DEVELOPMENT, VALIDATION, AND PSYCHOMETRIC ASSESSMENT OF LARGE MUSCLE PERFORMANCE TEST (LAMP-TEST) FOR THE SARCOPENIA GERIATRIC POPULATION TO ASSESS FUNCTIONAL MUSCLE STRENGTH BASED ON PERFORMANCE - STUDY PROTOCOL

Balamurugan Janakiraman[1], Arunachalam Ramachandran[2], Hariharasudhan Ravichandran[3], Mohammad Sidiq[4]

Article History: Received: 12.12.2022 **Revised:** 29.01.2023 **Accepted:** 15.03.2023

Abstract

Background: Sarcopenia related to advancement in aging among geriatric population remains common and a major challenge in clinical evaluation or management. Many geriatric people have ongoing disability related daily activities particularly related to large muscle sarcopenia. A uni-dimensional measure of limitation in activity is needed to monitor progress in function. However, the current measures are either patient reported or multidimensional constructs such as activity level, Performance-based construct of activities of daily life is scarce in this population. Therefore, the aim was to develop the clinician-observed large muscle performance test (LAMP), a interval level uni-dimensional measure of actual performance of daily activities, reflecting limitations of activity related to large muscle sarcopenia.

Methods; A prospective clinician observed outcome measure (LAMP-test) development study will be conducted and the constructs will be based on the actual performance of repetitive activities reflecting the ADL related to large muscle groups among geriatric population. This study is approved by the IEC, MMCHRI, India and Initially a conceptual framework will be drafted followed by item generation; (existing sarcopenic measures, existing ADL measures in Geriatric, literature informed drafting of conceptual framework, Focus group), and item selection; (selection criteria, importance, and feasibility ratings, pilot testing, Rasch analysis). Based on the focus group interviews with 10 geriatric adults, 2 geriatric physicians, 4 physiotherapists and a literature review informed drafting of conceptual framework will be development. The recommendations of COSMIN for development new tool will be used. A cognitive debriefing interview with 10 older adults of both gender, and 8 health professionals will be conducted to ascertain content validity. The LAMP test tool will be field tested with 250 community dwelling geriatric people. Rasch psychometric analysis will be conducted for scale reduction, and psychometric testing of the LAMP tool with an additional 125 participants.

Discussion;This research will help development of a new clinician observed measure with functional dimension construct with potentially good psychometric properties to evaluate the large muscle group based ADL related functional strength among geriatric people. It is envisioned that the LAMP-test will be a promising outcome tool to measure large muscle group sarcopenia related activity limitations among older people. The construct of content will be uni-dimensional and feasible for use in both clinical and home settings, and a suitable tool for researches exploring activity limitations related sarcopenia among geriatric people.

Keywords: Clinician observed outcome measure, Activity limitations, Sarcopenia, Geriatrics

[1]Department of Research and Faculty of Physiotherapy, Meenakshi Academy of Higher Education and Research (MAHER), India
[2]Faculty of Physiotherapy, Madhav University, Abu road, Rajasthan, India
[3]Alva's College of Physiotherapy and Research Centre, Dakshina Kanada, Karnataka, India
[4]Department of Physiotherapy, School of Medical and Allied Health Sciences, Galgotias University, Greater Noida, Uttar Pradesh, India

DOI: 10.31838/ecb/2023.12.s2.196

1. Background

The World Health Organization (WHO, 2016), International Statistical Classification of Diseases and Related Health Problems (ICD) has recognized sarcopenia as a disease (code ICD-10-CM, M62.84) [1]. Sarcopenia is an age-associated loss of skeletal muscle function, and mass of the muscle, which is common with advancement of age among older adults [2–4]. The global prevalence of sarcopenia among adults aged above 65 years is estimated to be 6 to 22 %, with a variation across countries, population studied, and study settings. The proportion of older adults with sarcopenia will continue to grow at a rapid phase alongside the increasing population of older adults globally [5–7].

At the age of 70 years, older adults may incur an estimated 40% loss of muscle mass, and a concomitant 30% decline in muscle strength [8]. This decline in mass and strength of the muscles is associated with adverse health-related outcomes like falls, decreased physical functions, and disability. Functional limitations or constrains due to sarcopenia and its related consequences for instance lack of balance, alongside with strength usually results in older adults experiencing an ongoing disability particularly during activities of daily life [9]. According to the international Classification of Functioning, Disability and Health (ICF framework), activity limitations are difficulties an individual may have in performing activities or tasks [10,11]. Older adults with sarcopenia may be limited in activities like getting up from bed, sit-to-stand or vice-versa, raising up or door on stairs/steps, lifting a mug or bucket with water, or carrying items. Such limitations in ADL might dent their independence and may also adversely influence their level of participation in societal roles [12]. Hence, it is important to be able to measure these constructs, so that sarcopenia-related muscle function decline relating to activity can be screened to monitor functional progress and chose appropriate task/activity oriented interventions. This requires a clinician observable measure that is both muscle function and activity dimensional with 2-factor construct of both muscle function and activities, with sound psychometric properties, relevant, and clinically feasible [2,13–15].

There is no clear cut-off points for sarcopenia but functional decline related to muscle mass reduction in evident. Further, none of currently used performance-based outcome measures in older adults with sarcopenia measures the bi-construct of muscle function and activity limitations. For example; Physical Performance Test (PPT-7), Dynamometry hand grip strength, & lower extremity strength test, Timed-Up Go test (TUG), Bergs balance Scale (BBS), and Fall Efficacy Scale (FES) [8,16–18]. Outcome measures with multiple constructs in one outcome measure and summing of the sub-score's into one total score may vague the outcome predicted. To assess the activity limitations in older adults with sarcopenia or recovering from sarcopenia, a dimensional outcome measure with suitable construct is required. Further, there is little or limited psychometric information of measures in older adults with sarcopenia, particularly during basic activities of daily life.

Therefore, there is a need to develop a new uni-dimensional outcome measure with sound psychometric properties that can assess activity limitations in older adults with sarcopenia. This study aims to outline the conceptual framework, and develop, measure construct, test dimensionality (Rasch analysis) and validate the LArge Muscle Performance test (LAMP-Test), a clinician observed measure based on actual performance of repetitive activities reflecting the ADL among geriatric population

2. Methods

The protocol was presented to MMCHRI human Ethics committee and approval obtained (MMCH & RI IEC/Faculty/01/Jan/2023) and the proposal is submitted for CTRI registration (Clinical Trial Registry India, Ref no; 2023/.02/063704). This study will be conducted following the guidelines of the Declaration of Helsinki [19] and Institutional Ethical approval will be obtained. Written informed consent will be obtained using a participant consent form and participant information sheet explaining the project.

The construct of this new outcome measure is (temporarily) defined as SArcopenia Related Activity Limitations (SARALs); the ability to perform activities and/or tasks using large muscle groups that closely reflects the activities components of the *International Classification of Functioning Disability and Health* framework [20] among geriatric population with sarcopenia.

The development of the new LAMP test outcome measure will comprise of two phases **(Figure 1)**; phase one Item generation and phase two Item selection.

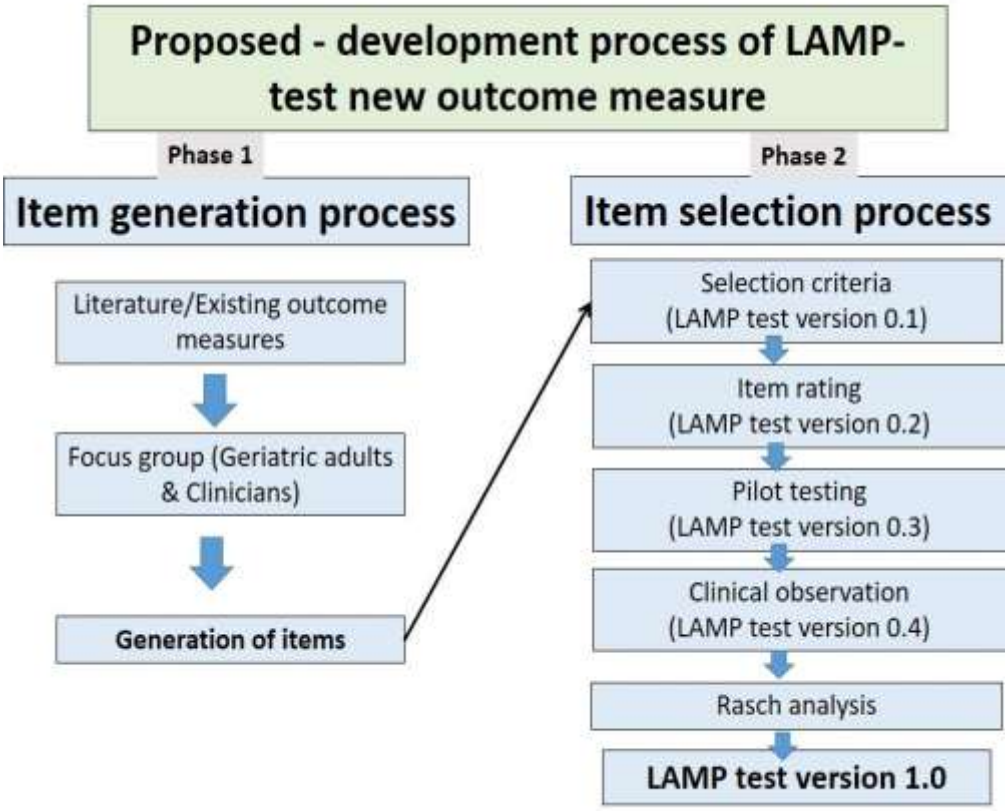
A pool of items will be generated from the existing outcome measures related to sarcopenia and/or activity limitations among geriatric people, a literature informed drafting of conceptual framework, and focus groups interview panel with geriatric adults and clinicians. Then, the items for LAMP-test will be selected using the following stepwise approach; Selection criteria, Item ratings, Pilot testing, Clinical observation, and Rasch analysis for dimensions.

Item generation – proposed methods;
The items to be pooled will be identified by conducting a systematic review of outcome measures used in sarcopenia among geriatric population, their uses, and psychometric properties based on selection criteria Table 01.

Table 01 Pre-determined selection criteria for item selection;

1	Can be categorized in ICF categories of the Activities For e.g. d4 Mobility, d5 self-care, d6 domestic life
2	Can be described as daily task
3	Requires minimal or no equipment
4	Feasible to test, easy, and timeliness
5	Can be administered by wide range of health professionals

Figure 1; The proposed development process for LAMP-test outcome meaasure



Stages of generation and selection of items , including the versions at each stages; Proposed

Additional items will be generated from the focus groups, which will be conducted by the PI and Co-PIs as moderators, with up to 8 participants in each group. Two focus groups will include older adults with sarcopenia diagnosed by hand grip strength, and lower extremity muscle strength testing. The 2 focusgroup will also include clinicians; physicians (geriatric medicine), and physiotherapist. Older adult participants based on characteristics ensuring diversity will included by purposive sampling.

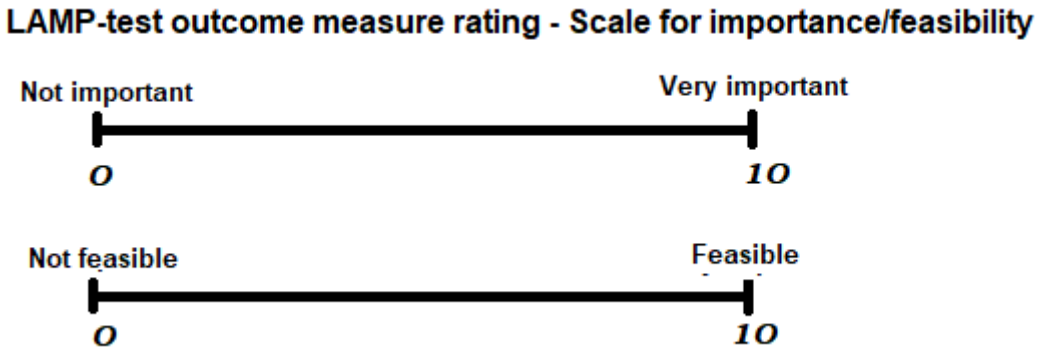
Item selection process – new LAMP test outcome measure

Based on the recommended guidelines (COSMIN), four methods; selection based on pre-determined criteria, item ratings by the focus group members, clinical testing, and Rasch analysis. Two investigators will independently generate a list of items based on criteria, and consensus will be reached by discussion with the team.

Face validity of the new LAMP test outcome measure
To improve face validity further selection of the items will be based on feedback from the focus groups. An item rating questionnaire with a 10 point numeric scale (Figure 02) will be sent to the

experts about the importance and clinical testing feasibility (only by clinicians)

Figure 02 – Item rating scale for importance and feasibility



We are planning to set an arbitrary cut-off of 7/10 per item as a guideline for item selection or revisions. The items that is included will be named and defined for pilot-testing. This includes the description of positions, instructions, and scoring.
The scoring (for now) of the participants ability will be based on; unable, partially abled and abled. If an item was not practical, or could not discriminate for e.g. all people could perform the task or did not capture the construct of activity limitations related to sarcopenia then the item will be altered or removed.

Participants
A community-based survey and screening program will be conducted near the MAHER campus through an pamphlet based advertisement to identify potentially eligible participants based on the selection criteria (**Table 02**) and they will be invited to participate in this proposed study.

Table 02 Selection criteria of participants for new LAMP test development

Inclusion criteria	Aged 65 years and above, Both genders, Diagnosed to have sarcopenia by Hand-grip strength and lower extremity muscle strength battery test, Able to communicate and mentally stable (MMSE score), Available for recruitment for the next phase.
Exclusion criteria	Recent fall events or fear of fall, Visual impairments, Recent trauma (3 months) or unhealed injuries, Any diagnosed Neuro-musculoskeletal disorders, Wheel chair based locomotion's or dependent for ADL.

The socio-demographic characteristics of the participants recruited in the validation phase will be gathered through an interview.

Sample size calculation for the validation phase
The guidelines recommended by Linacre [21] for proposed sample size of a minimum of 100 for a stable estimation of item calibrations within the 0.5 logits (logarithmic odds units) with 95% confidence interval (uncertainty level) will be used.

Analysis
For descriptive and comparative statistics (t-test, $p < 0.05$) IBM Statistical Packae for Social Sciences 21 v will be used.

Rasch analysis
A comprehensive and pragmatic analysis using 2 Rasch models simultaneously for comparison [22,23], the Anrich-Rasch Grouped Rating Scale model and Rasch-Masters Partial Credit Model. The test functioning, specific item fit, person fit to the models will be checked. The guidelines recommended (Reasonable mean-square fit values) by Linacre and Wright [24] will be used to evaluate item and person fit with INFIT and OUTFIT mean square statistics, and values < 0.5 &> 0.2 will be considered fit for removal.
Further, item characteristics curves, differential item functioning analyses, the construct of the developed scale will checked for dimensionality using Principal Component Analysis. As proposed by Linacre an Eigenvalue of more than 2.0 will be considered indicative of presence of > 2 constructs. Reduction of dimensionality will be considered if needed or appropriate.
The recommendations for reliability estimate for a test [25]; Reliability coefficients of 0.80 corresponds with a separation coefficients of 2, and will be set as preferred reliability estimate for the LAMP-test.

3. Discussion

This study will develop new clinician observed outcome measure which assess the activity limitation domains of ICF model predominately among older adults with sarcopenia. We strongly believe that the proposed methods will surely produce a unidimensional functional based index which will be feasible, easy, accurate, and reliable.

Declarations

Ethical approval and consent to participate

This outcome measure development study was approved by the Institutional Ethics Committee, Faculty of Medicine, Meenakshi Medical College Hospital and Research Institute (Ref. No. MMCH & RI IEC/Faculty/01/Jan/2023). The purposes and the importance of the study will be explained to each participant. A written informed consent will be obtained from all the participants before inclusion in this study and this study will be conducted in accordance with the declaration of Helsinki

Funding: This study is not funded

Competing interests: The authors stated that they have no competing interests.

Consent for publication: Not applicable

4. References

Anker SD, Morley JE, von Haehling S. Welcome to the ICD-10 code for sarcopenia. Journal of cachexia, sarcopenia and muscle. Wiley Online Library; 2016;7:512–4.

Arai H. Sarcopenia diagnostic criteria update by EWGSOP: what has been changed? European Geriatric Medicine. Springer; 2018;9:733–4.

Yoshimura Y, Wakabayashi H, Yamada M, Kim H, Harada A, Arai H. Interventions for treating sarcopenia: a systematic review and meta-analysis of randomized controlled studies. Journal of the American Medical Directors Association. Elsevier; 2017;18:553-e1.

Rosenberg IH. Sarcopenia: origins and clinical relevance. Clinics in geriatric medicine. Elsevier; 2011;27:337–9.

Bianchi L, Abete P, Bellelli G, Bo M, Cherubini A, Corica F, et al. Prevalence and clinical correlates of sarcopenia, identified according to the EWGSOP definition and diagnostic algorithm, in hospitalized older people: the GLISTEN study. Journals of Gerontology Series A: Biomedical Sciences and Medical Sciences. Oxford University Press US; 2017;72:1575–81.

Landi F, Liperoti R, Fusco D, Mastropaolo S, Quattrociocchi D, Proia A, et al. Prevalence and risk factors of sarcopenia among nursing home older residents. Journals of Gerontology Series A: Biomedical Sciences and Medical Sciences. Oxford University Press; 2012;67:48–55.

Cerri AP, Bellelli G, Mazzone A, Pittella F, Landi F, Zambon A, et al. Sarcopenia and malnutrition in acutely ill hospitalized elderly: Prevalence and outcomes. Clinical nutrition. Elsevier; 2015;34:745–51.

Harris-Love MO, Benson K, Leasure E, Adams B, McIntosh V. The influence of upper and lower extremity strength on performance-based sarcopenia assessment tests. Journal of functional morphology and kinesiology. MDPI; 2018;3:53.

Kalyani RR, Corriere M, Ferrucci L. Age-related and disease-related muscle loss: the effect of diabetes, obesity, and other diseases. The lancet Diabetes & endocrinology. Elsevier; 2014;2:819–29.

Raghavendra P, Bornman J, Granlund M, Björck-Åkesson E. The World Health Organization's International Classification of Functioning, Disability and Health: implications for clinical and research practice in the field of augmentative and alternative communication. Augmentative and Alternative Communication. Taylor & Francis; 2007;23:349–61.

Badley EM. Enhancing the conceptual clarity of the activity and participation components of the International Classification of Functioning, Disability, and Health. Social science & medicine. Elsevier; 2008;66:2335–45.

Yee XS, Ng YS, Allen JC, Latib A, Tay EL, Abu Bakar HM, et al. Performance on sit-to-stand tests in relation to measures of functional fitness and sarcopenia diagnosis in community-dwelling older adults. European Review of Aging and Physical Activity. Springer; 2021;18:1–11.

Evans CJ, Chiou C-F, Fitzgerald KA, Evans WJ, Ferrell BR, Dale W, et al. Development of a new patient-reported outcome measure in sarcopenia. Journal of the American Medical Directors Association. Elsevier; 2011;12:226–33.

Cesari M, Fielding RA, Pahor M, Goodpaster B, Hellerstein M, Van Kan GA, et al. Biomarkers of sarcopenia in clinical trials—recommendations from the International Working Group on Sarcopenia. Journal of cachexia, sarcopenia and muscle. Springer; 2012;3:181–90.

Woo J, Leung J, Morley JE. Validating the SARC-F: a suitable community screening tool for sarcopenia? Journal of the American Medical Directors Association. Elsevier; 2014;15:630–4.

Martinez BP, Gomes IB, Oliveira CS de, Ramos IR, Rocha MDM, Forgiarini Júnior LA, et al. Accuracy of the Timed Up and Go test for predicting sarcopenia in elderly hospitalized patients. Clinics. SciELOBrasil; 2015;70:369–72.

Schaap L, Fox B, Henwood T, Bruyère O, Reginster J-Y, Beaudart C, et al. Grip strength measurement: towards a standardized approach in sarcopenia research and practice. European Geriatric Medicine. Elsevier; 2016;7:247–55.

Ida S, Murata K, Ishihara Y, Imataka K, Kaneko R, Fujiwara R, et al. A comparison of the associations of dynapenia and sarcopenia with fear of falling in elderly diabetic patients. Nihon Ronen Igakkaizasshi Japanese Journal of Geriatrics. 2017;54:537–45.

Williams JR. The Declaration of Helsinki and public health. Bulletin of the World Health

World Health Organization, World Health Organization. International classification of functioning. Disability and Health (ICF). 2001;28:66.

Linacre J. Sample size and item calibration stability. Rasch Mes Trans. 1994;7:328.

Smith E. Practical Rasch Measurement-Core Topics (Tutorial 3). Statistics com. 2012;

Lundgren Nilsson A, Tennant A. Past and present issues in Rasch analysis: the functional independence measure (FIM^{TM}) revisited. Journal of rehabilitation medicine. Foundation for Rehabilitation Information; 2011;43:884–91.

Wright B, Linacre J, Gustafson J, Martin-Löf P. Reasonable mean-square fit values. Rasch Measurement Transactions, 8, 370. Rasch Measurement Transactions. 1994;8.

Dey, N., Kumar, G., Vickram, A. S., Mohan, M., Singhania, R. R., Patel, A. K., ... & Ponnusamy, V. K. (2022). Nanotechnology-assisted production of value-added biopotent energy-yielding products from lignocellulosic biomass refinery–a review. Bioresource Technology, 344, 126171.

AS, V., Das, R., MS, S., Rao, K. A., & TB, S. (2013). Prediction of Zn concentration in human seminal plasma of Normospermia samples by Artificial Neural Networks (ANN). Journal of assisted reproduction and genetics, 30, 453-459.

Streiner D, Norman GR, Cairney J. Health measurement scales: a practical guide to their development and use. Aust NZJ Public Health. 2016;