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Title: Prospective validation of the nutrition screening tool for childhood cancer (SCAN)

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Abstract

Background & Aims:

Different nutritional screening tools have been proposed in childhood cancer, but none has shown convincing predictive capacity so far. The "nutrition screening tool for childhood cancer (SCAN)" has been specifically designed for this population and provides an easy-to-use, promising approach to identify patients at risk of malnutrition. We aim to:

1. Validate the SCAN tool prospectively in identifying malnourished patients or those who required nutritional support
2. Validate the SCAN tool prospectively in predicting toxicities or outcome
3. Compare performance of a pediatric screening tool ($STRONG_{KIDS}$) with SCAN

Methods

Children in our center with a new diagnosis of cancer from August 2018 to May 2019 were offered to participate in the study. Measurements (SCAN questionnaire, weight, height, body-mass index (BMI), and mid upper-arm circumference (MUAC)) were taken at diagnosis and at regular intervals throughout therapy. The last measurement was taken 6 months after finishing the intensive treatment phase. SCAN score at diagnosis was validated prospectively against variables of interest.

Results

A total of 49 patients were recruited. When considering malnutrition during therapy the SCAN tool showed a sensitivity of 37.5% and negative predictive value (NPV) of 81%. Patients who required nutritional support were identified with a sensitivity of 50% and NPV of 62%. The SCAN

tool was not able to predict increased toxicities, risk of relapse or decreased survival. The pediatric screening tool $STRONG_{KIDS}$ was unable to discriminate nutritional risk and labeled all 49 patients (100%) as medium or high-risk. Applying SCAN periodically during therapy increased sensitivity for identifying malnutrition to 87.5%.

Conclusions:

In our study, applying the SCAN tool at diagnosis showed low sensitivity in identifying patients who go on to develop malnutrition during therapy. However, patients labeled as "not at risk" were unlikely to need nutritional support in the form of nasogastric tube or total parenteral nutrition. Using SCAN throughout therapy could be helpful in building awareness for malnutrition and successfully discriminates between patients who need further support and those who don't.

Keywords:

Nutritional screening, pediatric hematology-oncology, nutrition and cancer, SCAN

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Main text: 2370 words

Number of figures: 2

Number of tables: 4

65 Abbreviations key:

ALL	Acute lymphoblastic leukemia
BMI	Body-mass index
CTCAE	Common Terminology Criteria for Adverse Events
DIPG	Diffuse intrinsic pontine glioma
HL	Hodgkin lymphoma
IQR	Interquartile range
LGG	Low-grade glioma
MUAC	Mid-upper arm circumference
NG tube	Nasogastric tube
NHL	Non-Hodgkin lymphoma
NPV	Negative predictive value
PICU	Pediatric intensive care unit
PPV	Positive predictive value
RMS	Rhabdomyosarcoma
SD	Standard deviation
SCAN	Nutrition screening tool for childhood cancer
TPN	Total parenteral nutrition
zBMI	Z-score for body mass index
zMUAC	Z-score for mid-upper arm circumference
zHeight	Z-score for height/length

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Main text

Introduction

There is an increasing recognition of the importance of nutritional status in the pediatric oncology population. Malnutrition is thought to be linked to increased toxicity and worse outcomes (1-3). Though facing different realities, this is a matter affecting both high-income and low/middle-income countries (4).

One of the many challenges with malnutrition is finding a cost-effective, unified way of identifying at-risk patients early on. This allows the medical team to council families appropriately and provide nutritional support when required. A variety of nutritional screening tools for the pediatric population have been published, such as "SGNA" (5), "pediatric nutritional risk score" (6), "PYMS" (7), "STAMP" (8), PeDiSMART" (9), "$STRONG_{KIDS}$" (10), "PNST" (11) and "SCAN" (12). None so far has shown convincing predictive value (13-16). Besides, since there is no unified, gold-standard approach to diagnosing malnutrition (17, 18), validating these tools objectively becomes a very difficult endeavor.

We recently published our experience with the "nutrition screening tool for childhood cancer (SCAN)" (19) in identifying at-risk patients at diagnosis. In the current paper, we expand our previous research by analyzing how the SCAN tool fares prospectively. We wondered how a pediatric screening tool would perform in the oncology setting and incorporated $STRONG_{KIDS}$ into this analysis. Henceforth, we formulated the following research questions:

1. Is SCAN predictive of malnutrition or nutritional support?
2. Does SCAN predict toxicities or outcome?
3. Is $STRONG_{KIDS}$ able to predict malnutrition or need for nutritional support?

4. Does a positive SCAN result at any point in time correlate with malnutrition or nutritional support?

Methods

Study design: Prospective observational case series.

Setting: We recruited patients with a new diagnosis of malignancy for a 10-month period (August 2018 to May 2019) in a tertiary care hospital, the "Hospital Infantil Universitario Niño Jesús" in Madrid, Spain. Patients had scheduled nutritional assessments every 2 – 3 months and were followed from time of recruitment until 6 months after completion of intensive chemotherapy.

Participants: As described in our previous publication (19), all patients newly diagnosed with cancer were eligible. Inclusion criteria were ages from birth to 18 years old and being newly diagnosed with cancer. Patients with second malignancies, relapses, or with a history of nutritional support requirement were excluded. The study has been carried out in accordance with The Code of Ethics of The World Medical Association (Declaration of Helsinki). Written informed consent was obtained from one of both parents and from patients over 12 years of age. This study was approved by our local Ethics Committee before patient enrollment (R-0045/18).

Variables: The SCAN questionnaire (supplementary figure 22) was completed for all patients at diagnosis and during re-assessments(12). Weight, height/length, and mid upper-arm circumference (MUAC) were collected at all determined timepoints. Chart review during therapy was undertaken for documentation of toxicities (graded as per the "Common Terminology Criteria for Adverse Events" v5.0), length of hospital stays (calculated as sum of total days admitted during treatment), and outcome variables (relapse, progression, or death). $STRONG_{KIDS(10)}$ (supplementary figure 33)

was calculated during data analysis phase with available answers from the SCAN questionnaire. We defined malnutrition as BMI z-score ≤ -2 and/or MUAC z-score ≤ -2, as well as any drop by 2 standard deviations or more at any time point compared to diagnosis in BMI z-score and/or MUAC z-score.

Measurements: SCAN questionnaire and anthropometric measurements were undertaken by two nurses specialized in pediatric nutrition. We used z scores for BMI and height/length from the World Health Organization reference patterns for children under 5 years of age (20) and for those between 5 and 19 years of age (21). They were calculated with the available macro for SPSS package. For MUAC, we used the values published by Abdel-Rahman et al in 2016 for all ages (22).

Study size: Sample size was limited by the number of cases who presented to our center during the aforementioned period.

Statistical methods: Statistical analysis was conducted in ¨R¨ (23) with the following packages for importing databases, analysis and figures: "readxl" (24), "epiDisplay" (25), "dplyr" (26), "ggplot2" (27), "ggpubr" (28), "survival" (29), "survminer" (30), "ranger" (31), "ggfortify" (32). Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated based on 2x2 tables. Median values and interquartile ranges (IQR) are given for non-normally distributed variables. Comparisons between groups have been done with Mann-Whitney U test (non-normally distributed variables), Chi-square test (categorical variables) and Fisher's exact test (if cells presented expected count less than 5). Normality was confirmed by visual inspection of normal Q-Q plots and significance of Shapiro-Wilk's test. We did not provide confidence intervals in our tables due to the wide ranges with a small sample size and the lack of statistical significance in most calculations.

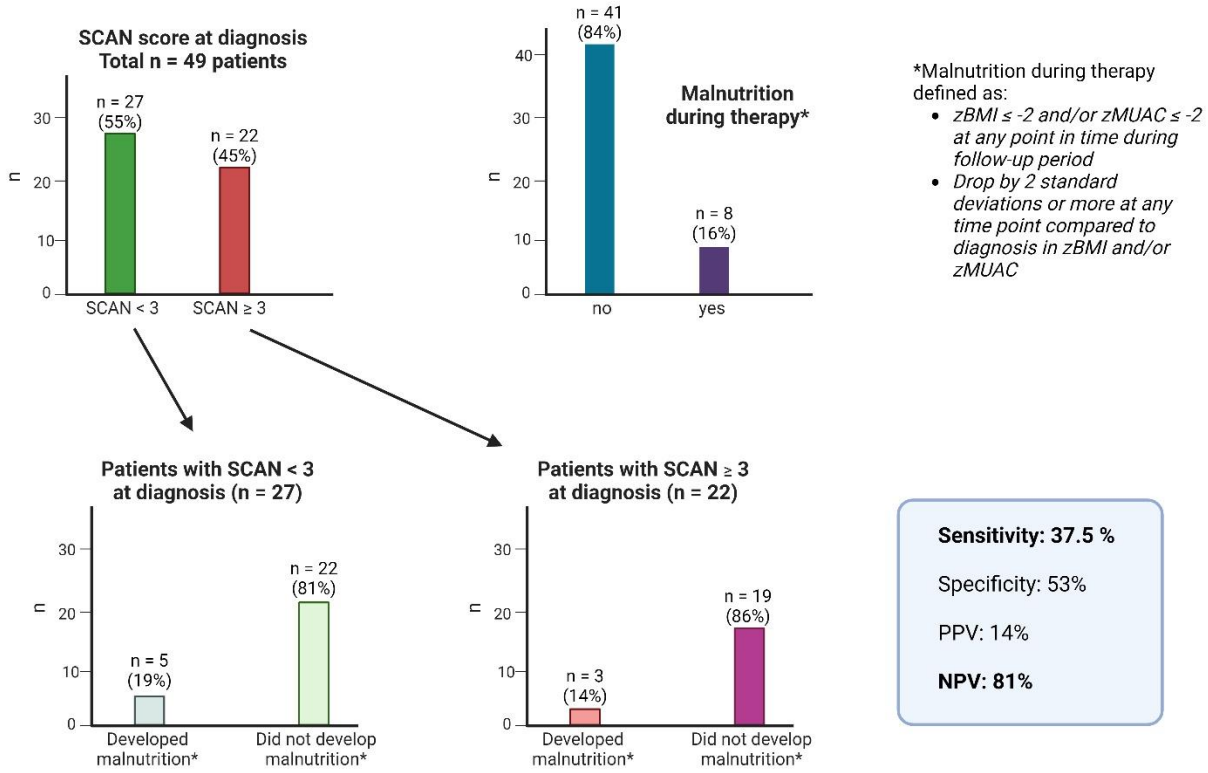
Results

Is SCAN predictive of malnutrition or nutritional support?

Forty-nine patients were included for final analysis (supplementary figure 1). Characteristics of the study population are detailed in supplementary table 1. At diagnosis, 22 patients were "at risk of malnutrition" as per the SCAN tool (SCAN ≥3) and 27 were not (figure 1). Considering measurements taken during the whole follow-up period, 8 patients (16%) could be diagnosed with malnutrition at some point. Of those, 5 patients were not initially labeled as "at risk of malnutrition" by the SCAN tool. This renders the tool a sensitivity of 37.5% and a negative predictive value (NPV) of 81%. From the whole population, 21 patients (43%) were referred to the dietician at some point, and 18 (37%) needed nutritional support (oral supplements, nasogastric tube and/or total parenteral nutrition) (table 1). Reasons for referring patients were "anorexia" in 15 patients, "weight loss" in 5 patients, and protocol mandated pre-transplant assessment in one patient. The SCAN tool showed an NPV of 88% for nutritional support.

Supplementary table 2 shows all patients who were diagnosed with malnutrition in more detail. Those who were missed by the SCAN tool had solid tumor diagnoses, mostly recovered in their final assessment and only one patient needed nutritional support. Also of note, not all patients correctly identified by the SCAN tool were referred to the dietician.

Figure 1: SCAN results at diagnosis and malnutrition during therapy



NPV: negative predictive value; PPV: positive predictive value; zBMI: z-score for Body-mass index; zMUAC: z-score for mid-upper arm circumference. Figure created with BioRender.com.

Table 1: SCAN at diagnosis and nutritional support requirement during therapy

Variable	All patients n = 49	SCAN ≥ 3 at diagnosis n = 22	SCAN < 3 at diagnosis n = 27	*p-value*	Sensitivity	Specificity	PPV	NPV
Referred to dietician	21 (43%)	12	9	*0.09*	57%	66%	57%	66%
Nutritional support	18 (37%)	9	9	*0.7*	50%	55%	43%	62%
Oral supplements	13 (26%)	6	7	*0.9*	46%	55%	30%	71%
NG tube	4 (8%)	2	2	*1*	50%	56%	10%	92%

TPN	7 (14%)	5	2	*0.2*	71%	60%	24%	92%

NG tube: nasogastric tube; NPV: negative predictive value; PPV: positive predictive value; TPN: total parenteral nutrition

Does SCAN predict toxicities or outcome (table 2 and figure 2)?

Toxicities grade ≥ 3 (including hemodynamic, respiratory, hematological, cutaneous, renal, endocrine, gastrointestinal, liver, infectious, metabolic, visual, hearing loss, and psychiatric) were present in 86% of the whole cohort, which dropped to 53% when excluding hematological toxicities, since most patients suffered severe neutropenia. There was no statistical significance when comparing groups with SCAN score ≥3 and <3 regarding toxicities and pediatric intensive care unit (PICU) admissions. Hospital stays were overall longer in the SCAN≥3 group with a median of 86.5 total days for the "at risk" group, compared to 44 days for the "not at risk" group. The same is true when considering days for chemotherapy administration or due to toxicity for supportive care. Final outcomes are shown in figure 2. Event-free survival (event being relapse or progression) plateaued at 83.7%, overall survival at 95.7%. Four patients relapsed (with diagnoses of neuroblastoma, Ewing's sarcoma, Hodgkin lymphoma and non-Hodgkin lymphoma), one patient with low-grade glioma progressed requiring second-line therapy, and two patients (diagnoses of DIPG and osteosarcoma) progressed and subsequently passed away. There was no significant difference in outcome between SCAN groups (at risk versus not at risk of malnutrition). Maximum follow-up time was 21 months.

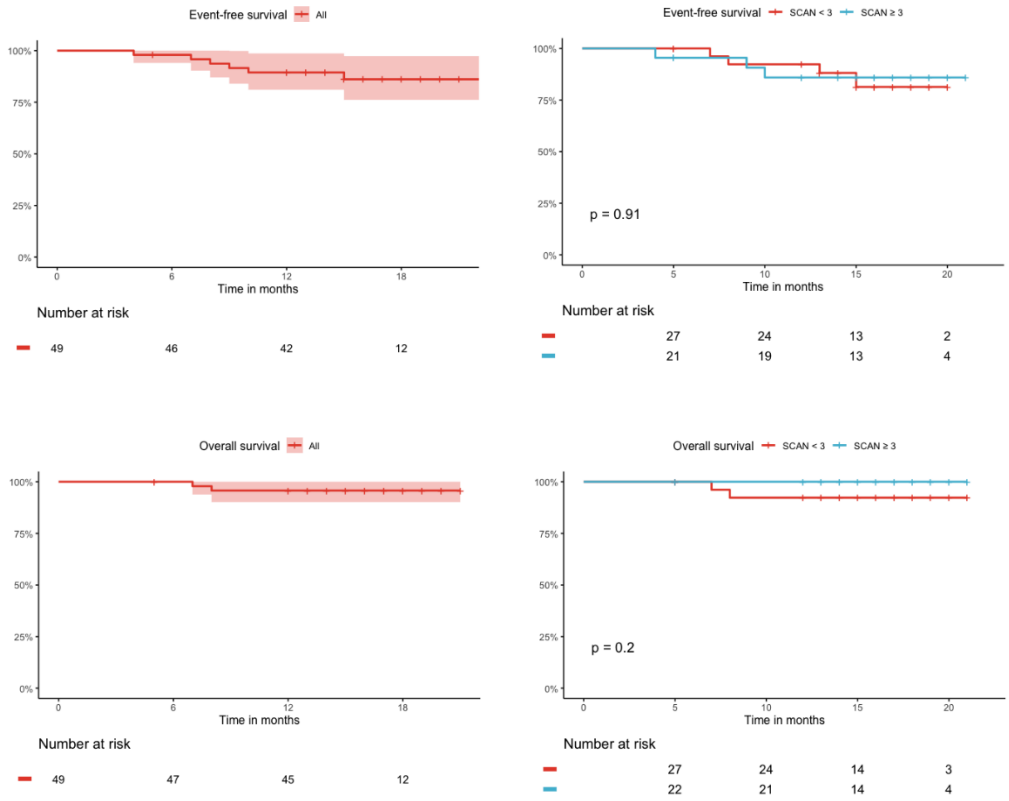
Table 2: SCAN and toxicities

Variable	All patients n = 49	SCAN ≥ 3 at diagnosis n = 22	SCAN < 3 at diagnosis n = 27	*p-value*	Sensitivity	Specificity	PPV	NPV
≥3 grade toxicities*	42 (86%)	20	22	*1*	47%	60%	91%	12%
≥3 grade toxicities* (excluding hematological)	26 (53%)	13	13	*1*	50%	61%	65%	45%
PICU admission	11 (22%)	6	5	*0.5*	54%	58%	27%	81%
Median number of total days in hospital (IQR)	71 (73)	86.5 (26.5)	44 (73)	*0.02*				
Median number of total days in hospital for chemotherapy (IQR)	32 (48)	49 (33)	8 (37)	*0.01*				
Median number of total days due to toxicities (IQR)	16 (36)	32.5 (33.5)	10 (24)	*0.01*				

*Toxicities graded as per the "Common Terminology Criteria for Adverse Events (CTCAE) version 5.0"(33).

IQR: interquartile range; NPV: negative predictive value; PICU: pediatric intensive care unit; PPV: positive predictive value

Figure 2: Outcome



Is $STRONG_{KIDS}$ able to predict malnutrition or need for nutritional support (table 3)?

There was no patient in the "low risk" category, 39 patients (80%) in the "medium risk" category and 10 patients (20%) in the "high-risk" category. Considering the "high risk" cut-off for validity calculations, $STRONG_{KIDS}$ had a sensitivity of 25% and NPV of 85% for malnutrition. Regarding nutritional support, it showed a sensitivity of 17% and NPV of 58%.

Table 3: $STRONG_{KIDS}$ as predictor of malnutrition and nutritional support requirement

Variable	All patients n = 49	$STRONG_{KIDS}$ High Risk (Score 4 or 5) n = 10	$STRONG_{KIDS}$ Medium Risk (Score 1, 2 or 3) n = 39	*p-value*	Sensitivity	Specificity	PPV	NPV
Malnutrition	8 (16%)	2	6	*0.7*	25%	80%	20%	85%
Referred to dietician	21 (43%)	3	18	*0.7*	14%	78%	33%	54%
Nutritional support	18 (37%)	3	15	*0.7*	17%	78%	33%	58%
Oral supplements	13 (26%)	1	12	*0.4*	8%	77%	12%	67%
NG tube	4 (8%)	2	2	*0.2*	50%	84%	22%	95%
TPN	7 (14%)	1	6	*1*	14%	80%	11%	84%

NG tube: nasogastric tube; NPV: negative predictive value; PPV: positive predictive value; TPN: total parenteral nutrition

Does a positive SCAN result at any point in time correlate with malnutrition or nutritional support (table 4)?

In this scenario, the SCAN tool identified 44 patients (90%) as being "at risk of malnutrition". Sensitivity for malnutrition rose to 87.5%. Need for nutritional support also rose to a sensitivity of 94%, whereas oral supplements and TPN had an NPV of 100%.

Table 4: SCAN at any point during therapy

Variable	All patients n = 49	SCAN ≥ 3 in any of the assessments n = 44	SCAN < 3 in all assessments n = 5	*p-value*	Sensitivity	Specificity	PPV	NPV
Malnutrition	8 (16%)	7	1	*1*	87.5 %	9.8 %	16%	80%
Referred to dietician	21 (43%)	20	1	*0.09*	95%	15%	46%	80%
Nutritional support	18 (37%)	17	1	*0.6*	94%	15%	42%	80%
Oral supplements	13 (26%)	13	0	*0.3*	100%	16%	33%	100%
NG tube	4 (8%)	3	1	*0.4*	75%	9%	7%	80%
TPN	7 (14%)	7	0	*1*	100%	12%	17%	100%

NG tube: nasogastric tube; NPV: negative predictive value; PPV: positive predictive value; TPN: total parenteral nutrition

Discussion

To answer our first question, the SCAN tool was not able to discriminate between those patients who might develop malnutrition or need nutritional support during therapy and those who won't. In this regard, our findings differ from those described in the original SCAN paper (12). There, they evaluated the SCAN tool against the pediatric "subjective global nutrition assessment" (SGNA) published by Secker and Jeejeebhoy in 2007 (5) and against nutrition anthropometric parameters. They achieved a sensitivity of 100% and NPV of 100% in the first study, whereas in study 2 they found that "no subjects in the 'not at risk of malnutrition' group […] had a BMI Z score ≤ -2". We cannot comment on the results of study 1 since we did not use SGNA as comparison. However, with anthropometric measurements we have not been able to reproduce the findings of study 2. Our findings indicate a far lower sensitivity and NPV.

Moving on to toxicities and outcome, patients with a higher SCAN score did not fare worse. Patients with SCAN score ≥3 did have longer hospital stays for chemotherapy and due to toxicity. However, in our opinion, this is most likely a bias from identifying high-risk patients that inevitably receive higher-intensity chemotherapy protocols. These are usually given as inpatient and are generally more toxic. Interestingly, this intensity did not translate into a higher PICU admission rate or toxicity grading in this population. No difference was seen in outcome between the two groups, keeping in mind the very short follow-up time and small sample size.

A recent consensus statement from the Italian Association of Pediatric Hematology and Oncology (AIEOP) recommends the $STRONG_{KIDS}$ tool as screening tool for oncology patients, which led us to consider if $STRONG_{KIDS}$ would perform any better compared to a specific screening tool designed for the hematology-oncology environment like SCAN. The main problem with pediatric screening tools is the over-estimation of risk in patients with a cancer diagnosis. The

second question regarding "High risk disease" in the $STRONG_{KIDS}$ questionnaire assigns a baseline of two points to all hematology-oncology patients. In our cohort for example, all patients fall into the "medium" or "high" risk categories, without any in the low-risk category (10). We investigated whether using the "high-risk" group would improve validity (table 3), but it showed a low sensitivity in identifying undernourished patients or those who needed nutritional support.

Finally, we wanted to know whether using SCAN at different points in time during therapy would be beneficial for picking up patients at risk of malnutrition (table 4). Almost all patients in the cohort were considered "at risk of malnutrition" at some point. We find this to be a compelling argument towards using the SCAN tool throughout treatment. It would function as a "monitoring" tool, rather than an exclusive screening strategy. Patients might not need support at diagnosis but develop that need later since during a long and intensive treatment protocol, the patients' reality is constantly changing. This complexity is highlighted in supplementary table 2. Looking at patients On2 and On60 e.g., they were both picked up by the SCAN tool as being "at risk of malnutrition" and were anthropometrically undernourished at diagnosis. However, they did not need any nutritional support and recovered measurements with supportive care. Patients On31 and On15 on the other hand were not picked up by SCAN even though presenting more than -2 standard deviations in both MUAC and BMI. However, they also recovered measurements without additional nutritional support. Presumably, these patients were able to keep eating adequately by mouth during or in between therapy cycles to maintain/recover their nutritional status.

So, is there a rationale for the use of any screening tool in the pediatric oncology setting? Is SCAN the right one? Should a more thorough nutritional assessment (such as SGNA) be the gold standard? Most patients not picked up by the SCAN tool at diagnosis did not develop malnutrition or require nutritional support in our cohort. This is even more true when screening at

different points in time. Pediatric tools like $STRONG_{KIDS}$ are not able to tell apart patients with malnutrition risk in this context. A score like SGNA requires calculations of mid parental height, access to the patient's previous records to recognize trends, and anthropometric measurements. This is time-consuming and unrealistic to apply repeatedly in a busy routine. We would therefore recommend SCAN to be used for screening, at diagnosis and throughout therapy. Aside from the nutritional assessment, it would serve as an awareness tool, highlighting the importance of nutritional status in the ever-changing scenario of an oncology treatment course. The most straightforward strategy would be to include the SCAN questionnaire as part of the tests to be done at certain phases of the treatment protocols. This, as we showed in table 4, would pick up almost all patients who could become undernourished over time or might need nutritional support at some point.

Conclusions:

We would recommend the SCAN tool for everyday clinical practice. Since it foregoes anthropometric measurements, it is easy and quick to use in a busy clinical setting. Patients not picked up by the tool are unlikely to require nutritional support in the future (in the form of NG tube or TPN). One should bear in mind that a significant number of patients might still develop some sort of malnutrition during therapy or require nutritional support. Therefore, aside from referring to the dietician in the light of concerning symptoms, we believe screening should be repeated periodically. Incorporating a screening method at diagnosis and into treatment protocols might raise awareness for patients, oncologists, and dieticians to the ongoing issue of nutrition during cancer treatment and the patient's changing needs.

Limitations and bias:

There are several limitations to this study, including a small sample size and single center recruitment. Patients had a short follow-up time, which could limit outcome analysis. We only focused on undernutrition and did not address overnutrition. Diagnoses were analyzed as one entity and each disease was not considered separately. $STRONG_{KIDS}$ calculations were performed during data analysis phase based on SCAN answers, which could lead to inaccurate scoring. Information bias could have occurred with the study's close monitoring of patients interfering with doctor's day-to-day decisions around dietician referral.

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Authors contribution:

Gustavo de Oliveira Canedo: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft. **Laura María Palomino Pérez**: Conceptualization, Methodology, Investigation. **Laura Puerta Macfarland**: Investigation. **David Ruano Dominguez**: Conceptualization, Supervision. **Elvira Cañedo-Villaroya**: Conceptualization, Methodology. **Beatriz Garcia Alcolea**: Investigation. **Luis Madero López**: Supervision, Project administration. **Consuelo Pedrón-Giner**: Conceptualization, Methodology, Writing – Review & Editing, Supervision, Project administration.

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