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**Translation, cross-cultural adaptation and validation of the  
Scored Patient-Generated Subjective Global Assessment (PG-SGA)  
for the Portuguese setting**

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## DECLARATIONS

I, João Pedro Tente Albuquerque Pinho, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

No quotation from this thesis can be published without the prior written consent from the author.

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## ABSTRACT

**Background and aims:** The Scored Patient-Generated Subjective Global Assessment (PG-SGA) was first published in 1996 by Faith Ottery and enables nutritional screening, the assessment of the nutritional status and the risk factors of malnutrition, allowing the triage and monitoring of nutritional interventions to prevent and treat malnutrition.

The several advantages of the PG-SGA justify its application in numerous clinical settings, including the Portuguese. Thus far, no validated Portuguese version of the PG-SGA was available. To be able to use the PG-SGA in Portugal, the original instrument should be translated, cross-culturally adapted and validated. Therefore, the aim of this study was to translate, cross-culturally adapt and validate the original PG-SGA for the European Portuguese setting.

**Methods:** The translation and cross-cultural adaptation of the PG-SGA to the Portuguese setting was performed according to the guidelines of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). The process included 10 steps: preparation, forward translation, reconciliation, back translation, back translation review, harmonisation, cognitive debriefing, review of cognitive debriefing results and finalisation, proofreading, and final report. To ensure the validity and reliability of the Portuguese PG-SGA, face validity, acceptability, difficulty and comprehensibility, relevance (content validity) and intra-rater reliability (test-retest) were evaluated. The “Consensus-based standards for the selection of health measurement instruments” (COSMIN) checklist was used to evaluate the methodological quality of the study.

**Results:** The 10-step translation and cross-cultural adaptation process were successfully conducted. The tool has shown to be accessible (100%), comprehensible ( $S-CI=0.94$ ) and not difficult ( $S-DI=0.94$ ) for patients. Healthcare professionals demonstrated excellent scores in terms of comprehension ( $S-CI=0.99$ ), difficulty ( $S-DI=0.97$ ), relevance ( $S-SVI=0.98$ ) and face validity (100%). Regarding reliability, Intraclass Correlation Coefficient (ICC) was 0.832 ( $p<0.001$ ) for numerical score and weighted kappa was 0.727 ( $p=0.023$ ) for the PG-SGA categories. In the evaluation of the methodological quality, the study design covered most of the design requirements and statistical methods as included in the COSMIN checklist.

**Conclusions:** The translation, cross-cultural adaptation and validation process of the PG-SGA for the Portuguese setting adequately captured the concepts of the original English version of the PG-SGA, thereby demonstrating its conceptual, semantic and cultural equivalence. The

Portuguese version of the PG-SGA is a valid and reliable instrument to screen and assess malnutrition and its underlying risk factors in day-to-day clinical practice and in research.

**Keywords:** PG-SGA; Nutrition Assessment; Translation; Crosscultural Adaptation; Validation studies.

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## LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
BMI	Body Mass Index
CHMA,EPE	Centro Hospitalar Médio Ave, Entidade Pública Empresarial
CTT	Classical Test Theory
ECOG	Eastern Cooperative Oncology Group
ESPEN	European Society for Clinical Nutrition and Metabolism
HIV	Human Immunodeficiency Virus
HR-PRO	Health-Related Patient-Reported Outcomes
I-CI	Item Comprehensibility Index
I-CVI	Item Content Validity Index
I-DI	Item Difficulty Index
ICC	Intraclass Correlation Coefficient
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IRP	Item-Response Theory
IRT	Item Response Theory
mg	milligrams
NA	Not Applicable
NIS	Nutrition Impact Symptoms
PG-SGA	Scored Patient-Generated Subjective Global Assessment
PG-SGA SF	Scored Patient-Generated Subjective Global Assessment Short Form
PRO	Patient-Reported Outcomes
S-CI	Scale Comprehensibility Index
S-CVI	Scale Content Validity Index
S-DI	Scale Difficulty Index
SGA	Subjective Global Assessment
SPSS	Statistical Package for the Social Sciences

## INTRODUCTION

The Scored Patient-Generated Subjective Global Assessment (PG-SGA) (© FD Ottery, 2005, 2006, 2015) was first published and copyrighted in 1996 by Faith Ottery<sup>1</sup>. The PG-SGA is an interdisciplinary global assessment tool which spans several relevant aspects as far as the nutritional status of the patient is concerned: weight, food intake, nutritional impact symptoms, activities and function, stage of the disease, metabolic demand and physical examination.

The PG-SGA enables screening and assessment of the nutritional status and underlying risk factors for malnutrition, allowing the triaging for interventions and monitoring of nutritional status over time. The use of the PG-SGA is recommended by the Academy of Nutrition and Dietetics<sup>2</sup>, the Dietitians Association of Australia<sup>3</sup>, and the Dutch Working Group of Oncology Dietitians<sup>4</sup>, since it is a simple, no-cost, fast tool and it is considered the reference method in the assessment of the nutritional status of cancer patients, as well as of other chronic catabolic conditions<sup>5-7</sup>.

So far, almost 170 studies have been published on PubMed using this tool, reaching areas and populations so different as oncology, nephrology, neurology and also in cases involving elderly people and acute care setting<sup>8-11</sup>. In the original PG-SGA study (1996), predominantly cancer patients were included (lung, prostate, colon, non-Hodgkin lymphoma, rectal, oesophageal, melanoma, cervical), but patients with end stage renal disease and diabetes mellitus were included as well<sup>1</sup>. Subsequently, results have been published or reported using the PG-SGA in the following patient populations: cancer (lung, gastrointestinal, head and neck, gynaecological, urological, acute leukaemia, multiple myeloma, haematological stem cell transplantation); stroke; Human Immunodeficiency Virus (HIV); Parkinson's disease; elderly; chronic kidney disease; haemodialysis and others<sup>5,8-11</sup>.

The PG-SGA is a validated tool in terms of content, concurrent and predictive validity. The PG-SGA covers all domains of the malnutrition definition (content validity)<sup>12</sup>. Furthermore, PG-SGA scores are associated with body weight, body mass index (BMI), body composition and hand grip strength<sup>11,13-16</sup> (concurrent validity). It is also related with clinical outcome, like length of stay, hospital readmissions, duration of neutropenic fever, quality of life and survival in both cancer patients and non-cancer patients, indicating its predictive validity<sup>3,11,16-28</sup>.

Besides the full PG-SGA, the PG-SGA Short Form (PG-SGA SF), the patient-component of the PG-SGA (also known as abridged PG-SGA), has also shown good validity. Higher scores on the PG-SGA

Short Form have been associated with increased length of hospital stay, decreased tolerance to chemotherapy and increased mortality<sup>14</sup>.

The use of the same tool in different population setting provides a consistent means of identifying patients with malnutrition and measuring outcomes of nutrition intervention, as patients move through the spectrum of health care delivery systems. In addition, results obtained from different populations can be compared with each other<sup>5</sup>.

Several studies using the PG-SGA have found a high prevalence of malnutrition in cancer patients<sup>13,16,30</sup>. In a study carried out among 226 cancer patients, Marín Caro *et al.* have observed that 64% showed some degree of malnutrition, and even up to 83% in patients in palliative care<sup>30</sup>. Furthermore, in a sample of 781 patients with cancer at an advanced stage, Segura *et al.* have observed that 52% showed moderate or severe malnutrition, in which prevalence of malnutrition was highest in patients with cancer in the digestive tract<sup>16</sup>.

In malnourished patients, symptoms such as changes in taste and smell, lack of appetite, nausea, early satiety, constipation, pain, mouth sores, diarrhoea and vomiting occur very frequently<sup>13</sup>. Some of those symptoms are associated with poor functional ability, poor quality of life and low energy intake. Timely and appropriate nutrition intervention is essential to improve nutritional status and quality of life<sup>13</sup>. A study by Lim *et al.*<sup>31</sup> showed that quality of life was significantly lower in severely malnourished patients than in well-nourished ones.

## LITERATURE REVIEW

### Clinical relevance of the nutritional assessment

Cancer is one of the catabolic conditions in which malnutrition is highly prevalent. Both the disease itself and treatment-related symptoms may deteriorate the nutritional status. Frequently reported nutrition-impact symptoms include in patients with cancer include loss of appetite, nausea, vomiting (especially chemotherapy-induced), depression, loss of energy, as well as a hypercatabolic state, due to the process of an expanding or invasive tumour<sup>7,32,33</sup>. The consequences of malnutrition in patients with cancer include impaired immune function, reduced vitality and reduced survivability, which may lead to an increase in complications and increased morbidity and mortality<sup>1,17,34-40</sup>.

Assessment of nutritional status and identification of relevant risk factors are the basis of the intervention for nutritional management and prevention of malnutrition in cancer patients<sup>41</sup>. Malnutrition, as assessed by PG-SGA, has demonstrated to be an independent predictor of survival in several studies<sup>17,35,37-39,42</sup>.

According to the clinical guidelines of the American Society for Parenteral and Enteral Nutrition<sup>43</sup>, cancer patients who are nutritionally at risk should undergo nutrition screening to identify those requiring formal nutrition assessment with development of a nutrition care plan. There is clear evidence that nutrition screening using the appropriate tools will identify cancer patients who are malnourished. Among the available tools validated for the oncology setting, the PG-SGA is the most commonly used tool to identify patients at risk for malnutrition or already malnourished. The patient-generated component of this tool, the PG-SGA Short Form (SF) can be used as screening tool to identify malnutrition risk and underlying risk factors in patients<sup>5</sup>. Furthermore, similar to the full PG-SGA, the PG-SGA SF allows triaging for interdisciplinary interventions.

Early and intensive nutritional intervention provides beneficial outcomes in terms of minimising weight loss, deterioration in nutritional status, global quality of life and physical function in ambulatory cancer patients receiving radiotherapy to the gastrointestinal or head and neck area<sup>44-47</sup>. Weight maintenance in this population leads to beneficial outcomes and suggests that this, rather than weight gain, may be a more appropriate aim of nutrition support during radiotherapy<sup>13,46,47</sup>. All patients having risk factors for malnutrition, e.g. patients receiving

radiotherapy to the gastrointestinal or head and neck area, should have regular and individualised nutrition assessment and support that continues post-radiotherapy, as required<sup>48</sup>. If staff levels are not sufficient to allow for this level of nutritional monitoring and therapy, implementation of screening and triaging systems is recommended, to ensure that those patients most in need of care receive a level of nutrition support that demonstrates better outcomes<sup>49</sup>.

The maintenance of an adequate nutritional status during cancer treatment has been demonstrated to be beneficial in these patients in terms of their treatment tolerance, quality of life, morbidity and mortality<sup>13,24,36,50,51</sup>. Moreover, the nutritional status has an impact on cancer recurrence when a stable disease or complete remission is achieved<sup>52</sup>.

Although there is limited evidence available specifically examining the efficacy of nutrition screening in improving clinical outcomes in cancer patients, the detrimental effects of weight loss on outcomes has been demonstrated<sup>1,29,46,53-59</sup>. In addition, the benefits of nutrition counselling in cancer patients have been reported<sup>3,13,27,46,47,60,61</sup>. It seems logical that routine nutrition screening should be performed in every cancer patient to identify individuals at risk who require a formal nutrition assessment, in an attempt to minimise weight changes and functional deterioration, and to identify individuals who may benefit from further nutrition intervention<sup>43</sup>.

### PG-SGA

#### Historical evolution of the PG-SGA

The PG-SGA is a modification of the Subjective Global Assessment (SGA), which was published in 1984 and first published in a usable format in 1987, by Detsky *et al.*<sup>62</sup>. The SGA includes the History (weight change, dietary intake change, gastrointestinal symptoms, functional capacity and disease and its relation to nutritional requirements), Physical examination and SGA rating. The SGA allows to categorise patients as *well-nourished* (Category A), *Moderately (or suspected of being) malnourished* (B) or *Severely malnourished* (C)<sup>62</sup>. The SGA is an assessment tool of the nutritional status which is used in different clinical scenarios, offering high sensitivity and specificity<sup>63</sup>.

In 1994 the SGA was adapted by Ottery<sup>64</sup>, in order to specifically evaluate the needs of cancer and other patients, namely those symptoms which occur more frequently among this population, such as mucositis, dry mouth, taste change, constipation, pain and dysgeusia, as well

as the symptoms already included in the SGA: nausea, vomiting, diarrhoea and anorexia. In addition, in the PG-SGA the clinician-generated items of the SGA were converted to patient-generated components. Therefore, the first four Boxes are to be completed by the patient. In the PG-SGA, the functional capacity is evaluated by a modification of the Eastern Cooperative Oncology Group (ECOG) classification, measuring the functional capacity from 0 (no dysfunction) to 4 (bedridden). As far as weight changes are concerned, in the adaptation carried out by Ottery some information was added regarding recent weight loss (3 months and 1 month) and the corresponding percentage of weight loss. Finally, new information regarding the staging of the disease was also added.

The PG-SGA<sup>1</sup> was published for the first time in 1996, after several adaptations on the previous publication. The first four Boxes of the 1996 version of the PG-SGA included:

- Weight: Current weight and height; weight 6 months ago; weight 3 months ago; weight 1 month ago; weight change over the last two weeks;
- Food intake: food intake over the last month compared with the usual intake and current food intake;
- Symptoms: symptoms that occurred in the past two weeks;
- Functional capacity: functional capacity presented by the patient over the last month.

The section to be completed by the health professional includes:

- The disease and its relation to nutritional requirements: diagnosis; staging; metabolic demand (stress);
- Physical examination;
- Global Assessment (A, B or C).

The scored PG-SGA is a further adaptation of the PG-SGA that was published in 2001. It also included a numeric score and nutritional triage recommendations<sup>29,65</sup>. In the patient-generated historical component, the symptom “problems swallowing” was added to Box 3. In the section to be completed by the health professional, new information was added as well, concerning the scoring for weight loss; the catabolic conditions and age; the criteria for metabolic stress were described (fever severity, fever duration, steroids), as well as the criteria for the physical examination and for the global assessment categories (A, B and C).

The global assessment categories and numerical score are two different, yet related rating systems. The global assessment categories reflect the professional assessment of the patient's nutritional status at a given time, based on the Boxes 1-4 (PG-SGA SF) and Worksheet 4 (physical examination), allowing to categorise patients as *well-nourished or anabolic* (stage A), *moderately*

*malnourished or at risk of malnutrition* (B) or *severely malnourished* (C). The numerical score (0 - >9) can determine smaller changes in nutritional status and determine the most appropriate nutrition intervention.

In 2005 slight structural changes were introduced, being the first page of the tool dedicated to the completion by the patient and the second page by the health care professional<sup>66</sup>. The item “fatigue” was added to Box 3, and “chronic renal insufficiency” was added to Worksheet 2, since they were frequently referred in “Other” and in “Other relevant diagnoses”, respectively. The PG-SGA was re-edited in 2006, 2014 and 2015 from a structural standpoint. The most recent version of the PG-SGA is shown in Appendix 1.

In 2014 the *PG-SGA/Pt-Global Platform*<sup>5</sup> was created, supported by a website ([www.pt-global.org](http://www.pt-global.org)). It aims to set the standard for and to facilitate optimal diagnosis and proactive treatment of malnutrition to improve clinical outcome and patient quality of life, by creating and sharing knowledge and materials on patient global assessment. This platform is managed by the author of the PG-SGA, Faith Ottery, MD, PhD, *Fellow of the American College of Nutrition* and visiting professor at the *Hanze University of Applied Sciences*, and by Harriët Jager-Wittenaar, PhD, Registered Dietitian and professor at the *Hanze University of Applied Sciences* (Groningen, The Netherlands). On this platform the paper versions of the (metric and non-metric) PG-SGA are available in English, Dutch and, recently, in European Portuguese. Several other materials are available on the website, including manuals, videos and also the scientific publications related to the PG-SGA.

In 2014 the digital application of the PG-SGA, the *Pt-Global app and webtool*, was launched as well. This electronic application has been designed for use on computers, tablets and large screen smartphones.

## Description of the PG-SGA

The scored PG-SGA includes the four patient-generated historical items (weight loss, food intake, nutrition impact symptoms, and functional capacity), the professional items (diagnosis, age, metabolic stress, and physical exam), the global assessment categories (A, B and C), the total numerical score, and nutritional screening recommendations<sup>5,67</sup>.

### 1. Patient-Generated Historical Components

The purpose of the patient-generated component is to get the patient involved in the process of assessment, to be able to easily identify their current situation (in terms of symptoms, food



intake and functional capacity), as well as to optimise time management on the health professional's side<sup>68</sup>. When the completion of the first four Boxes is not possible by the patient himself, due to limitations in physical and/or cognitive capacity, the health professional should assume the task of asking the patient or their caregiver. In any case, it is always preferable to have it completed by the patient, since some aspects such as food intake or symptoms might be unknown by their relatives<sup>5</sup>.

### Box 1 – Weight

The following items are assessed in this Box: current weight, height, weight 1 month ago, weight 6 months ago and evolution of weight in the last 2 weeks. The score of the Box 1 is the scoring of weight loss (Worksheet 1) and add one extra point if patient has lost weight during the past 2 weeks.

Weight loss is included as an item in the PG-SGA, since it is a frequent complication in cancer patients, even at the beginning of the treatments, and that can lead to malnutrition. Weight loss can be caused by the systemic effects of the tumour (such as anorexia and altered metabolism), the local effects of the tumour (malabsorption, obstruction, diarrhoea, and vomiting), or the side effects of anticancer treatment (fatigue, depression, nausea, vomiting, anxiety and pain)<sup>47</sup>. The prevalence of weight loss and malnutrition can, in some cases, (depending on type of cancer and progress) reach 80%<sup>47</sup>.

According to the European Society for Clinical Nutrition and Metabolism (ESPEN), unintentional weight loss higher than 10% in less than 6 months or 5% in less than one month is an indicator of malnutrition<sup>48</sup>. According to *Benoist et al.*<sup>69</sup>, weight loss by itself is the best and most simple parameter of detection of nutritional risk. Body weight loss or variation are still important indicators for the assessment of the patient's nutritional condition<sup>58</sup>.

Unintentional weight loss is associated with lesser tolerance to treatments (toxicity treatments)<sup>59,70,71</sup>, more advanced stage of the disease<sup>54</sup>, a lower activity level<sup>57</sup>, an impaired subjective quality of life<sup>57</sup>, a poor outcome and an increase in morbidity and mortality<sup>13,43,53,72,73</sup>. In fact, about 20% of the patients suffering from cancer die due to the effects of malnutrition rather than the malignancy itself<sup>47</sup>. Weight loss is also associated with distress in some patients, since it may "make the disease visible" and can be taken as signifying the proximity of death. Weight loss can encompass functional components, as decreased exercise capacity and muscle strength, systemic inflammation, the emotional consequences of the syndrome and its impact on the tolerability and effectiveness of treatment<sup>74</sup>.

Proactive identification and treatment of nutrition-related symptoms can stabilise or reverse weight loss in 50% to 88% of oncology cases<sup>75</sup>.

The paradigm regarding the cancer patient has been changing, being obesity more and more prevalent among such patients. Involuntary weight loss, and consequently muscle mass depletion, is associated with a decreased survival, even in obese patients in which this is usually underestimated<sup>71</sup>.

Sarcopenic obesity is the combination of low muscle mass in the presence of visceral obesity<sup>76</sup>. There are subtle variations in the exact definition of both conditions in various studies, depending on the method of assessment, although the latter is commonly defined as BMI  $\geq 30$  kg/m<sup>2</sup><sup>76</sup>.

The presence of sarcopenia in the obese patient is associated with an increase of the toxicity risk in anticancer treatments<sup>34,70,77</sup> and with a deterioration of the functional condition<sup>70,78</sup>. That is also related with a worse prognosis and lower survival rate in oncologic patients, regardless of gender, age and functional condition<sup>70,76,79,80</sup>. The link between visceral obesity and adverse outcomes in cancer patients may be partly due to increased insulin resistance and its influence on levels of endocrine hormonal secretion, which is also associated with cancer progression<sup>76</sup>. Also, in sarcopenic obesity, adipose tissue secretes pro-inflammatory cytokines and adipokines, and these pro-inflammatory markers can contribute towards low muscle mass and obesity<sup>76,78</sup>. It is important to be aware that sarcopenia may be present even in the absence of weight loss<sup>70</sup>.

### Box 2 – Food Intake

The purpose of this Box is to assess food intake concerning the past month compared to normal intake. The first question addresses changes in food intake in relation to quantity (the same, higher or lower amount). The second question is about current intake regarding consistency, and route of administration (normal food but less than normal amount, little solid food, only liquids, only nutritional supplements, very little of anything, only tube feedings or nutrition by vein only). The score for this section is not additive, so the highest score of both questions should be used. A higher score may indicate that the nutritional requirements are met to a lesser degree.

Food intake is affected by alterations in taste, lack of appetite, food aversions, depression, mechanical and functional alterations of the gastrointestinal tract, and the presence of digestive symptoms, which contribute to the deterioration of the nutritional status. This may lead to a vicious cycle of reduction of food intake, especially of protein-rich food, consequently accelerating muscle protein catabolism and causing the appearance of asthenia and mental and physical

fatigue. In turn, these factors contribute to the perpetuation of anorexia and weight loss, implying a reduction of the quality of life of patients, as well as a decrease in treatment tolerance<sup>81,82</sup>.

Reduced food intake in cancer patients can be caused by primary anorexia and by other symptoms, which can lead to weight loss, a common condition among these patients<sup>55,83</sup>.

Individual nutritional counselling significantly and positively influences energy and protein intake<sup>46</sup>, which are important factors to avoid the onset of cancer cachexia<sup>84</sup>.

### Box 3 – Symptoms

In Box 3 – Symptoms, the patient is requested to check all symptoms which hindered him in eating properly in the two previous weeks: anorexia, obstipation, oral mucositis, dysgeusia, dysphagia, pain, vomiting, diarrhoea, xerostomia, taste and smell changes, early satiety, fatigue and other causes (such as depression, financial or dental problems). This section is additive. The total is the score for this section.

The aetiology of the nutrition impact symptoms can originate from the disease itself, or secondarily from anticancer treatments (surgical, radio- or chemotherapy), from the pharmacologic therapy, or even from psychological factors<sup>85</sup>.

The tumour may cause local and systemic effects, and these may have a negative impact upon the nutritional status. Local effects are usually associated with obstruction, malabsorption, diarrhoea and vomiting, whereas systemic effects include anorexia and metabolic alterations, resulting from pro-inflammatory cytokines or hot-response to these cytokines<sup>41,47,86,87</sup>.

Furthermore, in case of existence of neoplasia of the gastrointestinal tract, for instance, tumour location might directly induce malnutrition, due to the total or partial obstruction of the tract in one or more places<sup>45</sup>.

Cancer treatment may cause and/ or exacerbate the nutrition impact symptoms, such as anorexia, dysgeusia, xerostomia, mucositis, nausea, vomiting, diarrhoea, obstipation, fatigue, distress and pain, which can lead to diminishing food intake and, consequently, to the deterioration of the nutritional status<sup>13,36,47,88</sup>.

Routine, detailed assessment of nutrition impact symptoms facilitates proactive symptom management, which may contribute to maintenance of nutritional status, and in turn may contribute to effectiveness of the cancer treatment<sup>89,60</sup>.

### - Anorexia

Anorexia is defined as the reduced desire to eat<sup>90</sup>. Overall, in any disease, loss of appetite is probably the most frequent cause of reduced food intake, deriving from both physical and psychosocial problems; hence, anorexia is a common contributor to malnutrition in cancer<sup>91</sup>.

This symptom is one of the most frequent complications associated with the cancer disease and anticancer therapies<sup>92</sup>, being present in about 24% of the patients at the time of diagnosis and it reaches 80% in advanced disease<sup>93</sup>.

The central serotonergic system seems to play an important role in anorexia associated with the cancer disease. In cancer patients, anorexia may result from increased plasma levels of tryptophan (serotonin precursor), which leads to an increase in the production of serotonin in the hypothalamic ventricular system<sup>82</sup>. Other factors, such as interleukin-1, neuropeptide Y and nitric oxide can also be involved. In general, metabolic changes resulting from neoplasia and from the patient's individual behaviour, namely their emotional state, seem to be connected with diminishing food intake and anorexia<sup>82</sup>.

### - Nausea and vomiting

Nausea and vomiting are common among cancer patients in advanced stages of the disease<sup>94</sup> and have been observed in about 60% of the patients at some point of the treatment<sup>95,96</sup>. These symptoms are considered by patients as the most severe secondary effects of chemotherapy<sup>97,98</sup>. When severe, they can result in complications such as dehydration, electrolytic imbalance and compromised quality of life. Nausea and vomiting are sources of intense anxiety and stress and these can interfere with treatment compliance<sup>51</sup>. Patients sometimes delay chemotherapy cycles and refuse future treatments because of anticipation of further episodes of nausea and vomiting<sup>99</sup>.

Chemotherapy-induced debilitating side effects like nausea and vomiting, though related, are actually two distinct symptoms and often go hand-in-hand. Nausea is an unpleasant sensation experienced in the back of the throat and epigastrium that may or may not result in the expulsion of contents from the stomach, while vomiting is the motor reflex resulting in forceful upward expulsion of contents from the stomach<sup>99</sup>.

Episodes of nausea and vomiting can be classified as acute, late-onset and anticipatory. Nausea and vomiting may be triggered by factors such as taste, odour, sight, thoughts or anxiety associated with the treatment<sup>99</sup>. These symptoms often occur together, accompanied by signs

and symptoms such as tachycardia, pallor, weakness, dizziness, and sudoresis<sup>51,100</sup>.

Nausea and vomiting are responsible for a serious decrease in food intake, resulting in severe malnutrition in some cases. They may also compromise the dose and the schedule of cancer treatments, thus affecting their outcome<sup>89,95,101</sup>.

#### - Diarrhoea

One of the most common side effects of treatment in patients undergoing chemotherapy and/or abdominal radiation therapy is diarrhoea<sup>102</sup>. Diarrhoea is a debilitating condition that can cause dehydration, electrolyte imbalance, renal insufficiency, malnutrition, hospitalisation and even death<sup>103</sup>. Depending on the severity of diarrhoea, therapy dose reductions or discontinuation of treatment can occur, resulting in less-than-optimal treatment outcomes<sup>44,51,104,105</sup>. This symptom requires a prompt and effective management to prevent complications, maintain the chemotherapeutic regimen and improve patient quality of life. A systematic approach to the management of treatment-induced diarrhoea is important<sup>104</sup>.

Chemotherapy causes damage to the intestinal mucosa, resulting in necrosis of the cells that line the intestine. Those necrotic (or dead) cells increase inflammation within the intestinal mucosa, causing decreased intestinal absorption and resultant diarrhoea. In addition, abdominal radiation therapy causes increased intestinal motility<sup>106</sup>.

Although the reported prevalence and severity of diarrhoea vary greatly, some chemotherapeutic regimens are associated with diarrhoea rates as high as 50%–80%<sup>44,107</sup>. Fluorouracil and irinotecan-based therapies have been reported to cause diarrhoea in 80% of the recipients, with 30% or more experiencing severe diarrhoea<sup>108</sup>. According to the Common Terminology Criteria for Adverse Events<sup>109</sup>, more than half of the patients receiving chemotherapy for colorectal cancer experience diarrhoea, requiring reduction, delay or discontinuation of therapy. Radiation-induced diarrhoea is the most frequent acute toxic response for patients undergoing adjuvant or primary treatment for gastrointestinal, gynaecologic or genitourinary cancer<sup>110</sup>. With radiation enteritis there is high incidence of diarrhoea, proportional to the radiation dose suffered by the patient<sup>111</sup>. Tumours in the gastrointestinal tract and neuroendocrine may also induce this symptom<sup>112</sup>.

With cancer treatment-induced diarrhoea the risk of infectious diseases increases, which might lead to sepsis in patients with chemotherapy-induced neutropenia. In addition, diarrhoea might have a serious, negative impact in the patient's quality of life<sup>113</sup>.

#### - Constipation

Constipation is an adverse effect from anticancer treatment. However, it should be distinguished from complications of the neoplasm itself. In fact, subocclusion and intestinal obstruction may result in constipation, especially in patients with cancer of the pelvic, gynaecological (ovarian), gastric, and pancreatic regions, arising as a result of tumour growth, plexus invasion, presence of adhesions, hernias, previous radiotherapy and peritoneal carcinomatosis<sup>51,66,114,115</sup>. Pharmacotherapy (namely opioids, vitamin supplements, diuretics, tranquilisers and sleeping medication) may also cause this symptom<sup>114</sup>.

Chemotherapy-induced constipation is recognised as a combination of the decrease in intestinal motility frequency and the increase in faecal consistency<sup>116</sup>. Some cytotoxic medicines can, by themselves, cause alterations to the autonomous nervous system, which provoke constipation and can also cause side effects such as diminishing oral intake due to anorexia, dehydration, diminishing intestinal motility, neuropathy, increase in reabsorption and obstruction, which thus lead to constipation<sup>89</sup>.

Constipation is also associated with physical, social and emotional stress, besides inducing headaches, fatigue, abdominal pain, haemorrhoids, nausea and vomiting, being considered a factor of abandonment of analgesic treatment<sup>117</sup>.

#### - Taste and smell changes

Taste and smell of food are the main motivating factors for eating<sup>118,119</sup>. Changes in taste and smell, including phantogeusia and hypogeusia, are frequently mentioned among cancer patients during and after treatment<sup>120</sup>. It is known that two thirds of patients suffering from cancer who are receiving chemotherapy complain about a decrease in sensory perception. This decrease in perception causes psychological anxiety and malnutrition, and contribute to a large extent to the quality of life of the patient, leading to a negative impact on survival<sup>119</sup>.

One-third of cancer patients have a reduction in their perception of sweet taste. Less frequent are aversions for or reductions in the taste of bitter, sour or salty. A metallic taste is described during chemotherapies containing cyclophosphamide, antibiotic treatments with imidazole and zinc deficiency. An aversion for new tastes is particularly frequent during chemotherapy. Moreover, a dislike for meat and all kinds of food with strong odours, either naturally or after cooking (meat, fish, cabbage, etc.), is common<sup>121</sup>.

Alterations in taste and smell result in food aversion and a diminishing food intake, which

contributes for the risk of malnutrition<sup>120</sup>. Alterations in taste can be attributed to ageusia (absence of taste perception), hypogeusia (decreased sensitivity to taste perception), dysgeusia (distortion of taste perception), or phantogeusia (an intermittent or persistent taste sensation not produced by an external stimulus, often described as metallic or salty). Alterations in odours or smell can be attributed to anosmia (absence of odour perception), hyposmia (decreased sensitivity to odour perception), dysosmia (distorted ability to identify odours), parosmia (altered odour perception in the presence of another odour), agnosia (inability to discriminate perceived odours), and phantosmia (odour perception without the presence of any odour)<sup>122,123</sup>.

#### - Xerostomia

Xerostomia is characterised by a drastic reduction in secretions of the salivary glands<sup>124</sup>. Mouth dryness, cracked lips, a sense of burning and papillary atrophy on the dorsal surface of the tongue, difficulty in the use of prosthetics and thirst are some of the most common symptoms in xerostomia. Chemotherapy and radiotherapy may damage the salivary glands and cause this symptom<sup>125</sup>.

Saliva has several important functions, including antimicrobial, mechanical cleansing action, control of pH and maintaining the integrity of the oral mucosa. The role in hygiene, which is normally attributed to saliva, is also altered by the presence of xerostomia, thus contributing for a diminishing oral pH, causing the development of plaque and dental caries, periodontal disease, mucositis and oral candidiasis. Lack of saliva interferes with speech, the capacity to chew and swallow (dysphasia), and it poses difficulties in the use of dental prosthetics<sup>18,53,54</sup>. Diminishing salivary secretion alters the quantity of chemicals released by food, leading to an alteration of perception of the usual taste of food (dysgeusia)<sup>47</sup>.

Xerostomia a common symptom in patients with advanced cancer. The main causes of xerostomia among these patients are cancer treatments (radiotherapy in the head and neck region and chemotherapy), consequences of the cancer itself, dehydration and general debility and concomitant use of medications such as opioids<sup>124</sup>. Other factors include depression, anxiety, stress and malnutrition<sup>126</sup>.

Patients experiencing xerostomia from head and neck radiation therapy or cancer chemotherapy are at particular risk of dental caries and infections from normal oral flora<sup>127</sup>. Oral ulcerations can become the nidus of invasive gram-positive and gram-negative infections, and opportunistic infections with fungal organisms such as *Candida* can occur<sup>128,129</sup>.

Patients with hyposalivation suffer from oral discomfort or pain, they find it difficult to speak,

eat, drink, chew or swallow (burning mouth), and run an increased risk of halitosis, dental caries or oral infection (e.g. candidiasis)<sup>128,130</sup>. Ultimately, this debilitating condition leads to a decrease in nutritional intake and weight loss, which may impair nutritional status and also negatively affect the quality of life<sup>124,126,131-133</sup>.

#### - Oral mucositis

Oral mucositis refers to erythematous and ulcerative lesions of the oral mucosa, observed in patients with cancer being treated with chemotherapy and/ or with radiation therapy to fields involving the oral cavity<sup>89,51,93,134</sup>. It is a common treatment-limiting side effect of cancer therapy that may have a significant impact on quality of life, patient distress, dose-limiting toxicity, reductions in dose intensity and interruption, delay or discontinuance of cancer therapy, contributing to poor treatment outcomes and significantly increasing costs within the healthcare system<sup>89,135-137</sup>. This symptom develops in approximately 90% of patients receiving radiation therapy to the upper aero-digestive tract<sup>137</sup>.

Mucositis occurs when cancer treatments break down the rapidly divided epithelial cells lining the gastrointestinal tract (which goes from the mouth to the anus), leaving the mucosal tissue open to ulceration and infection<sup>138</sup>. It is, therefore, clear that the clinical impact of mucositis is profound. Even when described as mild to moderate, oral mucositis is still associated with increased oral pain, weight loss, dietary modifications (including gastrostomy tube placement use), dehydration and reduced performance status; even mild mucositis results in more frequent hospitalisation and breaks in treatment. Severe oral mucositis is associated with systemic findings of weight loss out of proportion to calorie intake, as well as fatigue, anorexia, dehydration and general debility from chemoradiation treatment<sup>137</sup>.

#### - Early satiety

Early satiety, the sensation of being “full” after a small amount of solid food or liquids, is a common, but under-recognised, symptom in advanced cancer. This has significant symptomatic and nutritional consequences in patients with advanced cancer, contributing to or causing nausea, vomiting and anorexia<sup>139</sup>.

Early satiety can occur without anorexia. However, most cancer patients with early satiety complain of anorexia. Yet, when fasted, they become hungry, like healthy individuals. They have the desire to eat, although demonstrating inability to eat (except for small amounts) due to a

sense of fullness<sup>140</sup>.

Central and peripheral mechanisms may be involved in the genesis of early satiety, contributing to loss of appetite<sup>140</sup>. Central influences may be related to food aversions, taste changes, and diurnal variations in food intake (in cancer patients' satiety is not as high in the morning). Peripheral changes may include lack of gastric accommodation, delayed gastric emptying or altered enteric neuron sensory signals. The most likely cause of early satiety is reduced upper gastrointestinal motility, possibly due to a paraneoplastic syndrome or cancer treatment, producing autonomic nervous system dysfunction<sup>56</sup>. The reduced motility may cause nausea, bloating and other symptoms, commonly increasing in severity as the day goes on<sup>139</sup>. Visceral hypersensitivity may lead to early satiety<sup>141</sup>, and it can occur in the presence of increased brain tryptophan, dysfunctional hypothalamic membrane adenylate cyclase<sup>89,142</sup>.

#### - Dysphagia

Dysphagia is a condition resulting in a disturbance in the normal transfer of food from the oral cavity to the stomach. In cancer patients, dysphagia is one of the most frequently occurring syndromes in the head and neck, and brain tumours or as a sequel of chemoradiation or surgery for these malignancies, or generalised weakness due to no use or reduced use of muscles in the oral and pharyngeal region or even malnutrition<sup>51</sup>.

Based on the origin of dysphagia, it is classified as oropharyngeal or oesophageal. Oropharyngeal dysphagia is the difficulty emptying material from the oropharynx into the oesophagus; it results from abnormal function proximal to the oesophagus. Patients complain of difficulty initiating swallowing, nasal regurgitation and tracheal aspiration followed by coughing. Oesophageal dysphagia is characterised by difficulty passing food down the oesophagus. It results from either a motility disorder or a mechanical obstruction. When there is pain associated with the process of swallowing, the term odynophagia is used<sup>51</sup>.

Dysphagia may be attributed to tumour location and size and the extent of penetration to adjoining tissue. On the other hand, the magnitude of treatment-related effects is dependent on the extent of insult and the capacity of the patient to compensate<sup>143,144</sup>.

Prolonged dysphagia often leads to inadequate and compromised nutritional intake and can lead to malnutrition, weight loss exacerbation of medical condition and treatment outcomes. Swallowing difficulties negatively impact quality of life functioning<sup>143,144</sup>.

When unidentified and not treated, dysphagia can lead to tracheal aspiration of ingested material, oral secretions, or both. Aspiration can cause acute pneumonia; recurrent aspiration

may eventually lead to chronic lung disease<sup>89</sup>. Recurrent choking episodes may lead to food aversion among these patients<sup>145</sup>.

#### - Fatigue

Cancer-related fatigue is a disabling and distressing symptom defined as a subjective feeling of tiredness, weakness, or lack of energy that is associated with cancer and/ or its treatment<sup>146</sup>. It is persistent, extending in duration or severity beyond what might be expected, based on a subject's recent physical activity, and it is severe enough to cause distress and interfere with usual functioning<sup>89</sup>. Cancer-related fatigue is distinct from the typical tiredness that most people experience as a result of normal daily life in that it is not relieved by rest or sleep, nor does it correspond to the patient's level of exertion<sup>147</sup>.

This symptom is reported very frequently by patients with cancer<sup>148</sup> and is often the symptom that causes the most suffering and interference with function during both the treatment and survivorship<sup>149,150</sup>. Fatigue is one of the most important factors which has a considerable influence on quality of life in cancer patients<sup>151</sup>. It may happen as an isolated symptom, or as one component within a cluster of other symptoms, including depression, pain, sleep disturbance and menopausal symptoms<sup>148</sup>.

This symptom can occur at the time of diagnosis and becomes increasingly prevalent with advancing disease<sup>146</sup>. Cancer-related fatigue can be the result of cancer treatments (including surgery, chemotherapy, and radiation) and/ or the impact of the cancer itself, and can persist many years into survivorship<sup>150</sup>.

Work over the last decade has identified several hypotheses about the aetiology of cancer-related fatigue that include elevations in levels of pro-inflammatory cytokines, 5-hydroxytryptophan dysregulation, hypothalamic-pituitary-adrenal axis dysfunction, circadian rhythm disturbances and increased vagal tone<sup>150</sup>.

Pro-inflammatory cytokines, primarily interleukin-1 $\beta$  and tumour necrosis factor- $\alpha$ , send signals to the brain that promote sickness behaviours, including fatigue, disturbed sleep, and depressive symptoms, in vulnerable individuals. The neuroanatomy of cytokine-induced depression focuses on brain circuits, with evidence of decreased baseline activity in the frontal and temporal cortices and the insula and increased activity in the cerebellum and subcortical and limbic regions. Pro-inflammatory cytokines may act independently to produce cancer-related fatigue or may overlap or work synergistically with other mechanisms<sup>148,152</sup>.

Abnormalities in energy metabolism may be related to increased energy need (the

hypermetabolic state that can accompany tumour growth, infection, fever, or surgery), decreased substrates (e.g. anaemia, hypoxemia of any cause, poor nutrition), or abnormal accumulation of muscle metabolites (e.g. lactate) that impair intermediate metabolism or normal muscle functioning. Immobility and lack of exercise may also reduce the efficiency of neuromuscular functioning. Fatigue in patients and survivors might also be related to acute conditions, chronic comorbidities or unhealthy status, psychological/ psychiatric conditions, or long-term use of central nervous system stimulating/ sedating medications (e.g. opioids, benzodiazepine, and medicines containing codeine, tranquillisers, anxiolytics and antidepressants)<sup>151,152</sup>. It can also be influenced by such factors as diurnal rhythm distortion, skeletal muscles cachexia or pro-inflammatory cytokines production<sup>148,151</sup>.

Psychiatric symptoms and disorders can both cause fatigue and have fatigue as a manifestation. Depression and anxiety are the two most common psychiatric comorbidities that occur in individuals with cancer-related fatigue<sup>150</sup>. Decrements in physical, social, cognitive, and vocational functioning<sup>150,153–155</sup>, adverse mood changes<sup>150,155</sup>, sleep disturbances<sup>148,150</sup> and emotional and spiritual distress for both patients and their family members<sup>156</sup> are among the consequences of this symptom. Cancer-related fatigue also affects cancer treatment. It may compromise the timing or completion of treatment regimens, either because fatigue is a dose-limiting adverse effect, or because it reduces the patient's willingness to adhere to treatment<sup>147,148</sup>. Nutritional deficits also can contribute to fatigue. Poor appetite, gastrointestinal symptoms, weight loss and low albumin may signal a nutritional problem<sup>150</sup>.

#### - Pain

Pain is one of most afflicting symptoms reported by cancer patients<sup>157</sup>. Its prevalence in advanced cancer is about 70%, but rates vary per both cancer type and disease stage<sup>158</sup>, and persists in 33% of those who have completed curative treatments<sup>159</sup>.

Cancer pain is the result of complex interactions among cancer cells, the peripheral and central nervous systems, and the immune system. The perceptions of pain can vary depending on anxiety, depression and distraction, which indicates the presence of additional mechanisms that modulate pain response<sup>159</sup>.

Prolonged pain can lead to depression and loss of appetite, contributing to the syndrome anorexia-cachexia. Fatigue and loss of appetite are correlated with pain intensity<sup>87</sup>. Pain itself can be exhausting, and it also can lead to fatigue by interfering with sleep and decreasing abilities for physical activity. The consequences of suboptimal pain management on quality of

life, physical functioning and psychological distress can be devastating<sup>160</sup>. Although the treatment of pain often improves fatigue, sedating side effects of the pain medications can amplify fatigue<sup>150</sup>.

Pain relief is vital to the treatment of cancer<sup>157</sup>. Pain control may indirectly improve some symptoms and other measures, such as nausea and vomiting, well-being, mood and appetite<sup>161</sup>.

#### - Other symptoms

Symptoms and problems such as depression, dental problems, financial problems, social isolation, among others, can also affect food intake and hence compromise nutritional status<sup>5</sup>. The disease adaptation-related disturbances (anorexia, depressive conditions, among others) should also be taken into account, since cognitive-behavioural changes might also interfere in the nutritional status, due to qualitative and quantitative changes of the food intake<sup>47,162</sup>. The distress (i.e. a variety of psychological responses, including depression and anxiety) is not unusual in cancer patients after diagnose. In the beginning, distress is linked to cancer diagnosis and treatment and it is considered one of their 'acute' effects. Later in the cancer trajectory, it might be characterised by fear of cancer recurrence, financial difficulties or recognition of physical long-term or late effects of treatment<sup>163</sup>.

Proactive symptom management is extremely important within the nutritional approach and it is associated with a decrease in malnutrition risk and consequent improvement of the nutritional condition; improvement of the functional capacity; maintenance or increase in quality of life; diminishing of the toxicity and of the interruption of treatments and the maintenance of their target-doses, and, consequently, a lower mortality rate<sup>89</sup>.

#### Box 4 – Activities and Function

Box 4 is the ECOG Performance Status Scale in patient terms<sup>164</sup>. In this Box the patient rates his/her activity level/functional capacity over the past month, in terms of their ability to care for themselves, daily activity and physical ability (walking, working, etc.). The score for this section is not additive. The box checked with the highest point score is the total score for the section.

This functional capacity is rated regardless of the cause. Some conditions, such as fatigue or depression, may pose substantial challenges for patients' ability to remain active. In addition, decreased food intake and metabolic stress (use of corticosteroids, fever, inflammation, trauma) may impact activities/functional capacity<sup>164–166</sup>.

Physical function has been defined as the ability to ambulate and to perform normal activities of daily living<sup>167</sup>. Cancer fatigue has been found to have a significant effect on patients' abilities to function in usual roles and activities. Untreated cancer fatigue may result in a decrease or discontinuation of normal physical, social, interpersonal and recreational activities and interfere with home, family, work and educational role performance<sup>168</sup>.

The functional impairment can have an important role in the nutritional status, as physical inactivity is related to loss of muscle mass. Even 1 week of complete bed rest in a healthy male volunteer can be associated with up to 4% loss of lean tissue, due to reduced protein synthesis<sup>169</sup>.

Physical function may be improved through exercise both during and after cancer treatment<sup>168</sup>. Physical activity has the strongest supporting evidence as an intervention to reduce fatigue, improve physical functioning and enhance quality of life in cancer patients during and after cancer treatment<sup>168</sup>.

## 2. Professional Component

The second page of the PG-SGA is completed by the healthcare professional (e. g. dietitian, nurse or physician). This component includes the diseases and their relation to nutritional requirements, age, metabolic demand, physical examination and the global assessment rating (PG-SGA category). The professional component also includes nutritional triage recommendations based on the PG-SGA numerical score.

### Worksheet 1 – Scoring Weight Loss

In this Worksheet, the healthcare professional should calculate the percentage of weight loss in the previous month (or in the previous 6 months if the information regarding the last month is not available). This percentage of weight loss should be scored and added in Box 1 (Weight). Table 1 indicates the scoring for the weight loss, according with the Common Terminology Criteria for Adverse Events criteria<sup>170</sup>.

The scoring of weight loss is determined by adding subacute and acute weight changes. Subacute weight loss is based on weight loss during the previous one month period (or 6 months if past 1 month is not available). Point scores for acute weight loss during the past 2 weeks is found in parentheses directly next to the patient responses on the PG-SGA form (Box 1). These points are additive and make up the total score for the weight loss section.

Table 1 – Score for weight loss

Weight loss in 1 month	Points	Weight loss in 6 months
10% or greater	4	20% or greater
5 - 9.9%	3	10 – 19.9%
3 – 4.9%	2	6 – 9.9%
2 – 2.9%	1	2 – 5.9%
0 – 1.9%	0	0 – 1.9%

### Worksheet 2 – Disease and Its Relation to Nutritional Requirements

This Box includes multiple catabolic conditions that may have nutritional impact: cancer; Acquired Immune Deficiency Syndrome (AIDS); existence of trauma; decubitus ulcer, open wound or fistula; chronic renal failure; cardiac or pulmonary cachexia; age above 65 years. The score is derived by one point of each condition.

Other relevant diagnoses and the staging of the primary disease (stage I, II, III, IV or other) are also included.

### Worksheet 3 – Metabolic Demand

The score for metabolic stress is determined according to the presence of fever and use of corticosteroids (Table 2). These variables are known to increase protein needs as they stimulate muscle breakdown and also increase energy requirements<sup>171</sup>.

Table 2 - Score for metabolic demand

	None (0 points)	Low (1 point)	Medium (2 points)	High (3 points)
Fever (°C)	no fever	>37,2 and <38,3	≥38,3 and <38,8	≥38,8
Fever duration (h)	no fever	<72	72	>72
Corticosteroids (mg prednisone/day)	no corticosteroids	< 10 mg	≥ 10 and < 30	≥ 30

°C = Celsius degree; h = hours; mg = milligrams

The score regarding fever is accumulated for either presence of fever or fever duration, whichever is greater. Use of corticosteroids is evaluated in the context of daily dose, expressed in prednisone equivalents, according to Table 3<sup>5</sup>. Thus, this sheet's score will result in the sum of the scores regarding fever and corticosteroids.

Table 3 - Equivalents of prednisone

	Low (1 point)	Medium (2 points)	High (3 points)
Prednisone (mg/day)	10	20	30
Cortisone (mg/day)	50	100	150
Hydrocortisone (mg/day)	40	80	120
Prednisolone (mg/day)	10	20	30
Methylprednisolone (mg/day)	8	16	24
Dexamethasone (mg/day)	1.5	3	4.5

mg = milligrams

#### Worksheet 4 – Physical exam

The physical examination includes a subjective global assessment of 3 compartments of body composition: muscle status, fat stores and state of oedema.

Muscle status is evaluated in terms of both muscle mass and muscle tone, rating the degree of loss or deficit. The following muscle locations can be assessed: temples (*temporalis* muscle), clavicles (*pectoralis* & deltoids), shoulders (deltoids), interosseous muscles, scapula (*latissimus dorsi*, *trapezius*, deltoids), thigh (quadriceps) and calf (*gastrocnemius*). Regarding the fat stores, orbital fat pads, triceps skin fold and fat overlying lower ribs can be evaluated in terms of deficit or loss. Finally, ankle and sacral oedema and ascites can be assessed in order to evaluate the presence of oedema. These locations serve as a reference for the assessment of each body compartment, so it is not necessary to assess them all.

The locations should be assessed subjectively in a scale from 0 (no abnormality), 1 (mild), 2 (moderate), and 3 (severe). Each body compartment should be globally assessed according to the same classification.

The numerical score for the physical exam is determined by the overall subjective rating of total body deficit, using a scale from 0 (no deficit), 1 (mild deficit), 2 (moderate deficit), and 3 (severe deficit). The assumption should be made that the impact of muscle deficit is higher than the fat deficit or fluid excess<sup>68,172</sup>. The total numerical score for physical exam should not exceed 3 points.

The physical examination is important for the assessment of the patient's nutritional status. Moreover, while not specifically part of the PG-SGA, when the patient is being examined, there may be markers of specific nutritional deficiencies that can also be appreciated, e.g. scaly dermatitis of zinc deficiency<sup>173</sup>. In addition, appreciation of components of the physical examination can give additional insight. As an example, the distribution of the loss of muscle

mass can be important. If the patient is spending most of their time in bed or chair, the muscle loss observed below the waist will be a combination of disuse atrophy plus malnutrition, whereas that above the waist tends to be more prominently related to malnutrition<sup>5</sup>.

### 3. Global PG-SGA Category Rating

#### Worksheet 5 – PG-SGA Global Assessment Categories

The global assessment is subjective and intends to reflect a qualitative appreciation of Box 1 (Weight), Box 2 (Nutrient intake), Box 3 (Nutrition Impact Symptoms), Box 4 (Functioning) and Worksheet 4 (Physical Exam). For each item the health professional should check the most appropriate option and, according to the results obtained, select the stage: well-nourished (stage A), moderate/ suspected malnutrition (B) or severely malnourished (C) (Table 4).

Table 4 - PG-SGA Global Assessment Categories

Category	Stage A	Stage B	Stage C
	Well-nourished	Moderate/suspected malnutrition	Severely malnourished
Weight	No weight loss OR recent non-fluid weight gain	≤ 5% loss in 1 month (≤10% in 6 months) OR Progressive weight loss	> 5% loss in 1 month (>10% in 6 months) OR Progressive weight loss
Nutrient intake	No deficit OR Significant recent improvement	Definite decrease in intake	Severe deficit in intake
Nutrition Impact Symptoms (NIS)	None OR significant recent improvement allowing adequate intake	Presence of NIS (Box 3 of PG-SGA)	Presence of NIS (Box 3 of PG-SGA)
Functioning	No deficit OR Significant recent improvement	Moderate functional deficit OR Recent deterioration	Severe functional deficit OR Recent significant deterioration
Physical Exam	No deficit OR chronic deficit but with recent clinical improvement	Evidence of mild to moderate loss of muscle mass &/or muscle tone on palpation &/or loss of SQ fat	Obvious signs of malnutrition (e.g., severe loss muscle, fat, possible oedema)

### 4. Total PG-SGA Score

The PG-SGA numerical score is obtained through the sum of the scores in Boxes A (sum of Box 1, Box 2, Box 3 and Box 4), B, C and D. Generally, 80-90% of the total PG-SGA score is generated by the patient-generated items<sup>5</sup>.



## 5. Nutritional Triage Recommendations

The triage of medical nutrition therapy based on the numeric scoring of the PG-SGA is a quick multidisciplinary approach, which allows for identification and treatment of patients with malnutrition (and those who are at risk for developing malnutrition) in a variety of oncology care venues. This may include patient and family counselling, symptom management (including pharmacologic intervention), and the selection of the appropriate nutritional intervention through food, nutritional supplements and enteral or parenteral nutrition (Table 5)<sup>68</sup>.

It is important to mention that the first line of nutritional intervention corresponds to an optimal symptom management.

Table 5 - Triage based on PG-SGA numerical score

0-1	No intervention required at this time. Re-assessment on routine and regular basis during treatment.
2-3	Patient & family education by dietitian, nurse, or other clinician with pharmacologic intervention as indicated by symptom survey (Box 3) and lab values as appropriate.
4-8	Requires intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms (Box 3).
≥ 9	Indicates a critical need for improved symptom management and/or nutrient intervention options.

## RATIONALE

Thus far, the original PG-SGA has been cross-culturally adapted and validated for two other settings: the Brazilian Portuguese<sup>174</sup> and Dutch<sup>175</sup>. However, there was no validated European Portuguese version available until now and, in order to apply this tool in the Portuguese setting, a process of translation, cross-cultural adaptation and validation was needed.

This procedure is crucial for healthcare professionals and patients to be able to correctly understand and use the form; for the Portuguese version to have conceptual, semantic and content equivalence to the original one; and to allow comparison of data from populations with different cultures and languages.

## AIM OF THE STUDY

The aim of this study was to translate, cross-culturally adapt and validate the original PG-SGA for the European Portuguese setting.

## METHODS

### Instrument

The instrument translated and adapted for the Portuguese setting was the most recent version available (3.22.15) of the English Scored PG-SGA (metric version)<sup>5</sup> (Appendix 1).

### Translation, cross-cultural adaptation and validation process

In this study, the translation, cross-cultural adaptation and validation of the translated instrument was conducted according to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guideline: “Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation”<sup>176</sup>. The ISPOR guideline has also been used in the translation and cross-cultural adaptation of the PG-SGA to the Dutch setting<sup>175</sup>. The process included 10 steps aiming to produce a European Portuguese version of the PG-SGA with conceptual, semantic and operational equivalence<sup>177,178</sup>. In this work, the first 9 steps of the guidelines are presented, since the 10th is the publication itself. The different steps of the process are described in Figure 1.

#### Step 1 – Preparation

This study begins with the request of permission to the instrument developer (Faith Ottery) to translate, adapt and validate the PG-SGA to the Portuguese setting. In this step, the developer of the instrument and a key in-country person (Paula Ravasco) were invited to be involved in the project.

#### Step 2 – Forward Translation

The two project managers (the author of the present thesis and his colleague Sandra Gomes Silva) are native speakers of the target language, also fluent in the instrument’s original language. They independently translated and cross-culturally adapted the original version of the PG-SGA to the European Portuguese language (forward translations 1 and 2).

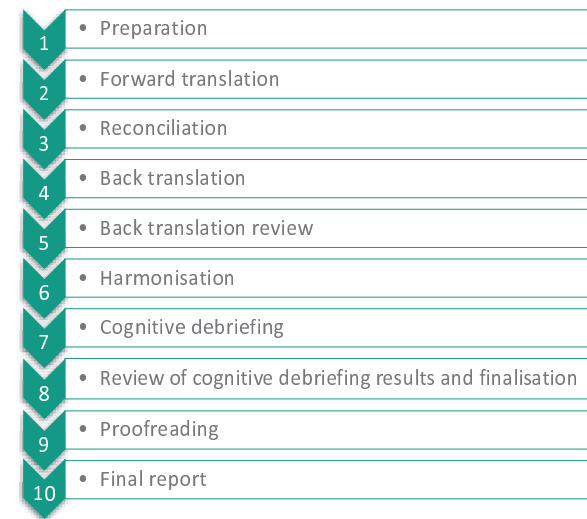


Figure 1 - Steps according to the ISPOR guideline

#### Step 3 – Reconciliation

The two forward translations were compared with each other and were transferred into one integrated forward translation (version 1) by the project managers.

Both project managers have taken part in the forward translation and the reconciliation. Integrated forward translation (version 1) was sent to be analysed by the key in-country person and by an independent group of experts that evaluated the equivalence of content (cultural, semantic, syntactic equivalences) between the original English version and version 1 of the Portuguese PG-SGA. The group of experts ( $n=16$ ) included nutritionists ( $n=7$ ), physicians ( $n=2$ ), nurses ( $n=4$ ), lawyer ( $n=1$ ), psychologist ( $n=1$ ) and English teacher ( $n=1$ ). After consensus was reached, the reconciled forward translation (version 2) was finalised.

#### Step 4 – Back Translation

Back translation is the quality control of the produced version. The two back translations of the reconciled forward translation were independently accomplished by two certificated translation companies (without knowledge of the original questionnaire).

**Step 5 – Back Translation Review**

Review of the two back translations against the source language was executed by the project managers, the developer of the PG-SGA, an international expert on cross-cultural adaptation of the PG-SGA (Harriët Jager-Wittenaar) and the key in-country person, and discrepancies were discussed.

**Step 6 – Harmonisation**

The two back translations were harmonised with each other and with the original English PG-SGA. The aim of this step was to detect and deal with any translation discrepancies that occurred between the Portuguese and English language versions, ensuring conceptual equivalence between the source and target language. A final Portuguese version of the PG-SGA was created and approved by the developer of the PG-SGA.

**Step 7 – Cognitive Debriefing**

In this step, a pilot test was developed to test comprehensibility and difficulty of the Portuguese version of the PG-SGA by patients and healthcare professionals. In addition, acceptability was tested by patients, and face validity and relevance (i.e. content validity) were tested by healthcare professionals. Furthermore, intra-rater reliability (test-retest) was assessed.

*Patients*

- Selection of participants: through a convenience sample we consecutively selected 18 patients in internal ward (inpatients) or ambulatory (nutrition appointment or performing anticancer treatments), on the Centro Hospitalar Médio Ave, Entidade Pública Empresarial (CHMA, EPE). Inclusion criteria were ability to give consent and to read, and age 18 years or above. Illiterate patients were excluded.

In the pilot test, patients filled in the Portuguese version of the PG-SGA and evaluated its comprehensibility and difficulty using a four-point *Likert* scale.

Acceptability is the reflection of the number of filled questions that shows whether the questionnaire is accessible for the patients or not<sup>179,180</sup>. Acceptability was calculated by the percentage (%) of completed items in the pilot test.

Regarding comprehensibility, each sentence of the first four Boxes was evaluated accordingly with the following scale: 1 – I didn't comprehend; 2 – I had much difficulty in comprehending; 3

– I had some difficulty in comprehending; 4 – I comprehend perfectly. For difficulty, the following scale was used: 1 – I couldn't answer; 2 – I had much difficulty in answering; 3 – I had some difficulty in answering; 4 – I did not have difficulty in answering.

Comprehensibility was operationalised by Item Comprehensibility Index (I-CI) and Scale Comprehensibility Index (S-CI), and difficulty by Item Difficulty Index (I-DI) and Scale Difficulty Index (S-DI)<sup>181,182</sup>. Scores 1 and 2 of the four-point *Likert* scale were considered “not present” and the scores 3 and 4 were considered “present”. I-CI and I-DI were calculated by dividing the number of “present” items by the total number of respondents. Item scores can range from 0-1 and if above 0.78 they are considered excellent and an item score <0.78 required further analysis of the item<sup>181</sup>. I-CI and I-DI scores of Boxes 1 to 4 are summarised into a S-CI and a S-DI for the patient-generated component of the PG-SGA. S-CI ≥ 0.80 and S-DI ≥ 0.80 are considered acceptable scores. S-CI ≥ 0.90 and S-DI ≥ 0.90 are considered excellent scores<sup>181,182</sup>. Item non-response was excluded from calculation of the index scores. Transparency of response was given by reporting overall item-response.

*Healthcare Professionals*

- Selection of participants: This sample includes physicians and nurses working at CHMA, EPE available on the day of application of the instrument; and nutritionists from other hospitals and faculties across the country that were invited to participate.

In the pilot test, healthcare professionals evaluated the professional component of the PG-SGA on comprehensibility, difficulty and relevance. Regarding comprehensibility and difficulty, the procedure was followed as described in the patients' section.

For the assessment of perceived relevance, each sentence of the PG-SGA was evaluated accordingly with the following scale: 1 – No relevance at all; 2 – Little relevance; 3 – Some relevance; 4 – High relevance. Relevance was operationalised by Item Content Validity Index (I-CVI) and Scale Content Validity Index (S-CVI). I-CVI was calculated and classified as I-CI and I-DI and S-CVI as S-CI and S-DI (as described in the patient section). Item non-response was excluded from calculation of the index scores.

Face validity is the subjective evaluation of the ability of a questionnaire to measure what it is supposed to measure<sup>179,180,183</sup>. For its measurement, after the pilot test, healthcare professionals were asked if the questionnaire seemed to measure what it was supposed to, using a yes/no question.

### *Intra-Rater Reliability*

The reliability of the instrument measures the extent to which scores for patients who have not changed are the same for repeated measurement under several conditions, i.e. the degree to which the measurement is free from measurement error. For the intra-rater reliability, a 72-hour test-retest was performed on the included inpatients.

The exclusion criteria were: hospital discharge within 72 hours after the first assessment, the absence of a stable clinical condition, and the inability to read.

To avoid inter-rater variability, one researcher performed the assessments during both the first and second assessment. Patients filled in the first four Boxes of the PG-SGA and the researcher inquired the professional components and repeated the process 72 hours later. Immediately before the second assessment, the researcher consulted the patients' clinical records to verify if any significant clinical alteration occurred during the previous 72 hours. If any, the patients were excluded. The agreement between the assessment 1 and 2 of the PG-SGA (numerical scores of the Boxes 1 - 4 and worksheets 1 - 5, total score and global category rating) were tested. Item non-response was excluded from calculation of the correlations.

### **Step 8 – Review of Cognitive Debriefing Results and Finalisation**

The review of the results from the pilot test was performed by the project coordinators and discussed with the developer of the PG-SGA, the international expert and the key in-country person, after which the Portuguese version of the PG-SGA was finalised by the project coordinators.

### **Step 9 – Proofreading**

The finalised translation was proofread by the key in-country person to check any remaining spelling, grammatical, or other errors.

### **Step 10 – Final Report**

The final report provides a description of all translation and cultural adaptation decisions, as well as the validation process. In this study, this thesis is the final report, in which the author is one of the project managers.

## **Evaluation of the methodological quality of the study**

In addition to following the steps of the ISPOR guideline, the quality of the methodology used in the cross-cultural adaptation and validation process and reliability analysis, was additionally

evaluated by the “Consensus-based standards for the selection of health measurement instruments” (COSMIN) checklist, following its four-step procedure<sup>184</sup>. The COSMIN checklist contains the following boxes: internal consistency (Box A), reliability (Box B), measurement error (Box C), content validity (including face validity) (Box D), construct validity (i.e. structural validity) (Box E), hypotheses testing (Box F), cross-cultural validity (Box G)), criterion validity (Box H), responsiveness (Box I), interpretability (Box J), Item Response Theory (IRT) Box and Generalisability Box.

The first step is the determination of which boxes need to be completed. The boxes should be filled accordingly with the measurement properties accessed. In this study, Box B, Box G and Generalisability Box for boxes B and G were completed.

The second step is the application of the IRT box. This is not applicable because IRT methods are not applied in this work.

Regarding Step 3:

- Box A, internal consistency (i.e. the degree of the interrelatedness among the items), was not performed;
- Box B, reliability (i.e. the proportion of the total variance in the measurements which is due to 'true' differences between patients), was assessed;
- Box C, measurement error (i.e. the systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured) was not assessed;
- Box D, content validity (i.e. the degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured) was not assessed;
- Box E, structural validity (i.e. the degree to which the scores of an HR-PRO instrument are an adequate reflection of the dimensionality of the construct to be measured) was not assessed;
- Box F, hypothesis testing (i.e. the degree to which the scores of an HR-PRO instrument are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the HR-PRO instrument validly measures the construct to be measured), was not assessed;
- Box G, cross-cultural validity, (i.e. the degree to which the performance of the items on a translated or culturally adapted HR-PRO instrument are an adequate reflection of the performance of the items of the original version of the HR-PRO instrument) was assessed;

- Box I, responsiveness, (i.e. the ability of an HR-PRO instrument to detect change over time in the construct to be measured), was not assessed;
- Box J, interpretability, was not applicable because it should only be used for studies that aim to assess the interpretability of an instrument.

Finally, in step 4, the Generalisability Box was completed for each propriety determined in step 1<sup>184</sup>.

Internal consistency, measurement error, content validity, construct validity, hypothesis testing criterion validity and responsiveness were not assessed in this study because these psychometric properties of the PG-SGA have already been studied in the original version and they are not the aim of the present study<sup>5,11–15,17,174,185,186</sup>.

### Statistical analysis

The data collected were entered into an electronic spreadsheet (Microsoft Office Excel®, version 2016), and, for the calculation of the indexes, simple descriptive statistics were used.

The IBM Statistical Package for the Social Sciences® (SPSS) (version 23) was used for the reliability statistics. To assess intra-rater reliability, the Intraclass Correlation Coefficient (ICC) (two-way random; single measure) was calculated, to test agreement between the first and second continuous PG-SGA score. ICC was evaluated using the following criteria: correlations ranging from 0.00 to 0.25 indicated minimal to no relationship; those from 0.25 to 0.50 indicated fair correlation; those from 0.50 to 0.75 indicated moderate to good; and those above 0.75 indicated good to excellent<sup>187</sup>. To test the agreement between the categories of the PG-SGA (considered as ordinal variables), the quadratic weighted kappa was calculated. For this measurement, an SPSS extension “STATS WEIGHTED KAPPA” was used. The criterion used for its classification was the following: poor (<0.2), fair (from 0.21 to 0.40), moderate (from 0.41 to 0.60), good (from 0.61 to 0.80) and very good (from 0.81 to 1)<sup>188</sup>. The null hypothesis was rejected when the level of its critical significance ( $p$ ) was less than 0.05.

### Ethical considerations

The study protocol was approved by the Ethics Committee of CHMA, EPE (internal reference: C.Ética/01/2015) and performed in accordance with the Helsinki declaration<sup>189</sup>. Written informed consent was obtained from all the patients included in this study.

## RESULTS

### Translation, cross-cultural adaptation and validation process

The translation and cross-cultural adaptation process was performed as described in the Methods section.

#### Step 1 – Preparation

Permission to translate, cross-cultural adapt and validate the PG-SGA by the instrument developer was achieved. Both the developer of the instrument and the key in-country person accepted to participate in the study.

#### Step 2 – Forward Translation

The two forward translations of the PG-SGA (forward translations 1 and 2) are presented in Appendix 2. From the 163 items of the tool, 18 were different between the two translations and generated debate.

#### Step 3 – Reconciliation

The discrepancies between independent translations were discussed and solved by the project managers. An integrated forward translation (version 1) was achieved (Appendix 2).

With the inputs by the key in-country person and the group of experts, the reconciled forward translation (version 2) was finalised (Appendix 2). Between the version 1 and 2, 41 items were changed.

#### Step 4 – Back Translation

The two back translations were independently accomplished by two certified translation companies (Appendix 3 and 4) and are presented in Appendix 5. Between the back translations 1 and 2, 86 items were different.

#### Step 5 – Back Translation

Review of the two back translations was executed and the discrepancies were discussed. Despite literal differences between the back translations and the original English PG-SGA, it was verified that the back translated version was equivalent to the original English version (Appendix 5), indicating an adequate translation of the original PG-SGA to the Portuguese language and

Portuguese setting.

### Step 6 – Harmonisation

In the harmonisation step, changes were made as some differences were detected regarding conceptual equivalence. Table 6 presents the 3 items that were changed to ensure the equivalence between the original and the final Portuguese version.

Table 6 - Comparison of version 2 and the final Portuguese version

Reconciled forward translation (version 2)	Final Portuguese version
poucos alimentos sólidos (comida normal mas em pouca quantidade)	poucos alimentos sólidos
feridas na boca (aftas)	feridas na boca
sinto-me enfiado (“cheio”) depressa	sinto-me cheio depressa

After these corrections, the final version of the Portuguese PG-SGA was accepted by the developer of the PG-SGA.

### Step 7 – Cognitive Debriefing

#### Patients

In the pilot test, 18 patients were recruited. Two patients were excluded due to their illiteracy, therefore, 16 patients filled in the Portuguese version of the PG-SGA. The sample included 7 female and 9 male patients, with a mean age of  $59.6 \pm 11.4$  years. The principal diagnosis was cancer in 12 patients: breast ( $n=4$ ), gastric ( $n=3$ ), colon ( $n=2$ ), oesophageal ( $n=1$ ) and colorectal ( $n=2$ ). The other diagnosis was stroke ( $n=2$ ), cirrhosis ( $n=1$ ) and esophagitis ( $n=1$ ). No missing items were found.

Regarding acceptability, all patients completed all items of the questionnaire. No missing items were found (100% acceptability). Comprehensibility and difficulty of the Portuguese PG-SGA as evaluated by the patients were considered to be excellent ( $S-CI=0.94$  and  $S-DI=0.94$ ), as shown in Appendix 6. When calculated the  $S-CI$  considering only the score 4 as “present”, the  $S-CI$  (4) would be 0.84. There was only one item “Not feeling up to most things, but in bed or chair less than half the day” with the same number of scores 3 and 4; the other items had more scores of 4 than scores of 3. Regarding difficulty, when calculated the  $S-DI$  considering only score 4 as “present”,  $S-DI$  (4) would be 0.83. There was only one item “Not feeling up to most things, but in bed or chair less than half the day” with the same number of scores 3 and 4; the other items had more scores of 4 than scores of 3.

The items with lowest scores of comprehensibility and difficulty were: “No último mês, comparando com o habitual, eu classificaria a minha alimentação como” (As compared to my normal intake, I would rate my food intake during the past month as) ( $I-CI=0.81$  and  $I-DI=0.81$ ); “comida normal mas em menor quantidade” (normal food but less than normal amount) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “poucos alimentos sólidos” (little solid food) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “apenas alimentos líquidos” (only liquids) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “apenas suplementos nutricionais” (only nutritional supplements) ( $I-CI=0.81$ ); “muito pouca quantidade de qualquer alimento” (very little of anything) ( $I-CI=0.81$  and  $I-DI=0.81$ ); “apenas alimentação por sonda ou pela veia” (only tube feedings or only nutrition by vein) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “alimentos têm agora um sabor estranho ou não têm sabor” (things taste funny or have no taste) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “sinto-me cheio depressa” (feel full quickly) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “Normal sem limitações e sou capaz de fazer a minha vida diária normal” (with no limitations) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “não estou normal, mas sou capaz de fazer grande parte das minhas atividades diárias habituais” (not my normal self, but able to be up and about with fairly normal activities) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “não me sinto capaz de realizar a maioria das minhas atividades e fico na cama ou sentado menos de metade do dia” (not feeling up to most things, but in bed or chair less than half the day) ( $I-CI=0.88$  and  $I-DI=0.88$ ); “sou capaz de realizar poucas atividades e passo a maior parte do dia na cama ou sentado” (able to do little activity and spend most of the day in bed or chair) ( $I-CI=0.81$  and  $I-DI=0.81$ ). However, the lowest scoring items were still considered to be excellent ( $I-CI$  and  $I-DI>0.78$ ).

#### Healthcare professionals

Twenty-two healthcare professionals participated in the study: physicians ( $n=4$ ), medical interns ( $n=5$ ), nutritionists ( $n=7$ ), nutrition students ( $n=2$ ) and nurses ( $n=4$ ). Although healthcare professionals were aware of the existence of PG-SGA, they were not trained in using the instrument.

Results regarding comprehensibility ( $I-CI$ ) are shown in Table 7 and the  $S-CI$  was 0.99. When calculated the  $S-CI$  considering only the score 4 as “present”, the  $S-CI$  (4) would be 0.67. Except the items “Muscle status” and “Fat stores”, where the  $I-CI$  (3) is higher than  $I-CI$  (4), the other items have more scores of 4 than scores of 3.

Results regarding difficulty ( $I-DI$ ) are shown in Table 8 and  $S-DI$  was 0.97. When calculated the  $S-DI$  considering only the score 4 as “present”, the  $S-DI$  (4) would be 0.60. Except the items “Muscle status”, “Fat stores” and “Fluid status” (Worksheet 4), where the  $I-DI$  (3) is higher than  $I-DI$  (4),

the other items have more scores of 4 than scores of 3.

Results regarding relevance (I-CVI) are shown in Table 9 and S-CVI was 0.98. When calculated the S-CVI considering only the score 4 as “present”, the S-CVI (4) would be 0.81. All the items have more scores of 4 than scores of 3.

All this results were classified as excellent, considering the calculation of indexes using both scores 3 and 4 as “present”. No missing items were found.

About face validity, all of the healthcare professionals answered that the questionnaire seemed to measure what it was supposed to (n=21; missing response: n=1).

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Table 7 - Evaluation of comprehensibility by healthcare professionals

	Comprehensibility																						n	I-CI	n of 3/4	I-CI (4)	n of 4	I-CI (3)
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22						
<b>Participant Worksheet 1</b>	1	2	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	20	0.91	2	0.09
Scoring Weight loss	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	16	0.73	6	0.27
<b>Participant Worksheet 2</b>	3	4	4	4	4	4	4	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	13	0.59	8	0.38
Conditions	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	13	0.59	8	0.38
Other relevant diagnoses	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	13	0.59	8	0.38
Primary disease staging	3	3	4	4	4	4	4	4	3	3	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	13	0.59	9	0.41
<b>Participant Worksheet 3</b>	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	17	0.77	5	0.23
Fever	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	17	0.77	5	0.23
Fever duration	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	17	0.77	5	0.23
Corticosteroids	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	17	0.77	5	0.23
<b>Participant Worksheet 4</b>	4	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	9	0.41	13	0.59
Muscle status	4	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	9	0.41	13	0.59
Fat stores	4	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	9	0.41	13	0.59
Fluid status	4	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	12	0.55	10	0.45
<b>Total PG-SGA Score</b>	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	18	0.82	4	0.18
<b>Global PG-SGA Category Rating</b>	4	4	4	4	4	2	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	0.91	17	0.77	3	0.15
																								<b>S-CI</b>		<b>S-CI (4)</b>		<b>S-CI (3)</b>
																								<b>0.99</b>		<b>0.67</b>		<b>0.32</b>

1, 2 – “not present” | 3, 4 – “present” | I-CI – Item Comprehensibility Index | S-CI – Scale Comprehensibility Index | I-CI (4) – Item Comprehensibility Index (only score 4 considered “present”) | I-CI (3) – Item Comprehensibility Index (only score 3 considered “present”) | S-CI (4) – Scale Comprehensibility Index (only score 4 considered “present”) | S-CI (3) – Scale Comprehensibility Index (only score 3 considered “present”) |

Table 8 - Evaluation of difficulty by healthcare professionals

	Difficulty																				n	I-DI	n of 4	I-DI (4)	n of 3	I-DI (3)			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20							21	22	
<b>Participant</b>																													
<b>Worksheet 1</b>																													
Scoring Weight loss	4	4	4	4	3	4	4	4	4	4	4	4	4	4	4	4	4	1	3	4	3	4	4	22	0.95	18	0.82	3	0.14
<b>Worksheet 2</b>																													
Conditions	3	4	4	4	4	4	3	3	4	4	4	4	4	4	4	4	4	4	4	3	4	4	4	22	1.00	18	0.82	4	0.18
Other relevant diagnoses	3	4	4	4	4	3	4	3	4	4	3	3	4	4	1	3	4	3	3	3	3	4	4	22	0.95	12	0.55	9	0.43
Primary disease staging	3	3	4	4	3	4	4	3	4	3	3	3	3	4	3	4	3	4	3	4	3	2	4	22	0.95	11	0.50	10	0.48
<b>Worksheet 3</b>																													
Fever	4	4	4	4	4	4	4	3	4	4	4	4	4	3	3	4	4	4	4	4	3	4	22	1.00	18	0.82	4	0.18	
Fever duration	4	4	4	4	4	4	3	4	4	4	4	4	3	4	3	4	3	4	3	4	3	4	22	1.00	16	0.73	6	0.27	
Corticosteroids	4	4	4	4	4	3	4	3	4	4	4	4	3	3	4	3	4	4	4	3	4	3	22	1.00	15	0.68	7	0.32	
<b>Worksheet 4</b>																													
Muscle status	2	3	4	3	3	3	3	3	4	3	3	3	3	3	3	3	3	3	3	3	2	3	3	22	0.91	3	0.14	17	0.85
Fat stores	3	3	4	4	3	3	3	4	3	3	3	3	2	3	3	3	4	3	2	3	4	3	4	22	0.91	5	0.23	15	0.75
Fluid status	4	3	4	4	3	3	3	4	4	3	4	3	4	3	3	4	3	4	3	3	3	3	3	22	1.00	8	0.36	14	0.64
<b>Total PG-SGA Score</b>	4	4	4	4	4	4	4	4	4	4	4	3	4	4	3	4	4	3	4	4	3	4	4	22	1.00	19	0.86	3	0.14
<b>Global PG-SGA Category Rating</b>	4	4	4	3	2	3	4	4	4	4	2	4	4	4	4	4	4	4	4	4	3	4	4	22	0.91	16	0.73	4	0.20
																						<b>S-DI</b>	<b>S-DI (4)</b>	<b>S-DI (3)</b>	<b>0.38</b>				
																						<b>0.97</b>	<b>0.60</b>	<b>0.60</b>					

1, 2 – “not present” | 3, 4 – “present” | I-DI – Item Difficulty Index | S-DI – Scale Difficulty Index | I-DI (4) – Item Difficulty Index (only score 4 considered “present”) | I-DI (3) – Item Difficulty Index (only score 3 considered “present”) | S-DI (4) – Scale Difficulty Index (only score 4 considered “present”) | S-DI (3) – Scale Difficulty Index (only score 3 considered “present”) |

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Table 9 - Evaluation of relevance by healthcare professionals

	Relevance																				n	I-CVI	n of 4	I-CVI (4)	n of 3	I-CVI (3)			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20							21	22	
<b>Participant</b>																													
<b>Worksheet 1</b>																													
Scoring Weight loss	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	3	4	4	4	22	1.00	20	0.91	2	0.09	
<b>Worksheet 2</b>																													
Conditions	4	4	4	4	4	3	4	4	4	4	4	4	4	4	4	3	4	4	3	4	4	4	22	1.00	18	0.82	4	0.18	
Other relevant diagnoses	4	4	4	4	3	4	4	4	4	4	4	3	4	4	2	4	4	3	3	4	3	4	2	22	0.91	16	0.73	4	0.20
Primary disease staging	4	4	4	3	3	4	2	4	4	4	4	4	4	4	3	3	4	3	4	3	4	3	2	22	0.91	14	0.64	6	0.30
<b>Worksheet 3</b>																													
Fever	4	4	4	4	4	4	4	4	4	3	4	3	4	3	4	4	4	4	4	4	4	4	22	1.00	19	0.86	3	0.14	
Fever duration	4	4	4	4	3	4	3	4	4	3	4	3	4	3	4	3	4	3	4	4	4	4	22	1.00	16	0.73	6	0.27	
Corticosteroids	4	4	4	4	4	3	3	4	4	3	4	3	4	3	4	3	4	3	4	3	4	4	22	1.00	15	0.68	7	0.32	
<b>Worksheet 4</b>																													
Muscle status	4	3	4	4	4	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	22	1.00	19	0.86	3	0.14	
Fat stores	4	3	4	4	4	3	3	4	4	4	4	4	4	4	4	4	3	4	4	3	4	4	22	1.00	18	0.82	4	0.18	
Fluid status	4	3	4	4	4	3	4	4	4	4	4	3	4	4	4	4	4	4	4	4	4	4	22	1.00	18	0.82	4	0.18	
<b>Total PG-SGA Score</b>	4	4	4	4	4	4	4	4	4	4	4	3	4	4	4	4	4	4	4	4	4	4	22	1.00	21	0.95	1	0.05	
<b>Global PG-SGA Category Rating</b>	4	4	4	4	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	4	4	22	1.00	20	0.91	2	0.09
																						<b>S-CVI</b>	<b>S-CVI (4)</b>	<b>S-CVI (3)</b>	<b>0.18</b>				
																						<b>0.98</b>	<b>0.81</b>	<b>0.81</b>					

1, 2 – “not present” | 3, 4 – “present” | I-CVI – Item Content Validity Index | S-CVI – Scale Content Validity Index | I-CVI (4) – Item Content Validity Index (only score 4 considered “present”) | I-CVI (3) – Item Content Validity Index (only score 3 considered “present”) | S-CVI (4) – Scale Content Validity Index (only score 4 considered “present”) | S-CVI (3) – Scale Content Validity Index (only score 3 considered “present”) |

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### Intra-rater reliability

From the recruited inpatients ( $n=12$ ), 3 were excluded from the test-retest, because their clinical condition significantly changed within the 72-hour interval or because of discharge and the results of 9 patients were analyzed. No missing items were found.

Between the two evaluations, agreement between the PG-SGA numerical scores on the first and second measurement was very good (ICC=0.832; 95% CI: 0.745; 0.892;  $p<0.001$ ).

Differences in total PG-SGA numerical score between the first and the second assessment ranged from 0 to 6 points.

Regarding the global category rating, weighted kappa was 0.727 (std. error 0.247) with evidence of statistical significance ( $p=0.023$ ), which is considered moderate to good (Table 10).

Table 10 - Agreement in PG-SGA Global Category rating between the first and second assessment

		1 <sup>st</sup> measurement		
		Stage A	Stage B	Stage C
2 <sup>nd</sup> measurement	Stage A	6	0	0
	Stage B	1	2	0
	Stage C	0	0	0

### Step 8 – Review of Cognitive Debriefing Results and Finalisation

Cognitive debriefing results were reviewed. No translation modifications were necessary for improvement. The translation was considered finalised by the project managers.

### Step 9 – Proofreading

The finalised translation was proofread by the key in-country person. No changes were made in this step.

### Step 10 – Final Report

Step 10 includes the current report. The final Portuguese version is available as download at [www.pt-global.org](http://www.pt-global.org) (Appendix 7).

## Evaluation of the methodological quality of the study

### Quality on reliability

In Table 11 the results of the COSMIN checklist on reliability (Box B) are presented. In Table 12, the Generalisability Box for Box B (Reliability) is presented.

Table 11- Box B - Reliability

Design requirements		Yes	No	?
1	Was the percentage of missing items given?	x		
2	Was there a description of how missing items were handled?	x		
3	Was the sample size included in the analysis adequate?		x	
4	Were at least two measurements available?	x		
5	Were the administrations independent?		x	
6	Was the time interval stated?	x		
7	Were patients stable in the interim period on the construct to be measured?	x		
8	Was the time interval appropriate?	x		
9	Were the test conditions similar for both measurements? e.g. type of administration, environment, instructions	x		
10	Were there any important flaws in the design or methods of the study?		x	
Statistical methods		Yes	No	NA
11	For continuous scores: Was an Intraclass Correlation Coefficient (ICC) calculated?	x		
12	For dichotomous/nominal/ordinal scores: Was kappa calculated?			x
13	For ordinal scores: Was a weighted kappa calculated?	x		
14	For ordinal scores: Was the weighting scheme described? e.g. linear, quadratic	x		

"?" - unknown | "NA" - Not Applicable

Table 12 - Generalisability Box (Box B - Reliability)

		Yes	No	NA
Was the sample in which the HR-PRO instrument was evaluated adequately described? In terms of:				
1	Median or mean age (with standard deviation or range)?		x	
2	Distribution of sex?		x	
3	Important disease characteristics (e.g. severity, status, duration) and description of treatment?		x	
4	Setting(s) in which the study was conducted? e.g. general population, primary care or hospital/rehabilitation care		x	
5	Countries in which the study was conducted?		x	
6	Language in which the HR-PRO instrument was evaluated?		x	
7	Was the method used to select patients adequately described? e.g. convenience, consecutive, or random		x	
		Yes	No	?
8	Was the percentage of missing responses (response rate) acceptable?	x		

"?" – unknown | NA – Not Applicable | "HR-PRO" - Health-Related Patient-Reported Outcomes

### Quality on cross-cultural validity

In Table 13 the results of the cross-cultural validity checklist by COSMIN (Box G) are presented.

In Table 14, the Generalisability Box for Box G (Cross-cultural validity) is presented.

Table 13 – Box G - Cross-cultural validity

Design requirements	Yes	No	?
1 Was the percentage of missing items given?	x		
2 Was there a description of how missing items were handled?	x		
3 Was the sample size included in the analysis adequate?	x		
4 Were both the original language in which the HR-PRO instrument was developed, and the language in which the HR-PRO instrument was translated described?	x		
5 Was the expertise of the people involved in the translation process adequately described? e.g. expertise in the disease(s) involved, expertise in the construct to be measured, expertise in both languages	x		
6 Did the translators work independently from each other?	x		
7 Were items translated forward and backward?	x		
8 Was there an adequate description of how differences between the original and translated versions were resolved?	x		
9 Was the translation reviewed by a committee (e.g. original developers)?	x		
10 Was the HR-PRO instrument pre-tested (e.g. cognitive interviews) to check interpretation, cultural relevance of the translation, and ease of comprehension?	x		
11 Was the sample used in the pre-test adequately described?	x		
12 Were the samples similar for all characteristics except language and/or cultural background?			x
13 Were there any important flaws in the design or methods of the study?		x	
Statistical methods	Yes	No	NA
14 For CTT: Was confirmatory factor analysis performed?			x
15 For IRT: Was differential item function (DIF) between language groups assessed?			x

“?” - unknown | “HR-PRO” - Health-Related Patient-Reported Outcomes | “NA” - Not Applicable | “CTT” - Classical Test Theory | “IRT” - Item-Response Theory

Table 14 - Generalisability Box (Box G - Cross-cultural validity)

	Yes	No	NA
Was the sample in which the HR-PRO instrument was evaluated adequately described? In terms of:			
1 Median or mean age (with standard deviation or range)?	x		
2 Distribution of sex?	x		
3 Important disease characteristics (e.g. severity, status, duration) and description of treatment?		x	
4 Setting(s) in which the study was conducted? e.g. general population, primary care or hospital/rehabilitation care	x		
5 Countries in which the study was conducted?	x		
6 Language in which the HR-PRO instrument was evaluated?	x		
7 Was the method used to select patients adequately described? e.g. convenience, consecutive, or random	x		
	Yes	No	?
8 Was the percentage of missing responses (response rate) acceptable?	x		

“?” – unknown | NA – Not Applicable | “HR-PRO” - Health-Related Patient-Reported Outcomes

## DISCUSSION

The diversity of the population worldwide and within institutions suggests a great need for cross-culturally validated research instruments or scales. Researchers and clinicians should have access and use reliable and valid instruments or scales in their own cultures and languages to conduct research and/or provide high quality patient care<sup>190</sup>. To facilitate the use of the PG-SGA in the Portuguese setting, the original English Scored PG-SGA was successfully translated, cross-culturally adapted and validated to the Portuguese setting.

Each culture also has its own characteristics that affect their written texts. Most of the differences in the expressions within the same language are thus explained by the differences in the vocabulary used in the various settings. Indeed, the translations in this study were not exactly the same as their originals, despite the fact that the medical language has similarities across different languages. Therefore, although there is something in common universally, cultural aspects still create linguistic variances<sup>191</sup>.

A clear distinction should be made between translation and cross-cultural adaptation. Translation is merely the first stage of the adaptation process. It is the single process of producing a document from a source version in the target language although it doesn't adequately ensure semantic equivalence between them<sup>192–194</sup>. All languages have differences in their word semantics, and thus, it is usually not possible to translate an instrument word by word<sup>195</sup>. Adaptation refers to the process of considering any differences between the source and the target culture so as to maintain equivalence in meaning. When adapting an instrument, cultural, linguistic and contextual aspects concerning its translation should be considered<sup>194,196,197</sup>.

By using the guideline proposed by ISPOR<sup>176</sup>, the original PG-SGA has been translated and cross-culturally adapted, resulting in a validated Portuguese version of the PG-SGA that maintained its conceptual, semantic, and content equivalence to the original PG-SGA. The ISPOR methodology provided a rigorous and systematic approach, maximising the validity of the process. This guideline was shown to be clear and user-friendly for the process of translation, cross-cultural adaptation and validation of the PG-SGA.

During the preparation step, as well as for the whole process, the contribution of the original instrument developer and the key in-country person was essential to avoid the misinterpretation of items or concepts.

The PG-SGA was translated by two Portuguese researchers fluent in the language of the original

instrument and experienced in clinical nutrition. This clinical experience was of great value in the translation process, so that not only the obvious meaning of the words and concepts were correct, but that they were also used in the specific context of clinical setting<sup>198,199</sup>. It is important that this step is being performed by two or more researchers rather than only one, to avoid a biased translation that includes too much of one person's own style of writing or speech habit. In this study, the two forward translations showed differences in some items. The translations that the project managers considered easier to understand by the patients were added to the integrated forward translation (version 1). The differences were mostly of an idiomatic origin. For instance, the terms "obstipação" and "intestino preso" have the same meaning (constipation), but each is used depending on the culture and literacy; so they were added together in the version 1 "obstipação (intestino preso)" to improve understanding by patients. As in Portugal the literacy level of the population is considered to be low<sup>200</sup> and the regional lexical variants are rooted in our population<sup>201</sup>, the collaboration of the group of experts living in different parts of Portugal and the key in-country person in the reconciliation step was crucial to improve the comprehension of this tool, promoting its adequacy across the country. The project managers evaluated the suggestions made by the panel and accepted most of them. In the reconciled forward translation (version 2), accordingly with the group inputs, items were changed to make the items more understandable and clear.

The independent back translations varied to a considerable extent in their terms, but the semantic meanings were frequently equivalent. The differences can be explained by the fact that the back translators were not familiar with the clinical context in which the nutrition assessment tools would be used.

The identification of 32 discrepancies between one forward translation and the final Portuguese version strengthens the need for multiple forward and backtranslations and discussion on discrepancies, reinforcing the importance of a validation process rather than a simple forward translation.

Cognitive debriefing of the final Portuguese version was important to assess the level of comprehensibility and cognitive equivalence of the translation. It is also used to highlight any items that may be inappropriate at a conceptual level, and to identify any other issues that cause confusion. Regarding this study, the cognitive debriefing revealed that the Portuguese version of the PG-SGA was accessible for patients and showed cognitive equivalence. Also, the PG-SGA showed to have face validity. Comprehensibility and difficulty of the patient-component were considered excellent on both item and scale level by the patients. Even considering only scores

of 4 as "present" for the calculation of indexes, the S-CI (4) is 0.84 and S-DI (4) is 0.83, which is still considerable acceptable. Almost all items presented a higher number of scores 4 than 3 for both difficulty and comprehensibility, except for one ("Not feeling up to most things, but in bed or chair less than half the day"), that presented an equal number of scores 3 and 4. The Portuguese PG-SGA also showed excellent acceptability by the patients, indicating there was no need to reword any item and that the PG-SGA can be considered adapted for use by patients in the Portuguese setting.

Regarding the evaluation by healthcare professionals, comprehensibility, difficulty and relevance were also considered excellent on both item and scale level. There was no need to reword any items in the professional component either. Considering only scores of 4 as "present" for the calculation of indexes, the S-CI (4) is 0.67, S-DI (4) is 0.60 and S-CVI (4) is 0.81. Despite that S-CI (4) and S-DI (4) are lower than the acceptable cut-off, they are still higher than S-CI (3) and S-DI (3). S-CVI (4) is considered acceptable. Regarding the items of the scale, the items in Worksheet 4 were those that presented lower I-DI and I-DI (4).

Scores on difficulty and comprehensibility of the Portuguese PG-SGA were quite comparable to those found in the study on the translation, cross-cultural adaptation and validation of the PG-SGA for the Dutch setting<sup>202</sup>. Portuguese patients reported some difficulty recording the weight 6 months ago (I-DI=0.88) even though they did understand the question (I-CI=1.00), similar to the Dutch patients (I-DI=0.83 and I-CI=1.00). Also, the item that evaluates the food intake in the past month comparing to normal intake had the lowest score on difficulty in both Portuguese patients (I-DI=0.81) and Dutch patients (I-DI=0.67). However, scores of the Portuguese patients were systematically higher than those of the Dutch patients. Similar to the findings in the Dutch study, Worksheet 4 and the Global Assessment Categories in the Portuguese version of the PG-SGA presented the lowest scores on difficulty, although they were again higher than in the Dutch study. As lower scores on difficulty indicate a certain lack of knowledge in the respondent, these results reinforce the need for training by healthcare professionals, to improve their comprehensibility and difficulty. Indeed training on the PG-SGA has shown to improve both difficulty and comprehensibility of the PG-SGA, as shown by the study by Sealy *et al.*<sup>186</sup>.

Similar to the Dutch study, the results of the current study revealed the adequacy of the Portuguese language version of the PG-SGA for difficulty and comprehensibility for patients and professionals. Although it remains unclear why scores on difficulty and comprehensibility of the Portuguese patients and professionals were higher, it cannot be ruled out that cultural differences between both countries may have played a role in the higher Portuguese scores.

The PG-SGA not only scored very high on comprehensibility, difficulty, relevance and face validity, but scored adequate on intra-rater reliability as well. In this measurement, the agreement between the two global category ratings was less strong than the agreement between the two numerical scores, which could be explained by the difference numbers of answers evaluated in each test. The numerical score is generated by a higher number of answers than the global category rating. As so, one slight change in one category rating will give a greater change in the agreement between the category ratings.

To evaluate the methodological quality of the study, the Boxes B (reliability) and G (cross-cultural validity) and the Generalisability Box of the COSMIN checklist were relevant. The study design covered most of the design requirements and statistical methods as included in these boxes of the COSMIN checklist.

In Box B the item 5 “Were the administrations independent?” was marked as “No”, because the checklist recommends to perform the test-retest by two independent researchers. In this study, the assessments in the two measurements were performed by one investigator only to avoid inter-rater variability. Furthermore, the COSMIN checklist recommends to use a time interval for the test-retest that is long enough to prevent recall bias, and short enough to ensure that patients have not been changed on the construct to be measured<sup>184</sup>. In the current study, a time interval of 72 hours was used, similar to that used in other studies<sup>203,204</sup>. Although we cannot rule out the risk of recall in both patients and the investigator, the use of a larger time interval (e.g. of 15 days as considered often appropriate by COSMIN<sup>184</sup> and used in other studies<sup>205,206</sup>) would not be appropriate and even not possible in the population studies, due to the usually shorter length of stay of patients in the internal ward and the high possibility of clinical changes during such a long period of time, especially considering the clinical nature/pathologies of the patients included in the study.

About the Generalisability Box for the reliability, the following items were marked as “No”: “Median or mean age (with standard deviation or range)?”, “Distribution of sex?” and “Important disease characteristics (e.g. severity, status, duration) and description of treatment?”. Median of age was not accessed because the instrument under study only includes age above 65 years-old. Distribution of sex was also not collected because is not included in the instrument. It cannot be ruled out that education (usually lower on elderly and females) can influence the results, but due to the simple and direct questions asked, we considered that it would not introduce significant bias to the results obtained. Additionally, the disease severity, status, duration and treatment were not assessed because they are not necessary for scoring of

the PG-SGA.

Regarding the Generalisability Box for the Cross-cultural validity, the following item were marked as “No”: important disease characteristics (e.g. severity, status, duration) and description of treatment?”. Although the primary diagnosis was collected (as shown in Results), the severity, status, duration and treatment were not assessed, as reported in the context of the reliability, because they are not necessary for the scoring of the PG-SGA.

Prior to the Dutch version, also a Brazilian version of the PG-SGA has been published<sup>174</sup>. As a different approach for the validation process was performed, the Brazilian version of the PG-SGA does not present comparable methodology, and consequently results, with the present study. Despite that, some differences between the European Portuguese and Brazilian Portuguese version of the PG-SGA can be discussed. It is known that Brazilian Portuguese differs from the European Portuguese particularly in phonology and prosody, so the Brazilian Portuguese language would not be appropriate to use in Portugal. From the comparison between the Portuguese and the Brazilian version, 92 items were different but understandable in the European Portuguese. The Brazilian version of PG-SGA includes 7 items with words that are not common in the European Portuguese language, such as “escores” (scores), “estresse” (stress) or “panturrilha” (calf). One word is common in both languages, but do not have the same meaning, such as “constipação” (constipation), that in European Portuguese refers to ‘cold’. Also, the Brazilian Portuguese language frequently employs gerund: “comendo” (eating), “sentindo” (feeling), “ficando” (staying), “passando” (spending), which is not a verb tense common in the European Portuguese language. Finally, another difference in the Brazilian Portuguese is usage of “ô”: “crônico” (chronic) or “tônus” (tone) where in European Portuguese an “ó” would be used. Accordingly, as there are some differences between the languages, it is appropriate to use different version in each country.

### Clinical implications/relevance of the study

By the conducted study, a Portuguese version of the PG-SGA was created and validated. This version has proved to have conceptual, semantic, and content equivalence to the original PG-SGA. A validated Portuguese version of the PG-SGA will now be available for healthcare professionals to be used in various settings. Hence, this availability of the PG-SGA for the Portuguese setting will allow the screening, the assessment of the nutritional status and the risk factors of malnutrition integrated in one instrument, in several patient populations throughout the chain of care. It will also allow comparisons of results between countries and provide quality

of patient care.

### Strengths and limitations of the study

An important strength of this study is that all steps of international recognised ISPOR guideline were performed. Following these steps ensured the quality of the process adopted, as confirmed by the results of COSMIN checklist. By doing two independent forward translations and also two independent back translations, we could ensure a greater cultural breadth and a smaller bias in the translated tool. In addition to the guideline, we assessed acceptability, face validity, and reliability. These additional evaluations, allowed a more rigorous and complete assessment of the validity of the translated tool. The results of this evaluation indicate that the methodology adopted has quality, both with respect to the cross-cultural validity as to reliability.

One potential limitation of this study may be the fact that the patient sample was recruited from only one hospital. This could have influenced the results of the evaluation of comprehensibility and difficulty in the cognitive debriefing step, since there are some cultural variations among the regions of the country (north vs south, continent vs autonomous regions, etc.), although these difference usually do not show up in the written texts. Also, the healthcare professionals, the group of experts and the key in-country person do not belong to the same hospital, nor even the same region of the country and this helps to ensure a more comprehensive cultural adaptation. Furthermore, we did not select patients or healthcare professionals according to their level of motivation to participate in the study, which prevented introduction of selection bias.

The educational level of the patients was not accessed in the present study. Although it could influence the results, some indicators show that the education level of this hospital' patients is usually very low<sup>207</sup>.

Another limitation of this study is the small sample size. In Box B on reliability, item 3 "Was the sample size included in the analysis adequate?" was marked as "No", because COSMIN advised a sample size of 50 participants and in this test-retest the sample size was smaller. Although testing reliability was not mandatory by the ISPOR guideline, it would be interesting to confirm the results by another evaluation in a larger sample size.

The absence of individuals in the Stage C on the test-rest may be the result of the small sample size and the usual lower prevalence of patients in Stage C, as described in other studies<sup>38,39,208-210</sup>.

Even though it is not considered a limitation, it should be noted that this cross-cultural adaptation was limited to the European Portuguese and cannot be generalised to be used in

other Portuguese-speaking countries. Linguistic and cultural differences are seen among people in each of these countries. A new translation and adaptation work should be conducted in other Portuguese-speaking cultures.

## CONCLUSION

The PG-SGA is considered the reference method for nutritional assessment and its utilisation is key in clinical practice. However, there was no validated European Portuguese version available until now and, in order to apply this tool in the Portuguese setting, a process of translation, cross-cultural adaptation and validation was needed.

The use of correctly validated tools will allow patients and healthcare professionals to correctly understand and use them. Also, the validation process is essential to ensure the equivalence to the original tool and the exchange of information in the scientific community.

The translation, cross-cultural adaptation and validation process of the PG-SGA for the Portuguese setting adequately captured the concepts of the original version, thereby demonstrating its conceptual, semantic and cultural equivalence. The Portuguese PG-SGA is a reliable and valid instrument to screen and assess the nutritional status in day-to-day clinical practice and in research.

## Future research

A next step would be the application of the PG-SGA in various health care settings across the country. Longitudinal use of the PG-SGA across the chain of care will give insight in changes in nutritional status and its risk factors over time, within populations and settings, as well as between populations and settings. Furthermore, it would be valuable to assess how the PG-SGA may contribute to patient awareness on malnutrition and the streamlining of the health care process. Finally, further insight is needed on the effectiveness of interventions on clinical outcome. The availability of the Portuguese PG-SGA facilitates research to assess whether dietary treatment and proactive symptom management may have a positive effect on nutritional status, to effectively treat or even possibly prevent malnutrition.

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Appendix 1 – English Scored PG-SGA metric version

APPENDICES

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<p align="center"><b>Scored Patient-Generated Subjective Global Assessment (PG-SGA)</b></p> <p align="center"><small>History: Boxes 1 - 4 are designed to be completed by the patient. [Boxes 1-4 are referred to as the PG-SGA Short Form (SF)]</small></p> <p><b>1. Weight</b> <i>(See Worksheet 1)</i></p> <p>In summary of my current and recent weight:</p> <p>I currently weigh about _____ kg          I am about _____ cm tall</p> <p>One month ago I weighed about _____ kg          Six months ago I weighed about _____ kg</p> <p>During the past two weeks my weight has:</p> <p><input type="checkbox"/> decreased (1)   <input type="checkbox"/> not changed (0)   <input type="checkbox"/> increased (0)</p> <p align="right"><b>Box 1</b>   <input type="checkbox"/></p>	<p align="center"><b>Patient Identification Information</b></p> <p><b>2. Food intake:</b> As compared to my normal intake, I would rate my food intake during the past month as</p> <p><input type="checkbox"/> unchanged (0)  <input type="checkbox"/> more than usual (0)  <input type="checkbox"/> less than usual (1)</p> <p>I am now taking</p> <p><input type="checkbox"/> normal food but less than normal amount (1)  <input type="checkbox"/> little solid food (2)  <input type="checkbox"/> only liquids (3)  <input type="checkbox"/> only nutritional supplements (3)  <input type="checkbox"/> very little of anything (4)  <input type="checkbox"/> only tube feedings or only nutrition by vein (0) <b>Box 2</b>   <input type="checkbox"/></p>
<p><b>3. Symptoms:</b> I have had the following problems that have kept me from eating enough during the past two weeks (check all that apply)</p> <p><input type="checkbox"/> no problems eating (0)   <input type="checkbox"/> vomiting (3)  <input type="checkbox"/> no appetite, just did not feel like eating (3)   <input type="checkbox"/> diarrhea (3)  <input type="checkbox"/> nausea (1)   <input type="checkbox"/> dry mouth (1)  <input type="checkbox"/> constipation (1)   <input type="checkbox"/> dry mouth (1)  <input type="checkbox"/> mouth sores (2)   <input type="checkbox"/> smells bother me (1)  <input type="checkbox"/> things taste funny or have no taste (1)   <input type="checkbox"/> feel full quickly (1)  <input type="checkbox"/> problems swallowing (2)   <input type="checkbox"/> fatigue (1)  <input type="checkbox"/> pain; where? (3) _____  <input type="checkbox"/> other (1) _____  <input type="checkbox"/> **Examples: depression, money, or dental problems <b>Box 3</b>   <input type="checkbox"/></p>	<p><b>4. Activities and Function:</b> Over the past month, I would generally rate my activity as:</p> <p><input type="checkbox"/> normal with no limitations (0)  <input type="checkbox"/> not my normal self, but able to be up and about with fairly normal activities (1)  <input type="checkbox"/> not feeling up to most things, but in bed or chair less than half the day (2)  <input type="checkbox"/> able to do little activity and spend most of the day in bed or chair (3)  <input type="checkbox"/> pretty much bed ridden, rarely out of bed (3)</p> <p align="right"><b>Box 4</b>   <input type="checkbox"/></p>
<p><i>The remainder of this form is to be completed by your doctor, nurse, dietitian, or therapist. Thank you.</i></p> <p align="right">©FD Ottery 2006, 2006, 2015 v3.22.15          email: <a href="mailto:faithotterympghd@aol.com">faithotterympghd@aol.com</a> or <a href="mailto:info@pt-global.org">info@pt-global.org</a></p>	
<p align="right"><b>Additive Score of Boxes 1-4</b>   <input type="checkbox"/> <b>A</b></p>	

Scored Patient-Generated Subjective Global Assessment (PG-SGA)

**Worksheet 1 – Scoring Weight Loss**  
To determine scores use 1-month weight data if available. Use 6-month data only if there is no 1-month weight data. Use points below to score weight change and add one extra point if patient has lost weight during the past 2 weeks. Enter total point score in Box 1 of PG-SGA.

Weight loss in 1 month	Points	Weight loss in 6 months
10% or greater	4	20% or greater
5-9.9%	3	10-19.9%
3-4.9%	2	6-9.9%
2-2.9%	1	2-5.9%
0-1.9%	0	0-1.9%

**Numerical score from Worksheet 1**

**Additive Score of Boxes 1-4 (See Side 1)**

**5. Worksheet 2 – Disease and its relation to nutritional requirements:**  
Score is derived by adding 1 point for each of the following conditions:

- Cancer
- Presence of decubitus, open wound or fistula
- AIDS
- Presence of trauma
- Pulmonary or cardiac cachexia
- Age greater than 65
- Chronic renal insufficiency
- Chronic renal insufficiency
- Other relevant diagnoses (specify)

Primary disease staging (circle if known or appropriate) I, II, III, IV Other

**Numerical score from Worksheet 2**

**6. Worksheet 3 – Metabolic Demand**  
Score for metabolic stress is determined by a number of variables known to increase protein & caloric needs. Note: Score fever intensity of duration, whichever is greater. The score is additive so that a patient who has a fever of 38.8 °C (3 points) for < 72 hrs (1 point) and who is on 10 mg of prednisone chronically (2 points) would have an additive score for this section of 5 points.

Stress	low (1)	moderate (2)	high (3)
Fever	> 72 and < 38.3	≥ 38.3 and < 38.8	≥ 38.8 °C
Central nutrition	low dose	moderate dose	high dose
Corticosteroids	< 10 mg prednisone equivalents/day	10-30 mg prednisone equivalents/day	> 30 mg prednisone equivalents/day

**Numerical score from Worksheet 3**

**7. Worksheet 4 – Physical Exam**  
Exam includes a subjective evaluation of 3 aspects of body composition: fat, muscle, & fluid. Since this is subjective, each aspect of the exam is rated for degree. Muscle definition impacts point score more than fat deficit/loss. Definition of categories: 0 = no abnormality, 1+ = mild, 2+ = moderate, 3+ = severe. Rating in these categories is not additive but are used to clinically assess the degree of deficit (or presence of excess fluid).

**Muscle Status**

Category	0	1+	2+	3+
Wasting	0	1+	2+	3+
Visible muscle	0	1+	2+	3+
Midline temporal subtraction	0	1+	2+	3+
Abdominal (pectus) & deltoid	0	1+	2+	3+
Interscapular muscles	0	1+	2+	3+
Scapula (distal/dorsal, ventral, deltoid)	0	1+	2+	3+
Triceps skin fold	0	1+	2+	3+
Global fat deficit rating	0	1+	2+	3+

**Fluid Status**

Category	0	1+	2+	3+
Swelling	0	1+	2+	3+
Crackles	0	1+	2+	3+
Global fluid status rating	0	1+	2+	3+

Clinician Signature \_\_\_\_\_ ID \_\_\_\_\_ RN/PA/MD/DO/Other \_\_\_\_\_ Date \_\_\_\_\_

**Worksheet 5 – PG-SGA Global Assessment Categories**

**Weight**

Category	0	1	2	3
Weight-maintained	0	1	2	3
Mild/moderate undernutrition	0	1	2	3
Severe undernutrition	0	1	2	3
OR: 10% weight loss in 6 months	0	1	2	3
OR: 20% weight loss in 12 months	0	1	2	3
OR: 30% weight loss in 18 months	0	1	2	3
OR: 40% weight loss in 24 months	0	1	2	3
OR: 50% weight loss in 36 months	0	1	2	3
OR: 60% weight loss in 48 months	0	1	2	3
OR: 70% weight loss in 60 months	0	1	2	3
OR: 80% weight loss in 72 months	0	1	2	3
OR: 90% weight loss in 84 months	0	1	2	3
OR: 100% weight loss in 96 months	0	1	2	3

**Nutritional Status**

Category	0	1	2	3
Well-nourished	0	1	2	3
Mild/moderate undernutrition	0	1	2	3
Severe undernutrition	0	1	2	3
OR: 10% weight loss in 6 months	0	1	2	3
OR: 20% weight loss in 12 months	0	1	2	3
OR: 30% weight loss in 18 months	0	1	2	3
OR: 40% weight loss in 24 months	0	1	2	3
OR: 50% weight loss in 36 months	0	1	2	3
OR: 60% weight loss in 48 months	0	1	2	3
OR: 70% weight loss in 60 months	0	1	2	3
OR: 80% weight loss in 72 months	0	1	2	3
OR: 90% weight loss in 84 months	0	1	2	3
OR: 100% weight loss in 96 months	0	1	2	3

**Functional Status**

Category	0	1	2	3
Independent	0	1	2	3
Mild/moderate dependence	0	1	2	3
Severe dependence	0	1	2	3
OR: 10% weight loss in 6 months	0	1	2	3
OR: 20% weight loss in 12 months	0	1	2	3
OR: 30% weight loss in 18 months	0	1	2	3
OR: 40% weight loss in 24 months	0	1	2	3
OR: 50% weight loss in 36 months	0	1	2	3
OR: 60% weight loss in 48 months	0	1	2	3
OR: 70% weight loss in 60 months	0	1	2	3
OR: 80% weight loss in 72 months	0	1	2	3
OR: 90% weight loss in 84 months	0	1	2	3
OR: 100% weight loss in 96 months	0	1	2	3

**Global PG-SGA Score (Total numerical score of A+B+C+D)**

Global PG-SGA Category Rating (Stage A, Stage B or Stage C) \_\_\_\_\_

**Nutritional Triage Recommendations:** Address score is used to define specific nutritional interventions, including point-of-family education, symptom management, and/or referral to dietitian, pharmacist, nutritionist, and appropriate support intervention (food, fluids, oral nutrition supplements, enteral nutrition, intravenous nutrition, and appropriate symptom management).

**Triage based on PG-SGA point score**

Point Score	Intervention
0-1	No intervention required at this time. Re-assessment on routine and regular basis during treatment.
2-3	Mild/moderate undernutrition. Consider oral nutrition supplements and/or enteral nutrition. Pharmacologic interventions as indicated by symptom survey (Box 3) and lab values as appropriate.
4-5	Severe undernutrition. Consider oral nutrition supplements and/or enteral nutrition. Pharmacologic interventions as indicated by symptom survey (Box 3) and lab values as appropriate.

**Total PG-SGA Score (Total numerical score of A+B+C+D)** \_\_\_\_\_

**Global PG-SGA Category Rating (Stage A, Stage B or Stage C)** \_\_\_\_\_

email: [fatoherteyndphd@aol.com](mailto:fatoherteyndphd@aol.com) or [info@pgt-global.org](mailto:info@pgt-global.org)

Appendices

Translation, cross-cultural adaptation and validation of the PG-SGA for the Portuguese setting.

Appendix 2 - Results of the forward translations

Forward translation 1	Forward translation 2	Integrated forward translation (version 1)	Revised forward translation (version 2)
<p>Avaliação Global Subjetiva – Gênero pelo utente cobada (PG-SGA)</p> <p>História: As caixas 1-4 foram concebidas para serem preenchidas pelo utente.</p> <p>[As caixas 1-4 constituem a versão PG-SGA Short Form]</p> <p>Identificação do utente:</p> <p>Peso</p> <p>Resumo do meu peso atual e recente:</p> <p>Eu atualmente peso cerca de kg</p> <p>Eu meço cerca de m</p> <p>Há 1 mês pesava cerca de kg</p> <p>Há 6 meses pesava cerca de kg</p> <p>Durante as duas últimas semanas o meu peso:</p> <p>Diminuiu</p> <p>Não mudou</p> <p>Aumentou</p> <p>Caixa 1</p> <p>Ingestão alimentar:</p> <p>Comparativamente com a minha ingestão habitual, eu classificaria a minha alimentação durante o último mês como:</p> <p>Igual</p> <p>Menor do que o habitual</p> <p>Eu agora ingiro</p> <p>Alimentos habituais mas em menor quantidade</p> <p>Poucos alimentos-sólidos</p> <p>Apenas alimentos líquidos</p> <p>Apenas suplementos nutricionais</p> <p>Muito pouco de qualquer coisa</p> <p>Apenas alimentação por sonda ou pela veia</p> <p>Caixa 2</p> <p>Sintomas:</p> <p>Durante as últimas duas semanas, tenho tido os seguintes problemas que me têm impedido de comer o suficiente (preencher todos os aplicáveis):</p> <p>Não tive problemas em comer</p> <p>Não tive apetite, não me apeteceu comer</p> <p>Náuseas</p> <p>Intestino preso</p> <p>Dores na boca</p> <p>Alimentos têm agora um sabor estranho ou não têm sabor</p> <p>Dificuldades em engolir</p> <p>Dor: onde? _____</p> <p>Outros: _____</p> <p>ex. Depressão, problemas dentários ou financeiros, etc.</p> <p>Vômitos</p> <p>Diarreia</p>	<p>Avaliação Global Subjetiva – Gênero pelo utente cobada (PG-SGA)</p> <p>História: As caixas 1-4 foram concebidas para serem preenchidas pelo utente.</p> <p>[As caixas 1-4 constituem a versão PG-SGA Short Form]</p> <p>Identificação do utente:</p> <p>Peso</p> <p>Resumo do meu peso atual e recente:</p> <p>Eu atualmente peso cerca de kg</p> <p>Eu meço cerca de m</p> <p>Há 1 mês pesava cerca de kg</p> <p>Há 6 meses pesava cerca de kg</p> <p>Durante as duas últimas semanas o meu peso:</p> <p>Diminuiu</p> <p>Não mudou</p> <p>Aumentou</p> <p>Caixa 1</p> <p>Ingestão alimentar:</p> <p>Comparativamente com a minha ingestão habitual, eu classificaria a minha ingestão alimentar durante o último mês como:</p> <p>Igual</p> <p>Menor do que o habitual</p> <p>Eu agora ingiro</p> <p>Alimentos habituais mas em menor quantidade</p> <p>Poucos alimentos-sólidos</p> <p>Apenas alimentos líquidos</p> <p>Apenas suplementos nutricionais</p> <p>Muito pouco de qualquer coisa</p> <p>Apenas alimentação por sonda ou pela veia</p> <p>Caixa 2</p> <p>Sintomas:</p> <p>Durante as últimas duas semanas, tenho tido os seguintes problemas que me têm impedido de comer o suficiente (preencher todos os aplicáveis):</p> <p>Não tive problemas em comer</p> <p>Não tive apetite, não me apeteceu comer</p> <p>Náuseas</p> <p>Obstipação</p> <p>Dores na boca</p> <p>Alimentos têm agora um sabor estranho ou não têm sabor</p> <p>Dificuldades em engolir</p> <p>Dor: onde? _____</p> <p>Outros: _____</p> <p>ex. Depressão, problemas dentários ou financeiros, etc.</p> <p>Vômitos</p> <p>Diarreia</p>	<p>Avaliação Global Subjetiva – Gênero pelo utente cobada (PG-SGA)</p> <p>História: As caixas 1-4 foram concebidas para serem preenchidas pelo utente.</p> <p>[As caixas 1-4 constituem a versão PG-SGA Short Form]</p> <p>Identificação do utente:</p> <p>Peso</p> <p>Resumo do meu peso atual e recente:</p> <p>Eu atualmente peso cerca de kg</p> <p>A minha altura é cm</p> <p>Há 1 mês pesava cerca de kg</p> <p>Há 6 meses pesava cerca de kg</p> <p>Durante as duas últimas semanas o meu peso:</p> <p>Diminuiu</p> <p>Ficou igual</p> <p>Aumentou</p> <p>Caixa 1</p> <p>Ingestão alimentar:</p> <p>No último mês, comparando com o habitual, eu classificaria a minha alimentação como:</p> <p>Igual</p> <p>Mais do que o habitual</p> <p>Menos do que o habitual</p> <p>Eu agora como</p> <p>Comida normal mas em menor quantidade</p> <p>Poucos alimentos sólidos (comida normal mas em pouca quantidade)</p> <p>Apenas alimentos líquidos</p> <p>Apenas suplementos nutricionais</p> <p>Muito pouca quantidade de qualquer alimento</p> <p>Apenas alimentação por sonda ou pela veia</p> <p>Caixa 2</p> <p>Sintomas:</p> <p>Durante as duas últimas semanas, tenho tido problemas que me impediram de comer o suficiente (assinalar todos os aplicáveis):</p> <p>Não tive problemas em comer</p> <p>Não tive apetite, não me apeteceu comer</p> <p>Náuseas (enjôjos)</p> <p>Obstipação (prisão da vertice)</p> <p>Feridas na boca (aftas)</p> <p>Alimentos têm agora um sabor estranho ou não têm sabor</p> <p>Dificuldades em engolir</p> <p>Dor: onde? _____</p> <p>Outros: _____</p> <p>ex. Depressão, problemas dentários ou financeiros, etc.</p> <p>Vômitos</p> <p>Diarreia</p>	<p>Avaliação Global Subjetiva – Preenchida pelo Doente (PG-SGA)</p> <p>História: As caixas 1-4 foram feitas para serem preenchidas pelo doente.</p> <p>[As caixas 1-4 constituem a versão PG-SGA Short Form]</p> <p>Identificação do doente:</p> <p>Peso</p> <p>Resumo do meu peso atual e recente:</p> <p>Atualmente peso cerca de kg</p> <p>A minha altura é cm</p> <p>Há 1 mês pesava cerca de kg</p> <p>Há 6 meses pesava cerca de kg</p> <p>Durante as duas últimas semanas o meu peso:</p> <p>Diminuiu</p> <p>Ficou igual</p> <p>Aumentou</p> <p>Caixa 1</p> <p>Ingestão alimentar:</p> <p>No último mês, comparando com o habitual, eu classificaria a minha alimentação como:</p> <p>Igual</p> <p>Mais do que o habitual</p> <p>Menos do que o habitual</p> <p>Eu agora como</p> <p>Comida normal mas em menor quantidade</p> <p>Poucos alimentos sólidos (comida normal mas em pouca quantidade)</p> <p>Apenas alimentos líquidos</p> <p>Apenas suplementos nutricionais</p> <p>Muito pouca quantidade de qualquer alimento</p> <p>Apenas alimentação por sonda ou pela veia</p> <p>Caixa 2</p> <p>Sintomas:</p> <p>Durante as duas últimas semanas, tenho tido problemas que me impediram de comer o suficiente (assinalar todos os aplicáveis):</p> <p>Não tive problemas em comer</p> <p>Não tive apetite, não me apeteceu comer</p> <p>Náuseas (enjôjos)</p> <p>Obstipação (prisão da vertice)</p> <p>Feridas na boca (aftas)</p> <p>Alimentos têm agora um sabor estranho ou não têm sabor</p> <p>Dificuldades em engolir</p> <p>Dor: onde? _____</p> <p>Outros: _____</p> <p>ex. Depressão, problemas dentários ou financeiros, etc.</p> <p>Vômitos</p> <p>Diarreia</p>

Note: Items with differences between versions are marked with an \*.

Forward translation 1	Forward translation 2	Integrated forward translation (version 1)	Reconciled forward translation (version 2)
Boca seca Os cheiros: incoomodam-me Sinto-me cheio de depressa Fadiga Cansaço (fadiga) Caixa 3 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) História: As caixas 1-4 foram concebidas para serem preenchidas pelo utente. [As caixas 1-4 constituem a versão PG-SGA Short Form] Identificação do utente: Peso Resumo do meu peso actual e recente: Eu atualmente peso cerca de kg Eu meço cerca de m Há 1 mês pesava cerca de kg Há 6 meses pesava cerca de kg Durante as duas últimas semanas o meu peso: Diminuiu Não mudou Aumentou Caixa 1 Ingestão alimentar: No último mês, comparativamente com o habitual, eu classificaria a minha alimentação como: Igual • Maior do que o habitual • Menor do que o habitual Eu agora como • Comida normal mas em menor quantidade • Poucos alimentos-sólidos	Boca seca Os cheiros: incoomodam-me Sinto-me cheio de depressa Fadiga Cansaço (fadiga) Caixa 3 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) História: As caixas 1-4 foram concebidas para serem preenchidas pelo utente. [As caixas 1-4 constituem a versão PG-SGA Short Form] Identificação do utente: Peso Resumo do meu peso actual e recente: Eu atualmente peso cerca de kg Eu meço cerca de m Há 1 mês pesava cerca de kg Há 6 meses pesava cerca de kg Durante as duas últimas semanas o meu peso: Diminuiu Não mudou Aumentou Caixa 1 Ingestão alimentar: Comparativamente com a minha ingestão habitual, eu classificaria a minha ingestão alimentar durante o último mês como: Igual • Maior do que o habitual • Menor do que o habitual Eu agora ingiro • Alimentos habituais mas em menor quantidade • Poucos alimentos-sólidos	Boca seca Os cheiros: incoomodam-me Sinto-me "cheio" de depressa Fadiga Cansaço (fadiga) Caixa 3 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) História: As caixas 1-4 foram concebidas para serem preenchidas pelo utente. [As caixas 1-4 constituem a versão PG-SGA Short Form] Identificação do utente: Peso Resumo do meu peso actual e recente: Eu atualmente peso cerca de kg Eu meço cerca de m Há 1 mês pesava cerca de kg Há 6 meses pesava cerca de kg Durante as duas últimas semanas o meu peso: Diminuiu Aumentou Caixa 1 Ingestão alimentar: Comparativamente com a minha ingestão habitual, eu classificaria a minha ingestão alimentar durante o último mês como: Igual • Maior do que o habitual • Menor do que o habitual Eu agora como • Alimentos habituais mas em menor quantidade • Poucos alimentos-sólidos	Boca seca Os cheiros: incoomodam-me Sinto-me entorçado ("cheio") de depressa Cansaço (fadiga) Caixa 3 Avaliação Global Subjetiva – Preenchida pelo Doente (PG-SGA) História: As caixas 1-4 foram feitas para serem preenchidas pelo doente. [As caixas 1-4 constituem a versão PG-SGA Short Form] Identificação do doente: Peso Resumo do meu peso actual e recente: Atualmente peso cerca de kg A minha altura é cm Há 1 mês pesava cerca de kg Há 6 meses pesava cerca de kg Durante as duas últimas semanas o meu peso: Diminuiu Ficou igual Aumentou Caixa 1 Ingestão alimentar: No último mês, comparando com o habitual, eu classificaria a minha alimentação como: Igual Mais do que o habitual Menos do que o habitual Eu agora como Comida normal mas em menor quantidade Poucos alimentos sólidos (comida normal mas em pouca quantidade) Apenas alimentos líquidos Apenas suplementos nutricionais Muito pouco de qualquer alimento Apenas alimentação por sonda ou pela veia Caixa 2 Sintomas: Durante as últimas duas semanas, tenho tido os seguintes problemas que me têm impedido de comer o suficiente (preencher todos os aplicáveis): Não tive problemas em comer Não tive apetite, não me apeteceu comer Náuseas Distúrgio Dores na boca Alimentos têm agora um sabor estranho ou não têm sabor Dificuldades em engolir Dor, onde? _____ Dor, onde? _____
Boca seca Os cheiros: incoomodam-me Sinto-me cheio de depressa Fadiga Cansaço (fadiga) Caixa 3 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) História: As caixas 1-4 foram concebidas para serem preenchidas pelo utente. [As caixas 1-4 constituem a versão PG-SGA Short Form] Identificação do utente: Peso Resumo do meu peso actual e recente: Eu atualmente peso cerca de kg Eu meço cerca de m Há 1 mês pesava cerca de kg Há 6 meses pesava cerca de kg Durante as duas últimas semanas o meu peso: Diminuiu Não mudou Aumentou Caixa 1 Ingestão alimentar: Comparativamente com a minha ingestão habitual, eu classificaria a minha ingestão alimentar durante o último mês como: Igual • Maior do que o habitual • Menor do que o habitual Eu agora ingiro • Alimentos habituais mas em menor quantidade • Poucos alimentos-sólidos	Boca seca Os cheiros: incoomodam-me Sinto-me cheio de depressa Fadiga Cansaço (fadiga) Caixa 3 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) História: As caixas 1-4 foram concebidas para serem preenchidas pelo utente. [As caixas 1-4 constituem a versão PG-SGA Short Form] Identificação do utente: Peso Resumo do meu peso actual e recente: Eu atualmente peso cerca de kg Eu meço cerca de m Há 1 mês pesava cerca de kg Há 6 meses pesava cerca de kg Durante as duas últimas semanas o meu peso: Diminuiu Não mudou Aumentou Caixa 1 Ingestão alimentar: Comparativamente com a minha ingestão habitual, eu classificaria a minha ingestão alimentar durante o último mês como: Igual • Maior do que o habitual • Menor do que o habitual Eu agora ingiro • Alimentos habituais mas em menor quantidade • Poucos alimentos-sólidos	Boca seca Os cheiros: incoomodam-me Sinto-me "cheio" de depressa Fadiga Cansaço (fadiga) Caixa 3 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) História: As caixas 1-4 foram concebidas para serem preenchidas pelo doente. [As caixas 1-4 constituem a versão PG-SGA Short Form] Identificação do doente: Peso Resumo do meu peso actual e recente: Atualmente peso cerca de kg A minha altura é cm Há 1 mês pesava cerca de kg Há 6 meses pesava cerca de kg Durante as duas últimas semanas o meu peso: Diminuiu Ficou igual Aumentou Caixa 1 Ingestão alimentar: No último mês, comparando com o habitual, eu classificaria a minha alimentação como: Igual Mais do que o habitual Menos do que o habitual Eu agora como Comida normal mas em menor quantidade Poucos alimentos sólidos (comida normal mas em pouca quantidade) Apenas alimentos líquidos Apenas suplementos nutricionais Muito pouco de qualquer alimento Apenas alimentação por sonda ou pela veia Caixa 2 Sintomas: Durante as últimas duas semanas, tenho tido problemas que me impediram de comer o suficiente (assinalar todos os aplicáveis) Não tive problemas em comer Não tive apetite, não me apeteceu comer Náuseas (enjoo) Distúrgio (priso de ventre) Fadiga na boca (falta) Alimentos têm agora um sabor estranho ou não têm sabor Dificuldades em engolir Dor, onde? _____ Dor, onde? _____	

Note: Items with differences between versions are marked with an \*.

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Translation, cross-cultural adaptation and validation of the PG-SGA for the Portuguese setting

Forward translation 1	Forward translation 2	Integrated forward translation (version 1)	Reconciled forward translation (version 2)
Outros: ex. Depressão, problemas dentários ou financeiros, etc. Vómitos Diarreia Boca seca Os cheiros: incoomodam-me Sinto-me cheio de depressa Fadiga Caixa 3 ATIVIDADES E CAPACIDADE FUNCIONAL: Durante o último mês, eu classificaria a minha atividade como: Normal sem limitações Não estou no meu normal, mas sou capaz de realizar praticamente todas as minhas atividades habituais Não me sinto capaz de realizar a maior parte das minhas atividades, mas fico na cama ou sentado menos de metade do dia Sou capaz de realizar poucas atividades e passo a maior parte do dia sentado ou deitado Na maior parte do tempo estou na cama, levantando-me raramente Caixa 4 - O restante questionário será preenchido pelo seu nutricionista, médico ou enfermeiro. Obrigada Somatório das caixas 1 a 4 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) Somatório das caixas 1 a 4 (Ver página 1) Folha de Trabalho 1 – Pontuação da perda de peso Para determinar a pontuação usar o peso de há 1 mês. Usar o peso de há 6 meses apenas quando não existe o de há 1 mês. Usar os pontos abaixo para categorizar a oscilação de peso e adicionar 1 ponto extra se o utente tiver perdido peso durante as duas últimas semanas. Registrar a pontuação total na caixa 1 da PG-SGA. Perda de peso em 1 mês Pontos Perda de peso em 6 meses Cotação da folha de trabalho 1 Folha de Trabalho 2 – Patologias e a sua relação com as necessidades nutricionais * Pontuação é calculada adicionando um ponto por cada uma das seguintes condições clínicas que o doente apresente Cancro SIDA Doença Cardíaca ou Pulmonar Insuficiência renal crónica Úlçera de decúbito, ferida aberta ou fistula Existência de traumatismo Idade superior a 65 anos	Outros: ex. Depressão, problemas dentários ou financeiros, etc. Vómitos Diarreia Boca seca Os cheiros: incoomodam-me Sinto-me "cheio" de depressa Fadiga Caixa 3 ATIVIDADES E CAPACIDADE FUNCIONAL: Relativamente ao mês passado, eu classificaria a minha atividade como: Normal sem limitações Não estou no meu normal, mas sou capaz de realizar praticamente todas as minhas atividades habituais Não me sinto capaz de realizar a maior parte das minhas atividades, mas fico na cama ou sentado menos de metade do dia Sou capaz de realizar poucas atividades e passo a maior parte do dia sentado ou deitado Na maior parte do tempo estou na cama, levantando-me raramente Caixa 4 - O restante questionário será preenchido pelo seu nutricionista, médico ou enfermeiro. Obrigada Somatório das caixas 1 a 4 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) Somatório das caixas 1 a 4 (Ver página 1) Folha de Trabalho 1 – Pontuação da perda de peso Para determinar a pontuação usar o peso de há 1 mês. Usar o peso de há 6 meses apenas quando não existe o de há 1 mês. Usar os pontos abaixo para categorizar a oscilação de peso e adicionar 1 ponto extra se o utente tiver perdido peso durante as duas últimas semanas. Registrar a pontuação total na caixa 1 da PG-SGA. Perda de peso em 1 mês Pontos Perda de peso em 6 meses Cotação da folha de trabalho 1 Folha de Trabalho 2 – Patologias e a sua relação com as necessidades nutricionais * Pontuação é calculada adicionando um ponto por cada uma das seguintes condições clínicas que o doente apresente Cancro SIDA Doença Cardíaca ou Pulmonar Insuficiência renal crónica Úlçera de decúbito, ferida aberta ou fistula Existência de traumatismo Idade superior a 65 anos	Outros: ex. Depressão, problemas dentários ou financeiros, etc. Vómitos Diarreia Boca seca Os cheiros: incoomodam-me Sinto-me "cheio" de depressa Fadiga Caixa 3 ATIVIDADES E CAPACIDADE FUNCIONAL: Relativamente ao mês passado, eu classificaria a minha atividade como: Normal sem limitações Não estou no meu normal, mas sou capaz de realizar praticamente todas as minhas atividades habituais Não me sinto capaz de realizar a maior parte das minhas atividades, mas fico na cama ou sentado menos de metade do dia Sou capaz de realizar poucas atividades e passo a maior parte do dia sentado ou deitado Na maior parte do tempo estou na cama, levantando-me raramente Caixa 4 - O restante questionário será preenchido pelo seu nutricionista, médico ou enfermeiro. Obrigada Somatório das caixas 1 a 4 Avaliação Global Subjetiva – Genéda pelo utente cotada (PG-SGA) Somatório das caixas 1 a 4 (Ver página 1) Folha de Trabalho 1 – Pontuação da perda de peso Para determinar a pontuação usar o peso de há 1 mês. Usar o peso de há 6 meses apenas quando não existe o de há 1 mês. Usar os pontos abaixo para categorizar a oscilação de peso e adicionar 1 ponto extra se o utente tiver perdido peso durante as duas últimas semanas. Registrar a pontuação total na caixa 1 da PG-SGA. Perda de peso em 1 mês Pontos Perda de peso em 6 meses Cotação da folha de trabalho 1 Folha de Trabalho 2 – Patologias e a sua relação com as necessidades nutricionais * Pontuação é calculada adicionando um ponto por cada uma das seguintes condições clínicas que o doente apresente Cancro SIDA Doença Cardíaca ou Pulmonar Insuficiência renal crónica Úlçera de decúbito, ferida aberta ou fistula Existência de traumatismo Idade superior a 65 anos	Outros: ex. Depressão, problemas dentários ou financeiros, etc. Vómitos Diarreia Boca seca Os cheiros: incoomodam-me Sinto-me entorçado ("cheio") de depressa Cansaço (fadiga) Caixa 3 ATIVIDADES E CAPACIDADE FUNCIONAL: Relativamente ao mês passado, eu classificaria a minha atividade como: Normal sem limitações e sou capaz de fazer a minha vida diária Não estou normal, mas sou capaz de fazer grande parte das minhas atividades diárias habituais Não me sinto capaz de realizar a maioria das minhas atividades e fico na cama ou sentado menos de metade do dia Sou capaz de realizar poucas atividades e passo a maior parte do dia na cama ou sentado Passo a maior parte do tempo na cama Caixa 4 - O restante questionário será preenchido pelo seu nutricionista, médico ou enfermeiro. Obrigada Somatório das caixas 1 a 4 AVALIAÇÃO GLOBAL SUBJETIVA – PREENCHIDA pelo doente (PG-SGA) Somatório das caixas 1 a 4 (Ver página 1) Folha de Trabalho 1 – Pontuação da perda de peso Para determinar a pontuação usar o valor do peso de há 1 mês, se não existir o de há 6 meses apenas quando não existe o de há 1 mês. Usar os pontos abaixo para pontuar a variação de peso e adicionar 1 ponto extra se o doente tiver perdido peso durante as duas últimas semanas. Registrar a pontuação total na caixa 1 da PG-SGA. Perda de peso em 1 mês Pontos Perda de peso em 6 meses Pontuação da folha de trabalho 1 Folha de Trabalho 2 – Patologias e a sua relação com as necessidades nutricionais A pontuação é calculada adicionando um ponto por cada uma das seguintes condições clínicas que o doente apresente Cancro SIDA Doença Cardíaca ou Pulmonar Insuficiência renal crónica Úlçera de decúbito, ferida aberta ou fistula Existência de traumatismo Idade superior a 65 anos

Note: Items with differences between versions are marked with an \*.





Forward translation 1	Forward translation 2	Integrated forward translation (version 1)	Reconciled forward translation (version 2)
A.1.2 linha de intervenção nutricional corresponde a um controlo clínico de sintomas	A.1.2 linha de intervenção nutricional corresponde a um controlo clínico de sintomas	A.1.2 linha de intervenção nutricional corresponde a um controlo clínico de sintomas	A.1.2 linha de intervenção nutricional corresponde a um controlo clínico de sintomas
Tragem de acordo com a pontuação total da PG-SGA: Não é necessário intervenção nutricional de momento. Reavaliar regularmente e por rotina durante o tratamento	Tragem de acordo com a pontuação total da PG-SGA: Não é necessário intervenção nutricional de momento. Reavaliar regularmente e por rotina durante o tratamento	Tragem de acordo com a pontuação total da PG-SGA: Não é necessário intervenção nutricional de momento. Reavaliar regularmente e por rotina durante o tratamento	Tragem de acordo com a pontuação total da PG-SGA: Não é necessário intervenção nutricional de momento. Reavaliar regularmente e por rotina durante o tratamento
Aconselhamento ao utente e família por um nutricionista, enfermeiro ou outros, com intervenção farmacológica, como indicado pela caixa 3 (Sintomas) e valores laboratoriais apropriados;	Aconselhamento ao utente e família por um nutricionista, enfermeiro ou outros, com intervenção farmacológica, como indicado pela caixa 3 (Sintomas) e valores laboratoriais apropriados;	Aconselhamento ao utente e família por um nutricionista, enfermeiro ou outros, com intervenção farmacológica, como indicado pela caixa 3 (Sintomas) e valores laboratoriais apropriados;	Aconselhamento ao doente e família por um nutricionista, enfermeiro ou outros clínicos, com intervenção farmacológica, tal como indicado na caixa 3 (Sintomas) e por resultados laboratoriais conforme apropriado
Requer intervenção nutricional por nutricionista em conjunto com o enfermeiro ou médico conforme indicado na caixa 3 (Sintomas)	Requer intervenção nutricional por nutricionista em conjunto com o enfermeiro ou médico conforme indicado na caixa 3 (Sintomas)	Requer intervenção nutricional por nutricionista em conjunto com o enfermeiro ou médico conforme indicado na caixa 3 (Sintomas)	Requer intervenção nutricional por nutricionista em conjunto com o enfermeiro ou médico conforme indicado na caixa 3 (Sintomas)
Indica uma necessidade crítica para um melhor controlo dos sintomas e/ou intervenção nutricional.	Indica uma necessidade crítica para um melhor controlo dos sintomas e/ou intervenção nutricional.	Indica uma necessidade crítica para um melhor controlo dos sintomas e/ou intervenção nutricional.	Indica uma necessidade crítica para um melhor controlo dos sintomas e/ou intervenção nutricional.

Note: Items with differences between versions are marked with an \*.

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### Appendix 3 - Declaration from the translation company (1)



Appendix 4 - Declaration from the translation company (2)



**STATEMENT**

To all intents and purposes, **Alphatrad Portugal Unipessoal, Lda**, whose registered offices are located at Avenida da Liberdade, 69, 4<sup>th</sup> floor D, 1250-140 Lisbon, corporate body identification n.º 505 375 478, registered with the Registrar of Companies of Lisbon, 1st Section under n.º 10.233/010709, does hereby declare that the translation from Portuguese into English of an excel document entitled "Back translation 2\_PT\_EN\_final" carried out by our services under project number **P480/340**, constitutes a faithful translation of the original provided document.

By dint of the veracity hereof, and as it was requested of us, the present Statement is hereby issued and has been duly signed and stamped with the stamp in use at this company.

Lisbon, 30<sup>th</sup> June 2015.

Elisa Fontenete  
Translation Department



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Translation, cross-cultural adaptation and validation of the PG-SGA for the Portuguese setting

Appendix 5 - Results of the back translations and the final Portuguese version

Blinded back translation 1	Blinded back translation 2	Final Portuguese version
<p>Subjective global assessment – completed by the patient (PG-SGA)</p> <ul style="list-style-type: none"> <li>Background: boxes 1-4 were designed to be completed by the patient.</li> <li>Boxes 1-4 comprise the PG-SGA version-short form</li> </ul> <p>Patient identification:</p> <p>Weight</p> <p>Summary of my current and recent weight:</p> <ul style="list-style-type: none"> <li>I currently weigh around ____kg</li> <li>I am ____cm tall</li> <li>1 month ago I weighed around ____kg</li> <li>6 months ago I weighed around ____kg</li> <li>Over the last two weeks my weight has:                             <ul style="list-style-type: none"> <li>Decreased</li> <li>Remained the same</li> <li>Increased</li> </ul> </li> </ul> <p>Box 1 -</p> <p>Food intake</p> <ul style="list-style-type: none"> <li>I would classify my diet in the past month compared to my usual diet as                             <ul style="list-style-type: none"> <li>The same</li> <li>More than usual</li> <li>Less than usual</li> </ul> </li> <li>I am now eating:                             <ul style="list-style-type: none"> <li>Normal food but in lesser amounts</li> <li>Little solid food (normal food but in small amounts)</li> <li>Liquid food only</li> <li>Nutritional supplements only</li> <li>Very little or any food</li> <li>Via a tube or intravenously only</li> </ul> </li> </ul> <p>Box 2 -</p> <p>Symptoms</p> <ul style="list-style-type: none"> <li>Over the past two weeks I have had problems which have prevented me from eating (tick all applicable options)                             <ul style="list-style-type: none"> <li>I had no problems eating</li> <li>I have had no appetite, I didn't feel like eating</li> <li>Nausea (sickness)</li> <li>Constipation</li> <li>Oral lesions (colds/sores)</li> <li>Food now tastes strange or is tasteless</li> <li>Difficulties in swallowing</li> </ul> </li> <li>Pain; where? _____</li> <li>Others: _____</li> <li>e.g.: depression, dental or financial problems, etc.</li> </ul> <p>Vomiting</p> <p>Diarrhea</p> <p>Dry mouth</p> <ul style="list-style-type: none"> <li>The smell bothers me</li> <li>I feel "full" quickly</li> <li>Tiredness (fatigue)</li> </ul> <p>Box 3</p> <ul style="list-style-type: none"> <li>Activities and functional capacity: in relation to last month, I would classify my activity as _____</li> </ul> <p>Note: Items with differences between versions are marked with an *.</p>	<p>Subjective global assessment – completed by the patient (PG-SGA)</p> <ul style="list-style-type: none"> <li>History: boxes 1-4 are to be completed by patient</li> <li>Boxes 1-4 constitute the PG-SGA short form version</li> </ul> <p>Patient's identification</p> <p>Weight</p> <p>Summary of my current and recent weight</p> <ul style="list-style-type: none"> <li>I currently weigh about ____kg</li> <li>I am about ____cm tall</li> <li>One month ago I weighed about ____kg</li> <li>Six months ago I weighed about ____kg</li> <li>During the past two weeks my weight has                             <ul style="list-style-type: none"> <li>Decreased</li> <li>Not changed</li> <li>Increased</li> </ul> </li> </ul> <p>Box 1 -</p> <p>Food intake:</p> <ul style="list-style-type: none"> <li>As compared with my normal intake, I'd rate my food intake during the past month as                             <ul style="list-style-type: none"> <li>Unchanged</li> <li>More than usual</li> <li>Less than usual</li> </ul> </li> <li>I am now eating                             <ul style="list-style-type: none"> <li>Normal food but in less quantity</li> <li>Little solid food (normal food but in smaller quantity)</li> <li>Only liquid food</li> <li>Only nutritional supplements</li> <li>Very little quantity of any food</li> <li>Tube or intravenous feedings only</li> </ul> </li> </ul> <p>Box 2 -</p> <p>Symptoms:</p> <ul style="list-style-type: none"> <li>Over the past two weeks, I have been having problems which have prevented me from eating enough (check all that apply)                             <ul style="list-style-type: none"> <li>I have had no problems eating</li> <li>I have had no appetite, I did not feel like eating</li> <li>Nausea (sickness)</li> <li>Constipation (fecal impaction)</li> <li>Mouth wounds (thrush)</li> <li>Food now has a funny taste or no taste at all</li> <li>Difficulties swallowing</li> </ul> </li> <li>Pain; where? _____</li> <li>Others: _____</li> <li>e.g.: depression, dental or financial problems, etc.</li> </ul> <p>Vomiting</p> <p>Diarrhea</p> <p>Dry mouth</p> <ul style="list-style-type: none"> <li>The smell bothers me</li> <li>I feel "full" very quickly</li> <li>Tiredness (fatigue)</li> </ul> <p>Box 3</p> <ul style="list-style-type: none"> <li>Activities and functional capacity (Concerning the past month, I would rate my activity as _____)</li> </ul>	<p>Avaliação global subjetiva – preenchida pelo doente (PG-SGA)</p> <ul style="list-style-type: none"> <li>História: as caixas 1-4 foram feitas para serem preenchidas pelo doente.</li> <li>As caixas 1-4 constituem a versão PG-SGA short form</li> </ul> <p>Identificação do doente:</p> <p>Peso</p> <p>Resumo do meu peso atual e recente:</p> <ul style="list-style-type: none"> <li>Atualmente peso cerca de ____kg</li> <li>A minha altura é ____cm</li> <li>Há 1 mês pesava cerca de ____kg</li> <li>Há 6 meses pesava cerca de ____kg</li> <li>Durante as duas últimas semanas o meu peso:                             <ul style="list-style-type: none"> <li>Diminuiu</li> <li>Ficou igual</li> <li>Aumentou</li> </ul> </li> </ul> <p>Caixa 1</p> <p>Ingestão alimentar:</p> <ul style="list-style-type: none"> <li>No último mês, comparando com o habitual, eu classificaria a minha alimentação como                             <ul style="list-style-type: none"> <li>Igual</li> <li>Mais do que o habitual</li> <li>Menos do que o habitual</li> </ul> </li> <li>Eu agora como                             <ul style="list-style-type: none"> <li>Comida normal mas em menor quantidade</li> <li>Pouco alimentos sólidos</li> <li>Apenas alimentos líquidos</li> <li>Apenas suplementos nutricionais</li> <li>Muito pouca quantidade de qualquer alimento</li> <li>Apenas alimentação por sonda ou pela veia</li> </ul> </li> </ul> <p>Caixa 2</p> <p>Sintomas:</p> <ul style="list-style-type: none"> <li>Durante as duas últimas semanas, tenho tido problemas que me impediram de comer o suficiente (assinalar todos os aplicáveis)                             <ul style="list-style-type: none"> <li>Não tive problemas em comer</li> <li>Não tive apetite, não me apeteceu comer</li> <li>Náuseas (enjôjos)</li> <li>Obstipação (prisão de ventre)</li> <li>Feridas na boca</li> <li>Alimentos têm agora um sabor estranho ou não têm sabor</li> <li>Dificuldades em engolir</li> </ul> </li> <li>Dor; onde? _____</li> <li>Outros: _____</li> <li>ex. Depressão, problemas dentários ou financeiros, etc.</li> </ul> <p>Vómitos</p> <p>Diarreia</p> <p>Boca seca</p> <ul style="list-style-type: none"> <li>O cheiro incomoda-me</li> <li>Sinto-me cheio, depressa</li> <li>Cansaço (fadiga)</li> </ul> <p>Caixa 3</p> <ul style="list-style-type: none"> <li>Atividade e capacidade funcional: relativamente ao mês passado, eu classificaria a minha atividade como _____</li> </ul>

Blinded Back Translation 1	Blinded Back Translation 2	Final Portuguese version
<ul style="list-style-type: none"> <li>Normal with no restrictions and I am capable of leading my daily life</li> <li>I am not at normal levels, but I am capable of performing my usual activities reasonably well</li> <li>I don't feel capable of performing most of my activities, but I stay in bed or sitting down for less than half the day</li> <li>I am only capable of performing a few activities and I spend most of the day in bed or sitting down</li> <li>I spend most of my time in bed</li> <li>Box 4.</li> <li>The rest of the questionnaire is to be completed by the nutritionist, doctor or nurse. Thank you.</li> <li>Sum of boxes 1 to 4</li> <li>Subjective global assessment – completed by the patient (PG-SGA)</li> <li>Worksheet 1 – Score for loss of weight</li> <li>To establish the score use the weight registered 1 month ago. If available. Use the weight registered 6 months ago when the figure for 1 month ago is not available. Use the points below to score the variation in weight and add 1 extra point if the patient has lost weight in the last two weeks. Register the total score in box 1 of PG-SGA</li> <li>Loss of weight in 1 month</li> </ul>	<ul style="list-style-type: none"> <li>Normal, without limitations, being able to perform my daily tasks</li> <li>Not my normal self, but capable of performing most of my habitual daily tasks</li> <li>Not feeling capable of performing most of my daily tasks and remaining in bed or seated for less than half the day</li> <li>I'm capable of performing few tasks and spending most of my day in bed or seated</li> <li>Spending most of the time in bed</li> <li>Box 4.</li> <li>The remainder of this questionnaire is to be completed by your dietitian, doctor or nurse. Thank you.</li> <li>Sum of boxes 1 to 4</li> <li>Subjective global assessment – completed by the patient (PG-SGA)</li> <li>Total score for boxes 1 to 4 (See page 1)</li> <li>Worksheet 1 – Weight loss score</li> <li>To determine score, use 1 month ago weight data, when available. Use 6 months ago weight data only if the 1 month ago data does not exist. Use points below to score weight variation and add 1 extra point if patient has lost weight over the two previous weeks. Enter total score in box 1 of PG-SGA</li> <li>Perda de peso em 1 month</li> <li>Pontos</li> <li>Perda de peso em 6 meses</li> <li>Worksheet 1 score</li> <li>Worksheet 2 – Pathologies and their relation to nutritional requirements</li> <li>Score is calculated by adding one point for each of the following clinical conditions presented by the patient</li> <li>Cancer</li> <li>AIDS</li> <li>Pulmonary or Cardiac Cachexia</li> <li>Chronic renal insufficiency</li> <li>Decubitus ulcer, open wound or fistula</li> <li>Presence of trauma</li> <li>Aged over 65</li> <li>Other relevant diagnoses (please specify)</li> <li>Status of the primary disease (mark if known or appropriate) I III IV</li> <li>Other</li> <li>Score for worksheet 2</li> <li>Worksheet 3 – Metabolic demand</li> <li>Score for metabolic stress is determined by a number of variables known to increase protein and caloric needs.</li> <li>Note: The score for this worksheet is the result of adding the points corresponding to level or duration of fever (the highest value from these two variables) and corresponding to corticosteroids, so that a patient who has had a fever of 38.8°C (3 points) for less than 72 hours (1 point) and is being treated with 10mg of prednisone (3 points) gets a total 5 points</li> <li>Stress</li> <li>Sem stress</li> <li>None</li> <li>Low</li> <li>Moderate</li> <li>High</li> <li>Fever</li> <li>No fever</li> <li>Duration of fever</li> </ul>	<p>Normal sem limitações e sou capaz de fazer a minha vida diária não estou no normal, mas sou capaz de fazer grande parte das minhas atividades diárias habituais</p> <p>Não me sinto capaz de realizar a maioria das minhas atividades e fico na cama ou sentado mais de metade do dia</p> <p>Sou capaz de realizar poucas atividades e passo a maior parte do dia na cama ou sentado</p> <p>Passo a maior parte do tempo na cama</p> <p>Caixa 4</p> <p>O restante questionário se é preenchido pelo seu nutricionista, médico ou enfermeiro.</p> <p>Objetivo</p> <p>Somatório das caixas 1 a 4</p> <p>Avaliação global subjetiva – preenchida pelo doente (PG-SGA)</p> <p>Somatório das caixas 1 a 4 (Ver página 1)</p> <p>Folha de Trabalho 1 – Pontuação de perda de peso</p> <p>Para determinar a pontuação use o valor do peso de há 1 mês, se disponível. Use o valor de há 6 meses apenas quando não existir o de há 1 mês. Use os pontos abaixo para pontuar a variação de peso e adicionar 1 ponto extra se o doente tiver perdido peso durante as duas últimas semanas. Registrar a pontuação total na caixa 1 da PG-SGA</p> <p>Perda de peso em 6 meses</p> <p>Pontos</p> <p>Perda de peso em 6 meses</p> <p>Pontuação da folha de trabalho 1</p> <p>Folha de Trabalho 2 – Patologias e a sua relação com as necessidades nutricionais</p> <p>A pontuação é calculada adicionando um ponto por cada uma das seguintes condições clínicas que o doente apresenta</p> <p>Cancro</p> <p>SIDA</p> <p>Cachexia Cardíaca ou Pulmonar</p> <p>Insuficiência renal Crónica</p> <p>Úlcera de decúbito, ferida aberta ou fistula</p> <p>Existência de traumatismo</p> <p>Idade superior a 65 anos</p> <p>Todos os diagnósticos relevantes (especificar)</p> <p>Estadamento da doença primária (assinale se conhecido ou apropriado) I III IV Outro</p> <p>Pontuação da folha de trabalho 2</p> <p>Folha de Trabalho 3 – Necessidades metabólicas</p> <p>A pontuação para os stress metabólicos é determinada por um número de variáveis que estão associadas ao aumento das necessidades proteicas e calóricas</p> <p>Nota: A pontuação desta folha de trabalho resulta de um somatório dos pontos relativos a febre ou a duração da febre (o maior valor das duas variáveis) e relativos aos corticosteróides, de forma que um doente que tem de febre 38,8°C (3 pontos) há menos de 72 horas (1 ponto) e está em tratamento com 10mg de prednisona (3 pontos) obtêm 5 pontos</p> <p>Stress</p> <p>Sem stress</p> <p>None</p> <p>Baixo</p> <p>Moderado</p> <p>Elevado</p> <p>Febre</p> <p>Sem febre</p> <p>Duração da febre</p>

Note: Items with differences between versions are marked with an \*.

João Pedro Pinho

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Translation, cross-cultural adaptation and validation of the PG-SGA for the Portuguese setting

Blinded Back Translation 1	Blinded Back Translation 2	Final Portuguese version
<ul style="list-style-type: none"> <li>Corticosteroids</li> <li>No corticotherapy</li> <li>Low dose</li> <li>Moderate dose</li> <li>High dose</li> <li>Prednisone/day equivalents</li> <li>Score for Worksheet 3</li> <li>Worksheet 4 – Physical exam</li> <li>The physical exam includes a subjective assessment of 3 aspects of the body composition: muscle, fat and fluids.</li> <li>Although subjective, the impact of the muscular deficit is greater than that of fat.</li> <li>Definition of the categories: 0 = no deficit, 1+ = a slight deficit, 2+ = a moderate deficit, 3+ = a serious deficit</li> <li>The score for the deficit of these three factors is not added up but is used to clinically determine the overall degree of deficit (or swelling).</li> <li>State of the muscle compartment</li> <li>Temples (temporalis muscle)</li> <li>Clavicles (pectoralis &amp; deltoids)</li> <li>Shoulders (deltoids)</li> <li>Interoosseous muscles</li> <li>Scapula (trapezius/dorsi; trapezius, deltoids)</li> <li>Thigh (quadriceps)</li> <li>Calf (gastrocnemius)</li> <li>Global muscle status rating</li> <li>Fat reserves:</li> <li>Orbital fat pads</li> <li>Triceps skin fold</li> <li>Pat overlying lower ribs</li> <li>Global fat deficit rating</li> <li>State of fluids:</li> <li>Ankle edema</li> <li>Sacral edema</li> <li>Ascites</li> <li>Global fluid status rating</li> <li>Score for Overall State of Fluids</li> <li>The score for the physical exam is determined by the rating of the overall subjective body deficit</li> <li>No deficit</li> <li>Slight deficit</li> <li>Moderate deficit</li> <li>Severe deficit</li> <li>Score for boxes 1 to 4</li> <li>Sum of boxes 1 to 4</li> <li>Worksheet 4</li> <li>Score for Worksheet 4</li> <li>Total score of PG-SGA</li> <li>Global assessment score of A+B+C+D</li> <li>OVERALL ASSESSMENT (Phases A, B or C)</li> <li>Worksheet 5 – Categories of PG-SGA Overall Assessment</li> <li>The overall assessment is subjective and aims to provide a qualitative appreciation of Boxes 1-4 and Worksheet 4 (Physical Examination). Mark each item and in accordance with the results obtained select the Status (A, B or C).</li> <li>Weight</li> <li>Food intake</li> <li>Symptoms with nutritional impact</li> <li>Functional capacity</li> <li>Physical exam</li> </ul>	<ul style="list-style-type: none"> <li>Corticosteroids</li> <li>No corticotherapy</li> <li>Low dose</li> <li>Moderate dose</li> <li>High dose</li> <li>Equivalent prednisone/day</li> <li>Score for Worksheet 3</li> <li>Worksheet 4 – Physical examination</li> <li>Physical examination includes a subjective assessment of 3 aspects of body composition: muscle, fat and fluids. Once it is subjective, each item of this examination is measured by degree of deficit.</li> <li>Though subjective, the impact of muscular deficit is higher than fat deficit. Definition of categories: 0 no deficit, 1 mild deficit, 2 moderate deficit, 3 severe deficit</li> <li>Score of deficit of these three aspects is not a sum, but it is used to clinically determine the global deficit degree (for edema).</li> <li>Muscle status:</li> <li>Temple region (temporalis muscle)</li> <li>Clavicles (pectoralis and deltoids)</li> <li>Shoulders (deltoids)</li> <li>Interoosseous muscles</li> <li>Scapula (trapezius/dorsi; trapezius, deltoids)</li> <li>Thigh (quadriceps)</li> <li>Global muscle status rating:</li> <li>Calf (gastrocnemius)</li> <li>Fat reserves:</li> <li>Periorbital fat</li> <li>Triceps skin fold</li> <li>Pat overlying lower ribs</li> <li>Global fat deficit rating</li> <li>Fluid status:</li> <li>Ankle edema</li> <li>Sacral edema</li> <li>Ascites</li> <li>Global fluid status rating</li> <li>Score for physical exam is determined by overall subjective rating of total body deficit</li> <li>No deficit</li> <li>Mild deficit</li> <li>Moderate deficit</li> <li>Severe deficit</li> <li>Score for boxes 1 to 4</li> <li>Sum of boxes 1 to 4</li> <li>Worksheet 4</li> <li>Score for Worksheet 4</li> <li>TOTAL SCORE OF PG-SGA</li> <li>Global assessment score of A+B+C+D</li> <li>OVERALL ASSESSMENT (Stages A, B or C)</li> <li>Worksheet 5 – PG-SGA Global Assessment Categories</li> <li>The overall assessment is subjective and intends to reflect a qualitative assessment of Boxes 1-4 and Worksheet 4 (Physical Examination). Check each item and, according to results obtained, select Stage (A, B or C)</li> <li>Weight</li> <li>Nutrient intake</li> <li>Nutrition Impact Symptoms</li> <li>Functional capacity</li> <li>Physical examination</li> </ul>	<p>Corticosteróides</p> <p>Sem corticoterapia</p> <p>Dose baixa</p> <p>Dose moderada</p> <p>Dose elevada</p> <p>Equivalentes prednisona/dia</p> <p>Pontuação da Folha de Trabalho 3</p> <p>Folha de Trabalho 4 - Exame físico</p> <p>O exame físico inclui uma avaliação subjetiva de 3 aspetos da composição corporal: músculo, gordura e líquidos. Uma vez que é subjetivo, cada item deste exame é cotado pelo grau de défice.</p> <p>O exame subjetivo, o impacto do défice muscular é superior ao da gordura. Definição das categorias: 0 = sem défice; 1+ = défice ligeiro; 2+ = défice moderado; 3+ = défice grave</p> <p>A pontuação do défice destas três aspetos não é somatória mas é usada para determinar clinicamente o grau global de défice (ou de edema).</p> <p>Estado do compartimento muscular:</p> <p>Região do templo (músculos temporais)</p> <p>Clavículas (peitorais e deltóides)</p> <p>Ombros (deltóides)</p> <p>Músculos interósteos</p> <p>Omoplata (trapezius/dorsi; trapézio, deltóide)</p> <p>Coxa (quadríceps)</p> <p>Gêmeos (gastrocnémio)</p> <p>Classificação do Estado Muscular Global:</p> <p>Reservas de gordura:</p> <p>Gordura periorbitária</p> <p>Prega tricipital</p> <p>Gordura adjacente às costelas inferiores</p> <p>Classificação do défice global de gordura</p> <p>Estado de líquidos:</p> <p>Edema do tornozelo</p> <p>Edema do sacro</p> <p>Ascite</p> <p>Classificação do Estado de Líquidos Global</p> <p>A pontuação do exame físico e determinada pela classificação subjetiva global do défice corporal</p> <p>Défice ligeiro</p> <p>Défice moderado</p> <p>Défice grave</p> <p>Pontuação pontos</p> <p>Pontuação da folha de trabalho 4</p> <p>Pontuação dos défices totais</p> <p>PONTUAÇÃO TOTAL DA PG-SGA</p> <p>(pontuação nutricional total de A+B+C+D)</p> <p>AVALIACÃO GLOBAL (Estágios A, B ou C)</p> <p>Folha de Trabalho 5 - Categorias de Avaliação Global da PG-SGA</p> <p>A avaliação global é subjetiva e pretende refletir uma apreciação qualitativa das Caixas 1-4 e da Folha de Trabalho 4 (Ex. Físico). Assinale em cada item e, conforme os resultados obtidos, seleccione o Estágio (A, B ou C)</p> <p>Peso</p> <p>Ingestão alimentar</p> <p>Síntomas com impacto nutricional</p> <p>Capacidade funcional</p> <p>Exame Físico</p>

Note: Items with differences between versions are marked with an \*.



## Scored Patient-Generated Subjective Global Assessment [Avaliação Global Subjetiva – Preenchida Pelo Doente]

PG-SGA

História: As caixas 1-4 foram feitas para serem preenchidas pelo doente.  
(As caixas 1-4 constituem a versão PG-SGA Short Form)

**1. Peso:**

Resumo do meu peso atual e recente:

Atualmente peso cerca de \_\_\_\_\_ kg

A minha altura é \_\_\_\_\_ cm

Há 1 mês pesava cerca de \_\_\_\_\_ kg

Há 6 meses pesava cerca de \_\_\_\_\_ kg

Durante as duas últimas semanas o meu peso:

diminuiu <sup>(1)</sup>  ficou igual <sup>(2)</sup>  aumentou <sup>(3)</sup>

Caixa 1  Indicar somatório (Ver folha de trabalho 3)

**3. Sintomas:** Durante as duas últimas semanas, tenho tido problemas que me impediram de comer o suficiente **(assinalar todos os aplicáveis)**:

não tive problemas em comer <sup>(4)</sup>

não tive apetite, não me apeteceu comer <sup>(3)</sup>

náuseas (enjoo) <sup>(1)</sup>

obstipação (prisão de ventre) <sup>(2)</sup>

feridas na boca <sup>(2)</sup>

alimentos têm agora um sabor estranho ou não têm sabor <sup>(3)</sup>

dificuldades em engolir <sup>(2)</sup>

dor: onde? <sup>(3)</sup> \_\_\_\_\_

outros\*: <sup>(1)</sup> \_\_\_\_\_

\*ex. depressão, problemas dentários ou financeiros, etc.

Caixa 3  Indicar somatório

O restante questionário será preenchido pelo seu nutricionista, médico ou enfermeiro. Obrigado.

9FD 0269, 2005, 2006, 2015 403.22.15  
Portugal 15-003 407.17.15  
Email: [fabstarrvmd@nhs.uk](mailto:fabstarrvmd@nhs.uk) ou [info@pg-sga.org](mailto:info@pg-sga.org)

## Appendix 7 - Portuguese version of the PG-SGA

**Identificação do doente:**

**2. Ingestão alimentar:** No último mês, comparando com o habitual, eu classificaria a minha alimentação como:

igual <sup>(4)</sup>

mais que o habitual <sup>(3)</sup>

menos que o habitual <sup>(2)</sup>

Eu **agora** como:

comida normal mas em menor quantidade <sup>(1)</sup>

poucos alimentos sólidos <sup>(2)</sup>

apenas alimentos líquidos <sup>(3)</sup>

apenas suplementos nutricionais <sup>(4)</sup>

muito pouca quantidade de qualquer alimento <sup>(4)</sup>

apenas alimentação por sonda ou pela veia <sup>(5)</sup>

Caixa 2  Indicar valor mais alto

**4. Atividades e capacidade funcional:**  
Relativamente ao mês passado, eu classificaria a minha atividade como:

normal sem limitações e sou capaz de fazer a minha vida diária <sup>(4)</sup>

não estou normal, mas sou capaz de fazer grande parte das minhas atividades diárias habituais <sup>(3)</sup>

não me sinto capaz de realizar a maioria das minhas atividades e fico na cama ou sentado menos de metade do dia <sup>(2)</sup>

sou capaz de realizar poucas atividades e passo a maior parte do dia na cama ou sentado <sup>(3)</sup>

passo a maior parte do tempo na cama <sup>(1)</sup>

Caixa 4  Indicar valor mais alto

Somatório das caixas 1 a 4  **A**

## Scored Patient-Generated Subjective Global Assessment (PG-SGA)

Avaliação Global Subjetiva – Preenchida Pelo Doente

**Folha de Trabalho 1 - Pontuação da perda de peso**  
Para determinar a pontuação usar o valor do peso de há 1 mês, se disponível. Usar o valor de há 6 meses apenas quando não basta o de há 1 mês. Usar os pontos abaixo para pontuar a variação de peso e **agregar** o ponto **extra** se o doente tiver perdido peso durante as duas últimas semanas. Registrar a pontuação total na caixa 1 da PG-SGA.

Perda de peso em 1 mês	Pontos	Perda de peso em 6 meses	P anterior – P atual / 4,100 P anterior
5 - 9,9%	1	10 - 19,9%	1
3 - 4,9%	2	6 - 9,9%	2
2 - 2,9%	3	2 - 5,9%	3
0 - 1,9%	0	0 - 1,9%	0

Pontuação da Folha de Trabalho 1

**Folha de Trabalho 3 - Necessidades metabólicas**  
A pontuação é atribuída por um número de variáveis que estão associadas ao aumento das necessidades proteicas e calóricas. Marque a pontuação desta folha de trabalho resulto de um somatório dos pontos relativos à febre ou à duração da febre (o valor mais elevado destas duas variáveis) e relativos aos corticosteróides, de forma a que um doente que tem de febre 38,8°C (3 pontos) há menos de 72 horas (1 ponto) e está em tratamento com 10mg de prednisona (2 pontos) totalizaria 5 pontos.

Febre	Sem febre	Sem febre	Sem febre
37,2 e <38,3°C	0	37,2 e <38,3°C	0
>38,3 e <38,8°C	1	>38,3 e <38,8°C	1
>38,8 e <39,3°C	2	>38,8 e <39,3°C	2
>39,3 e <40,0°C	3	>39,3 e <40,0°C	3

**Stress Elevado** (1 pt)  **Stress Moderado** (2 pt)  **Stress Baixo** (3 pt)

Stress Elevado: Dose elevada (>10 x <3mg eqval. prednisona/dia) ou >72 horas

Stress Moderado: Dose moderada (3-10 x <3mg eqval. prednisona/dia) ou >72 horas

Stress Baixo: Dose baixa (<10mg eqval. prednisona/dia) ou <72 horas

Pontuação de Folha de Trabalho 3

**Folha de Trabalho 5 - Categorias de avaliação global da PG-SGA**  
A Avaliação Global é subjetiva e pretende refletir uma apreciação qualitativa das Caixas 1-4 e da Folha de Trabalho 4 (Exame Físico). Assinale em cada item e, conforme os resultados obtidos, selecione o Estádio (A, B ou C).

**ESTÁDIO A** Bem nutrido

**ESTÁDIO B** Moderadamente desnutrido ou em risco de desnutrição

**ESTÁDIO C** Gravemente desnutrido

**Peso**  
Sem perda de peso OU aumento recente de peso (sem edema) OU Sem edema OU melhora recente significativa

**Ingestão alimentar**  
Sem déficit OU melhora recente significativa

**Sintomas com impacto nutricional**  
Nenhuns OU melhora recente significativa

**Capacidade funcional**  
Sem déficit OU melhora recente significativa

**Exame físico**  
Sem déficit OU déficit moderado OU melhora recente significativa

Presença de sintomas com impacto nutricional (caixa 3) OU deterioração recente

Déficit funcional grave OU deterioração recente significativa

Sinais claros de desnutrição (ex. depleção grave de massa muscular e perda de gordura e possível perda subcutânea)

Presença de sintomas com impacto nutricional (caixa 3) OU deterioração recente

Déficit funcional grave OU deterioração recente significativa

Sinais claros de desnutrição (ex. depleção grave de massa muscular e perda de gordura e possível perda subcutânea)

**AValiação GLOBAL**  
Estádio A, B ou C

Per ponto de Trabalho 5

**Recomendações de tragem nutricional:**  
A pontuação total da PG-SGA é usada para determinar a intervenção nutricional individualizada incluindo o aconselhamento ao doente e família, o controlo de sintomas (incluindo intervenções farmacológicas) e a seleção da intervenção nutricional apropriada (através de alimentos, suplementos nutricionais, nutrição entérica ou parenteral).

**A 1ª linha de intervenção nutricional corresponde a um controlo ótimo de sintomas.**

**Tabela de acordo com a pontuação total da PG-SGA:**

0 - 1 Não é necessária intervenção nutricional de rotina.

2 - 3 Aconselhamento ao doente e família por um nutricionista, enfermeiro ou outros clínicos, com intervenção farmacológica, tal como indicado na caixa 3 (Sintomas) e por resultados laboratoriais, conforme apropriado;

4 - 5 Requer intervenção nutricional por nutricionista em conjunto com o enfermeiro ou médico conforme indicado na caixa 3 (Sintomas);

≥ 9 Indica uma necessidade crítica para um melhor controlo dos sintomas e/ou intervenção nutricional.

Assinatura do clínico: \_\_\_\_\_

Data: \_\_\_\_/\_\_\_\_/\_\_\_\_