup>®</sup> questionnaire (mean  $\pm$  SD)

Calculated using binary logistic regression adjusted for age, number of medications, and number of comorbidities

Floor and ceiling effects: none of the sarcopenic subjects scored 0 or 100 points (lowest/highest score). Subsequently, neither floor nor ceiling effects are present.

Construct validity: the associations between the total score of the SarQoL<sup>®</sup> and domains of SF-36 and EQ-5D questionnaires assessing convergent and divergent validity are shown in Table 4.

Very good to good correlations can be seen between the SarQoL<sup>®</sup> and some domains of the SF-36 and the EQ-5D questionnaires which were supposed to have similar dimensions such as: Physical functioning, Role limitation due to physical problems, Vitality, and Utility score. In regards to divergent validity, weaker correlations were found between total score of the SarQoL<sup>®</sup> and some domains of the SF-36 and the EQ-5D questionnaires which had different dimensions: Role limitation due to emotional problem, Mental health, Self-care, and Anxiety/depression.

Test-retest reliability: the test-retest analysis was performed on 54 (93.1%) subjects. Four subjects were excluded due to a change in health status during the interval period of 2 weeks. An intraclass correlation coefficient of 0.976 (95% CI 0.959–0.986) for the total score of the SarQoL<sup>®</sup> was found which marks an excellent agreement between test and retest. As can be seen in Table 2, the highest ICC was found for Activities of daily living (0.987, 95% CI 0.978–0.993) and the lowest ICC of 0.854 (95% CI 0.761–0.913) was found for Leisure activities.

# Discussion

The results of our study show that the Lithuanian version of the SarQoL<sup>®</sup> is reliable, valid and discriminant questionnaire, useful for the assessment of quality of life in subjects with sarcopenia. SarQoL<sup>®</sup> is the first quality of life questionnaire specific to sarcopenia that is available in Lithuanian. This instrument is necessary to better understand what impact sarcopenia has on quality of life. Publications of the SarQoL<sup>®</sup> validation are available in French, English, Romanian, Dutch, Polish, and Greek languages [20–25]. Our study was the first to use EWGSOP2 criteria in SarQoL<sup>®</sup> validation studies. A comparison of SarQoL<sup>®</sup> validation studies is shown in Table 5.

The analysis of psychometric properties showed that the Lithuanian version of the SarQoL<sup>®</sup> questionnaire is able

Table 4 Correlations of the total score of the SarQoL<sup>®</sup> questionnaire with SF-36 questionnaire and the EQ-5D questionnaire in sarcopenic subjects

	Scores, median (Q1–Q3)	Total score of the SarQoL <sup>®</sup> , <i>r</i>	p value
Convergent validity			
SF-36 Physical functioning	60 (55–75)	0.554	< 0.001
SF-36 Role limitation due to physical problems	50 (25-100)	0.519	< 0.001
SF-36 Vitality	60 (50-70)	0.559	< 0.001
EQ-5D Utility score	70 (53.5-80)	0.576	< 0.001
Divergent validity			
SF-36 Role limitation due to emotional problems	0 (0–100)	0.362	< 0.001
SF-36 Mental health	60 (59–76)	0.364	0.005
EQ-5D Self-care	2 (2–2)	-0.391	< 0.001
EQ-5D Anxiety/depression	2 (2–3)	-0.369	< 0.001

Calculated using Spearman's correlation, Q1-25th quartile, Q3-75th quartile, r correlation coefficient

Table 5	Comparison	of SarQoL®	questionnaire	validation studies
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Characteristics	French Beaudart et al. [21]	English Beaudart et al. [20]	Romanian Gasparik et al. [22]	Dutch Geer- inck et al. [23]	Polish Konstan- tynowicz et al. [24]	Greek Tse- koura et al. [25]	Lithu- anian [current study]
Sample size ( <i>n</i> )	296	297	100	92	106	176	176
Sarcopenic subjects (n)	43	14	13	30	60	50	58
Internal consistency (Cron- bach's alpha)	0.87	0.88	0.946	0.883	0.92	0.96	0.95
Discriminative power ( <i>p</i> value*)	< 0.001	0.01	0.018	0.003	0.013	< 0.001	< 0.001
Test-retest reliability (ICC)	0.91	0.95	-	0.976	0.99	0.96	0.976

Decimals are cited as provided in original articles

ICC intraclass coefficient correlation

\*Compared between total scores of the SarQoL® in non-sarcopenic and sarcopenic subjects

to discriminate between sarcopenic and non-sarcopenic subjects.

The Cronbach's alpha of the Lithuanian version of the SarQoL<sup>®</sup> was 0.95. Recommended values are between 0.7 and 0.9, and some have suggested an upper limit of 0.95 [26, 27]. The high alpha-value in this study suggests that some questions in the questionnaire may be redundant, i.e., testing the same but in a different approach. However, Romanian and Polish validation studies also reported higher Cronbach's alpha values as well (0.946 and 0.92, respectively), and Greek validation study reported Cronbach's alpha of 0.96 [22, 24, 25].

The convergent validity analyses revealed that the Lithuanian version of the SarQoL<sup>®</sup> questionnaire had significantly good correlations with similar domains of SF-36 and EQ-5D questionnaires, such as Physical functioning, Role limitation due to physical problems, Vitality, and Utility score. The divergent validity analyses showed that weak correlations were found between overall score of the SarQoL® and different domains of SF-36 and EO-5D, such as Mental health, Role limitation due to emotional problems, Self-care, Anxiety/depression. These results are similar to those in French, English, Romanian, Dutch, and Greek validation studies [20–23, 25]. Polish and French validations studies were not compared because divergent validity in French validation study was assessed using other domains, and Polish study did not provide results for separate SF-36 and EQ-5D domains [21, 24].

Test-retest reliability was found to be excellent, both for the total score and for the individual domains of questionnaire. These results are similar to those of French, English, Dutch, Polish, and Greek validation studies [20, 21, 23–25]. Due to lack of sarcopenic subjects, the Romanian validation did not examine test-retest reliability [22]. The SarQoL<sup>®</sup> questionnaire seems to be a reliable instrument.

Our study had some limitations. Due to the cross-sectional study design, sensitivity to change could not be assessed. Also,

study subjects were volunteers, and this could imply that they are more concerned about muscle disorders than a random sample of the population. This could mean that their quality of life was more impacted due to their concern from muscle disorders. The strengths of this study include: a large sample size of sarcopenic subjects, the largest recruited so far for any of the SarQoL<sup>®</sup> validation studies. Also, we used the updated EWGSOP2 criteria and our results are comparable with other validation studies.

In conclusion, our results show that the Lithuanian version of SarQoL<sup>®</sup> questionnaire is valid, reliable and consistent. It may be used to assess the quality of life in Lithuanian people with sarcopenia. The SarQoL<sup>®</sup> questionnaire has a greater sensitivity compared to general quality of life questionnaires.

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Author contributions CB, OB, JYR, VA and MT were involved in the design of the study. JK and AM managed the study and performed statistical analysis. JK, AM, and MT drafted the manuscript. VA, MT, AG, CB, OB, and JYR made critical revision of the manuscript. All the authors read and approved the final manuscript.

# **Compliance with ethical standards**

**Conflict of interest** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Ethics statement and informed consent Study protocol has been approved by Lithuanian regional biomedical research ethics committee. All subjects gave their written informed consent prior to enrolment.

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