A cohort study protocol of nutritional status and clinical outcomes in patients with common malignancies (NCOM study)

HeXiang Yang [1#], Yaxin Yu [1#], Haige Cao[1], Jinglin Li[1], Feng Liu[1], Xiaoqin Luo [1ID]

Malnutrition is common in cancer patients, impairing treatment tolerance, quality of life, and survival. However, its longitudinal association with clinical outcomes remains unclear. The Nutritional Status and Clinical Outcomes in Patients with Common Malignancies (NCOM) study investigates the long-term impact of nutritional status on cancer outcomes and identifies modifiable risk factors to support personalised nutritional care. This prospective, multicentre cohort includes cancer patients from 11 hospitals in China. Nutritional status is assessed within 48 hours of admission, with follow-ups at 1, 2, 3, 6, and 12 months, then annually for 4 years. Data include nutritional assessments, biomarkers, quality of life, psychosocial factors, physical activity, sleep, dietary knowledge, attitudes and practices, and survival outcomes. Multivariable models, survival analysis, and longitudinal methods will be used. Early findings reveal a high burden of nutritional risk, underscoring the importance of timely identification and intervention. The study will generate critical evidence to optimise nutrition-focused strategies and improve clinical outcomes in oncology.

Keywords Cancer, Nutritional status, Malnutrition, Clinical outcomes, Cohort study

Introduction

Cancer remains a leading cause of mortality worldwide, with nearly 20 million new cases and 9.7 million deaths reported in 2022. Approximately 20% of individuals will develop cancer in their lifetime, and 11% of men and 8% of women are expected to succumb to the disease(Bray *et al*). In China, rapid population growth, increasing demographics, and unhealthy lifestyles are driving an increasing cancer burden(Cao *et al*, 2021; Qiu *et al*, 2021).

Malnutrition is common among cancer patients, with prevalence rates ranging from 16–40% at diagnosis and increasing to 40–80% during treatment, depending on factors such as age, cancer type, and treatment modality(Bossi *et al*, 2021; Kaegi-Braun *et al*, 2021). Tumor location plays a crucial role, with the highest malnutrition rates observed in pancreatic (66.7%), esophageal/gastric (60.2%), head and neck (48.9%), and lung (45.3%) cancers(Huterne *et al*, 2014; Bossi *et al*, 2021).

Nutritional status in cancer patients is intricately linked to clinical outcomes. Tumor and therapeutic interventions notably impact nutritional health(Webb *et al*, 2020; Kipouros *et al*, 2023). Malnutrition significantly affects treatment tolerance, morbidity, survival, and quality of life(Huterne *et al*, 2014; Liu *et al*, 2021; Garutti *et al*, 2023). It can lead to reduced nutrient intake, cachexia, and impaired treatment efficacy(Muscaritoli *et al*, 2019; Holdoway *et al*, 2023). Early nutritional interventions have been shown to mitigate adverse clinical outcomes and reduce 30-day mortality in at-risk patients(Muscaritoli *et al*, 2019; Schuetz *et al*, 2019; Kipouros *et al*, 2023).

Although the association between malnutrition and adverse clinical outcomes has been well established (Muscaritoli *et al*, 2019; Liu *et al*, 2021; Kipouros *et al*, 2023), the benefits of nutritional improvement reported in different studies remain inconsistent (Schuetz *et al*, 2019; Kaegi-Braun *et al*, 2021). On the one hand, nutritional status might vary considerably over the course of treatment(Webb *et al*, 2020); on the other hand, psychological factors, sleep quality, and physical activity may further influence these outcomes (Nissim *et al*, 2024; Ye *et al*, 2024). High-quality and large-scale cohort studies that can capture dynamic changes in nutrition are needed to carry out more precise nutritional interventions or treatments to improve clinical outcomes. Hence, we established a cohort study to evaluate nutritional status and clinical outcomes in patients with common malignancies (NCOM study), aiming to provide evidence for personalized and precise nutritional treatment in oncology care.

Methods

Study design

The NCOM study is a multicenter, prospective cohort study designed to assess longitudinal changes in nutritional status and their impact on clinical outcomes in cancer patients. We aim primarily to identify modifiable risk factors associated with malnutrition-related morbidity and mortality and assess the effectiveness of targeted nutritional interventions. The secondary objectives include examining variations in nutritional status across cancer types and treatment modalities and exploring how nutritional health interacts with psychological well-being, sleep quality, and physical activity. Participants diagnosed with common malignancies across multiple hospitals undergo baseline nutritional assessments within 48 hours of admission, followed by structured follow-ups at 1, 2, 3, 6, and 12 months and then annually for an additional four years to track nutritional changes and key clinical endpoints (Riboli, 2001). Nutritional status, the primary exposure factor, is classified via validated screening tools and dietary intake assessments. Patients are stratified on the basis of malnutrition severity, dietary intake, and nutritional support status, with classifications updated at each follow-up, to evaluate their associations with short- and long-term outcomes (**Fig. 1**).

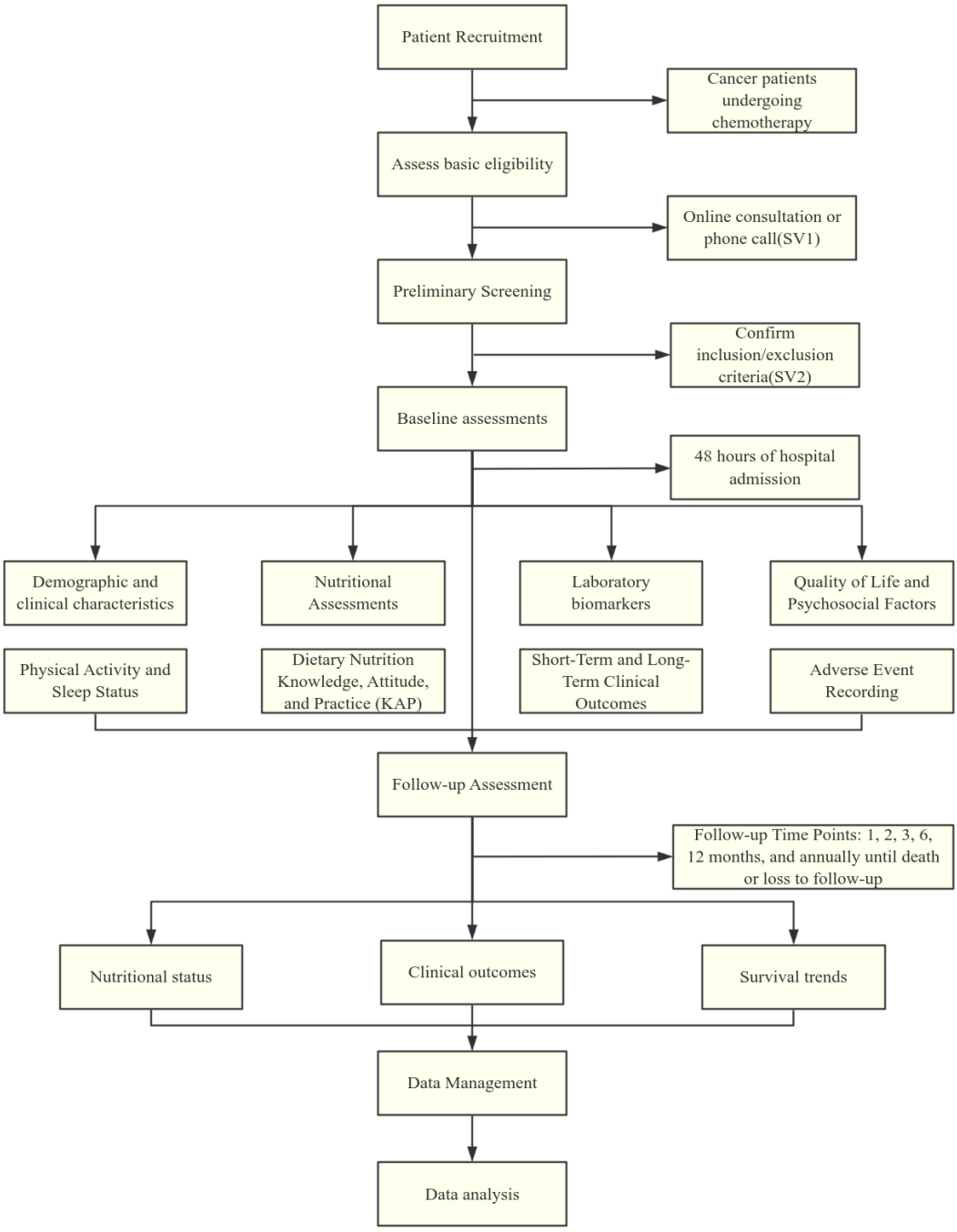

Fig. 1. The workflow of the NCOM study.

Study Setting & Population

Study sites

The NCOM study was conducted across 11 tertiary hospitals in Xi'an, Shaanxi Province, China. The participating institutions included Shaanxi Provincial Cancer Hospital; the First Affiliated

Hospital of Xi'an Jiaotong University; the Second Affiliated Hospital of Xi'an Jiaotong University; Shaanxi Provincial People's Hospital; the First Affiliated Hospital of the Fourth Military Medical University; the Second Affiliated Hospital of the Fourth Military Medical University; Shaanxi Provincial Chest Hospital; and the Affiliated Hospital of Northwest University Xi'an No.3 Hospital; Xi'an International Medical Center Hospital; The First Affiliated Hospital of Xi 'an Medical University; The Second Affiliated Hospital of Xi'an Medical University.

Recruitment strategy

Eligible patients will be recruited by clinical medical staff. Recruitment will primarily occur through direct physician referrals during oncology consultations, supplemented by promotional materials in hospitals, such as posters, brochures, and electronic notices. Patients and their families who learn about the study through these materials can also self-refer by contacting the research team. The screening process consists of two steps. The first screening visit (SV1) is conducted remotely via online consultation or phone call to assess basic eligibility, including willingness to participate and key exclusion factors such as pregnancy or concurrent trial participation. Informed consent is obtained at this stage. Patients who pass SV1 will proceed to the second screening visit (SV2), which will be conducted onsite at each hospital. During SV2, medical records will be reviewed, and clinical assessments will be performed to confirm whether patients meet the inclusion and exclusion criteria. Only patients who meet all the criteria will be formally enrolled.

Inclusion criteria

a. Age ≥ 18 years.

b. Histologically confirmed diagnosis of malignancy.

c. Patients are scheduled to receive oncologic treatment, including surgery, chemotherapy, radiotherapy, or a combination.

d. Mentally competent and able to provide informed consent.

e. Willingness to participate in follow-up assessments

f. Patients with multiple hospital admissions may be included in repeat assessments, with each admission counted as an independent case.

Exclusion criteria

Patients were excluded if they met any of the following criteria:

a. Severe comorbidities that may interfere with participation (e.g., end-stage liver/kidney disease or severe cardiac failure).

b. Patients with HIV/AIDS.

c. Prior organ transplantation recipients.

d. Expected survival of less than 6 months.

e. Pregnant patients.

f. Patients currently participating in another interventional clinical trial.

Sample size

The sample size for the NCOM study was determined on the basis of the impact of nutritional status on clinical outcomes in cancer patients, with a two-sided significance level (α) of 0.05 and 80% power ($1 - \beta = 0.80$) (von Elm *et al*, 2007; Arends *et al*, 2017). On the basis of previous studies on nutritional status and cancer outcomes, we assumed a baseline event rate of 20% ($P_1 = 0.50$) in the unexposed group and an expected rate of 24% ($P_2 = 0.40$) in the exposed group(Rasschaert *et al*, 2024). Given that longitudinal oncology cohort studies report attrition rates ranging from 30% to 50% over a multiyear follow-up period (Reeves *et al*, 2007; Schwedhelm *et al*, 2016), the final target sample size for this study was estimated to be approximately 1,538 participants.

Data collection

Data collection followed a standardized protocol across all participating hospitals to ensure consistency and accuracy. The baseline assessments will be conducted within 48 hours of hospital admission, and well-trained researchers will collect information on demographic and clinical data, nutritional status, laboratory biomarkers, quality of life, psychosocial factors, physical activity, sleep status, and knowledge, attitudes, and practices (KAPs). Follow-up assessments will be conducted at predefined intervals to track longitudinal changes in nutritional status and clinical outcomes.

To ensure data reliability, each hospital will designate 1 to 2 trained personnel to be responsible for questionnaires and clinical data recording. At the same time, a supervisor will be appointed to review the integrity of the data and coordinate follow-up work if necessary. All researcher personnel

must complete standardized training and pass competency assessments to ensure consistency in data collection and minimize variations.

Data management will be centralized through the Research Electronic Data Capture (REDCap) system, which ensures data security, accuracy, and accessibility(Harris *et al*, 2009). Standardized, validated measurement tools will be used at each site. Data entry will include built-in validation checks to identify missing values or inconsistencies, with routine audits and cross-site comparisons performed to maintain high data quality and study validity.

Data Content & Assessment Tools

Demographics & Clinical Data

Upon enrollment, trained personnel will obtain informed consent and record demographic details, including sex, age, marital status, occupation, education, and socioeconomic status. Lifestyle factors such as smoking, alcohol, and tea consumption are documented, given their potential influence on nutritional status and cancer progression(Yuan *et al*, 2023). Medical history, including chronic conditions, previous diagnoses, medication use, and family history of malignancies, will also be recorded to assess genetic predispositions.

Cancer-specific data will be collected at baseline and updated at follow-ups to monitor disease progression and treatment response. This includes pathology-confirmed diagnosis, TNM staging at first diagnosis, and available molecular markers. The tumor burden will be reassessed at each visit, alongside major treatments (surgery, chemotherapy, radiotherapy, targeted therapy, and immunotherapy), with details on the type, duration, and response. Nutritional support, including enteral or parenteral nutrition in the preceding week, will be tracked to evaluate its impact on treatment outcomes.

Karnofsky Performance Status (KPS): The KPS evaluates a patient's ability to perform daily activities, the presence of physical discomfort, and overall performance status, providing a standardized measure of functional impairment(McNair *et al*, 2023).

Nutritional assessments

Nutritional assessments will be conducted via validated screening tools to evaluate nutritional status, risk factors, and dietary intake patterns. Two primary tools and standardized anthropometric

measurements will be employed to assess malnutrition risk and severity:

Subjective Global Assessment (mPG-SGA): The mPG-SGA scoring system consists of five sections: weight loss history, dietary intake changes, symptoms, activity and function levels, and age. Patients' nutritional status will be categorized on the basis of scores as normal (0–2 points), mild malnutrition (3–6 points), and moderate malnutrition (≥7 points)(Huo *et al*, 2023a). The version used in this study, mPG-SGAL11, is an adapted and validated version developed for Chinese cancer patients who that incorporates modifications on the basis of nationwide clinical feedback and statistical validation(Fu *et al*, 2022; Huo *et al*, 2023b).

Nutritional risk screening (NRS-2002): The NRS-2002 screening tool evaluates nutritional risk on the basis of three components: disease severity, nutritional status, and age. A total score of ≥ 3 indicates nutritional risk, warranting nutritional intervention, whereas a score of <3 requires weekly reassessment to monitor changes in nutritional status(Zhang *et al*, 2021).

Standardized anthropometric measurements: These measurements will include body mass index (BMI), percentage of weight loss, mid-arm circumference (MAC), triceps skinfold thickness (TSF), and handgrip strength. All measurements will be made under controlled conditions and repeated to ensure accuracy and reliability. To ensure methodological consistency, all measurements will be taken under fasting conditions, with patients wearing minimal clothing and no shoes.

Simple Diet Self-Assessment Tool (SDSAT): A validated self-reported dietary intake tool will be used to estimate the dietary intake of cancer patients. Compared with 24-hour dietary recall, the SDSAT has good reliability and validity(Jin *et al*, 2020).

Nutrition support in and out of the hospital: To evaluate the nutritional support of patients in and out of the hospital, patients need to provide information on the type of nutritional support (enteral or parenteral), formula, and supplemental dose.

Laboratory biomarkers

Biochemical markers will be analyzed to assess nutritional status, systemic inflammation, and metabolic function. Blood samples will be collected, processed, and stored following standardized protocols to ensure consistency among sites.

Serum ALB, prealbumin, and transferrin can be measured as indicators of protein-energy malnutrition, providing insights into nutritional depletion and muscle wasting risk. These factors

will be analyzed alongside C-reactive protein (CRP) to account for inflammation-related reductions in protein levels[30]. Inflammatory cytokines, including interleukin-6 (IL-6), interleukin-1 (IL-1), and tumor necrosis factor-alpha (TNF-α), serve as markers of systemic inflammation and metabolic dysregulation in patients with cancer-related malnutrition and cachexia(Keller, 2019).

Additional biochemical parameters, including hematological markers such as blood glucose, hemoglobin, white blood cell count, neutrophil count, lymphocyte count, red blood cell count, monocyte count, and platelet count, will be recorded where available. The liver and kidney function markers used were AST, ALT, creatinine, blood urea nitrogen, total bilirubin, and direct bilirubin. Lipid profile: Total cholesterol, triglycerides, high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C)(Yang *et al*, 2019).

All values are based on the most recent test results closest to the evaluation. If certain parameters are not routinely available, they will be documented as unavailable. To ensure data reliability, assessments will follow strict quality assurance protocols, including routine calibration of analyzers, standardized sample handling procedures, and interlaboratory validation. When feasible, blood samples will be collected in a fasting state to minimize variability in metabolic markers.

Quality of Life & Psychosocial Factors

A comprehensive assessment of quality of life and emotional well-being will be conducted to evaluate the psychosocial impact of cancer and its treatment on patients. Standardized and validated measurement tools will be used across study sites to ensure the comparability and reliability of the data.

European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30): This questionnaire is used to evaluate the overall quality of life of cancer patients. This validated instrument consists of five functional scales (physical, role, cognitive, emotional, and social functions), three symptom scales (fatigue, pain, nausea/vomiting), six single-item symptom measures (dyspnea, appetite loss, sleep disturbance, constipation, diarrhea, and financial difficulties), and a global quality of life scale. Each scale and single-item measure is scored from 0 to 100, with higher scores indicating better quality of life. This tool has been widely applied in oncology research and provides valuable insights into patients' well-being, treatment-related side effects, and overall functionality(Aaronson *et al*, 1993).

Hospital Anxiety and Depression Scale (HADS): This questionnaire will be used to assess anxiety and depression levels in cancer patients. This scale consists of two subscales, measuring anxiety (HADS-A) and depression (HADS-D), each with seven items. The total score for each subscale ranges from 0 to 21, with the following interpretations: 0–7: normal; 8–10: mild anxiety/depression; 11–14: moderate anxiety/depression; and 15–21: severe anxiety/depression. The HADS is designed specifically for use in hospitalized patients, as it eliminates items related to somatic symptoms that may overlap with cancer-related physical effects, ensuring a more accurate psychological assessment in this population(Snaith, 2003).

Physical Activity & Sleep Status

Pittsburgh Sleep Quality Index (PSQI): This scale consists of seven components (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction), with total scores ranging from 0--21. A score of >5 indicates poor sleep quality, which is commonly observed in cancer patients because of disease-related symptoms, psychological stress, and treatment side effects(Divani *et al*, 2022).

Leisure-time physical activity levels: This questionnaire categorizes activity levels into mild, moderate, and vigorous-intensity exercise. This assessment provides insights into physical activity patterns and their role in cancer-related fatigue management, functional status, and long-term patient outcomes. The questionnaire captures the frequency, duration, and intensity of activity to allow for a detailed analysis of the impact of physical activity on patient well-being(Moore *et al*, 2016).

Dietary Nutrition Knowledge, Attitude, and Practice (KAP)

The KAP questionnaire is designed to assess cancer patients' nutrition-related knowledge, attitudes, and practices. It comprises three components, namely, nutritional knowledge, dietary attitudes, and dietary practices, with a total score ranging from 0--104, where higher scores indicate greater nutritional awareness, more positive dietary attitudes, and healthier dietary behaviors(Tang *et al*, 2023).

The nutritional knowledge section evaluates patients' understanding of nutrient composition, dietary recommendations, and the relationship between nutrition and cancer treatment outcomes. The attitude section measures patients' perceptions and beliefs regarding the importance of nutrition in managing cancer-related symptoms and treatment side effects. The practice section assesses

actual dietary behaviors, including food choices, meal frequency, and adherence to nutritional recommendations.

Short-Term & Long-Term Clinical Outcomes

Short-term clinical outcomes will focus on early posthospitalization events within 30 days of admission, providing insights into the immediate impact of nutritional status on patient recovery and complications. These outcomes will include 30-day survival status, intensive care unit (ICU) admissions, length of stay, and total hospitalization costs, with a specific breakdown of nutrition-related expenses, such as enteral and parenteral nutrition. Additionally, changes in body weight within 30 days of hospitalization will be monitored as a key indicator of early nutritional deterioration. The incidence of complications, including infections, malnutrition, and drug-related adverse effects, will be systematically recorded to assess treatment-related risks. These measures provide critical data on the role of nutritional status in influencing short-term recovery, treatment complications, and overall resource utilization.

Long-term clinical outcomes will be assessed through regular survival tracking at each scheduled follow-up visit. Patient survival status will be documented to analyze survival trends over time and the potential impact of nutritional interventions on overall prognosis. The follow-up evaluations will categorize patients as alive and disease-free, alive with disease progression, or deceased, with the cause of death recorded.

Adverse Event Recording

Adverse events (AEs) will be systematically recorded and monitored throughout the study to ensure patient safety and data integrity. AEs are defined as any unfavorable or unintended medical occurrence, regardless of their direct relationship with nutritional interventions or treatment. These may include treatment-related complications, gastrointestinal distress, metabolic imbalances, infections, allergic reactions, or other unexpected health changes.

At each follow-up visit, trained personnel will actively assess AEs by reviewing medical records and laboratory findings, while participants will be encouraged to self-report symptoms between visits. Serious adverse events (SAEs), including hospitalization, prolonged disability, or life-threatening conditions, will be reported following institutional and ethical guidelines.

All AEs and SAEs are classified by severity, duration, and potential causality, with standardized

procedures for data entry, review, and risk assessment. Necessary medical interventions or protocol adjustments will be implemented as needed. This structured monitoring system will increase patient safety, reduce risks, and provide insights into the impact of nutritional interventions on clinical outcomes.

Follow-up assessments and data collection timeline

Follow-up assessments will be conducted at predefined intervals to track longitudinal changes in nutritional status, clinical outcomes, and survival trends. In the first year, participants will be closely monitored at 1, 2, 3, 6, and 12 months to assess early nutritional changes and treatment-related complications. Afterward, annual follow-ups will continue for an additional four years or until death or loss to follow-up, with a focus on survival status and disease progression. In-person hospital visits will be prioritized for follow-up to ensure a comprehensive evaluation of nutritional status, clinical outcomes, and quality of life **(Table 1)**. If in-person visits are not feasible, telephone follow-ups serve as an alternative. Research personnel will document each follow-up attempt, including the method of contact, date, and details of the interaction. To minimize loss to follow-up, participants missing scheduled visits were contacted up to three times via phone calls or text messages. If a participant remains unreachable after three attempts, they will be classified as lost to follow-up, and their last recorded assessment will be used for analysis. Any known reasons for withdrawal, relocation, or health deterioration will be documented to ensure data transparency and completeness.

Variable	SV	Folllow-up					
		1st month	2nd month	3rd month	6th month	12th month	Annually follow-up for another 4 years

Demographics & Clinical Data	√						
KPS Scoring	√	√	√	√	√	√	√
mPG-SGA	√	√	√	√	√	√	√
NRS2002	√	√	√	√	√	√	√
Standardized anthropometric measurements	√	√	√	√	√	√	√
SDSAT	√	√	√	√	√	√	√
Nutrition support in and out of hospital Nutrition support	√	√	√	√	√	√	√
Laboratory biomarkers	√	√	√	√	√	√	√
EORTC QLQ-C30	√	√	√	√	√	√	√
HADS	√	√	√	√	√	√	√
PSQI	√	√	√	√	√	√	√
Leisure-time physical activity levels	√	√	√	√	√	√	√
KAP Questionnaire	√				√	√	√
Short-Term Clinical Outcome		√	√	√	√	√	√
Long-term clinical outcomes		√	√	√	√	√	√
Adverse Event Recording	√	√	√	√	√	√	√

Table 1. Follow-up schedule. SV: screening visit; KPS: Karnofsky Performance Status; mPG-SGA: Subjective Global Assessment; NRS-2002: Nutritional Risk Screening 2002; SDSAT: Simple Diet Self-Assessment Tool; EORTC QLQ-C30: European Organization for Research and Treatment of Cancer

Quality of Life Questionnaire C30; HADS: Hospital Anxiety and Depression Scale; PSQI: Pittsburgh Sleep Quality Index; KAP : Knowledge, Attitude, and Practice.

Statistical analysis plan

Baseline characteristics are summarized as the means ± standard deviations (SDs) for normally distributed variables, medians with interquartile ranges (IQRs) for skewed data, and percentages for categorical variables. For group comparisons (e.g., normal vs. mild malnutrition vs. moderate malnutrition patients), independent t tests or Mann–Whitney U tests were used for continuous variables, and chi–square tests or Fisher's exact tests were used for categorical data.

The primary outcome analysis will apply multivariate regression models, adjusting for age, sex, cancer stage, treatment modality, socioeconomic status, and baseline Karnofsky Performance Status (KPS). Logistic regression was used to assess binary outcomes (e.g., nutritional risk, survival), whereas linear regression was used to evaluate continuous variables (e.g., BMI changes, weight loss percentage). To account for repeated measures, generalized estimating equations (GEEs) model longitudinal variations in nutritional status, biomarkers, and quality of life.

For survival analysis, Kaplan–Meier curves were used to estimate overall survival (OS) and progression-free survival (PFS), with log-rank tests used to compare groups. Cox proportional hazards models were used to explore the associations between nutritional status and survival outcomes, incorporating time-dependent covariates where applicable.

Secondary analyses will investigate associations between nutritional status and psychosocial factors (e.g., EORTC QLQ-C30, HADS, PSQI) via paired t tests, mixed-effects models, and correlation analyses (Spearman or Pearson, depending on distribution).

To minimize bias and confounding factors, propensity score matching (PSM) will balance baseline differences between exposure groups. Multiple imputation will handle missing data to prevent systematic bias, and sensitivity analyses will exclude cases with extreme values, incomplete follow-ups, or protocol deviations.

Subgroup analyses will stratify findings by cancer type, treatment modality, and nutritional status category. Interaction terms are included in regression models to identify potential effect modifications, with exploratory analyses conducted if unexpected patterns arise.

By integrating multivariate modeling, survival analysis, repeated measures approaches, and

missing data imputation, this study ensures robust, high-quality, evidence-based insights into the impact of nutritional status on clinical outcomes and survival in cancer patients.

Informed Consent Process

Participation in this study is voluntary, and individuals may withdraw at any time without affecting their medical care. Before enrollment, participants and their families will receive detailed study information, including their purpose, methodology, potential risks, and benefits. A written informed consent form must be signed, confirming their understanding and voluntary participation.

The informed consent process will be conducted by trained research personnel, ensuring that participants fully understand the study's objectives and procedures; are aware of their right to withdraw at any time without impacting their current or future medical treatment; and have the opportunity to ask questions and receive clarifications before signing.

To accommodate diverse literacy levels, consent materials will be provided in clear, accessible language, with verbal explanations when needed. The informed consent form included both English and Chinese versions **(Supplementary File 1).**

Data Privacy & Confidentiality

This study strictly adheres to data privacy regulations, ensuring that all participant data remain confidential. Personal identifiers will not be recorded, and all collected data will be deidentified and stored securely in password-protected electronic databases with restricted access. Data will be used exclusively for research purposes and will not be disclosed or shared beyond the study's scope.

To further increase confidentiality, the following measures will be implemented: data encryption and anonymization before analysis; restricted access to the research database, limited to authorized personnel only; and periodic security audits to ensure compliance with institutional and regulatory data protection policies.

Participant Rights & Withdrawal Process

Participants have the right to withdraw at any time without affecting their treatment or medical care. If they choose to withdraw, previously collected data will remain in the research dataset unless they explicitly request removal. In such cases, all identifiable information will be deleted while preserving the scientific integrity of the study.

Discussion

The NCOM study was designed to assess the longitudinal impact of nutritional status on clinical outcomes in cancer patients. Through systematic data collection, including demographic, medical, and cancer-specific information, this study provides a comprehensive framework for evaluating malnutrition, treatment response, and survival. The integration of nutritional assessments, dietary intake data, biochemical markers, and inflammatory profiles will enable an in-depth exploration of nutritional risk factors and their biological impact on cancer progression(Phillips *et al*, 2019; Wu *et al*, 2023). Additionally, assessments of quality of life, psychological distress, and physical activity will help identify modifiable behavioral factors influencing treatment outcomes(Wu *et al*, 2024; Xiao *et al*, 2019; Zhu *et al*, 2024). Further statistical analyses will clarify the relationships between nutritional status, treatment tolerance, and long-term survival.

The prevalence of malnutrition among cancer patients varies widely, with reported rates ranging from 20% to over 70%(Beirer, 2021). The preliminary findings of this study align with this range, highlighting the variability in cancer type, stage, and assessment methods. Research has indicated that 28% of solid tumor patients are at high risk of malnutrition at diagnosis, with substantial variation by cancer site(Kadakia *et al*, 2022). Socioeconomic status (SES) is also a crucial determinant, as lower SES is associated with higher malnutrition risk due to disparities in living conditions, nutrition, and healthcare access(Sandström *et al*, 2023). The NCOM study, designed to integrate these factors, offers a comprehensive approach to understanding the interplay between cancer type, nutritional status, and treatment response. These findings reinforce the importance of personalized nutritional interventions, including oral supplements, enteral feeding, and parenteral nutrition, which have been shown to enhance immune function, improve treatment response, and prolong survival(Li *et al*, 2024).

This study also evaluated nutrition-related screening tools in oncology. Early detection of malnutrition is critical for timely interventions, and the PG-SGA is widely recognized as a sensitive tool for identifying patients at risk(Zhou *et al*, 2021). Preliminary baseline data revealed that 68.05% of patients were classified as at nutritional risk by the mPG-SGA, whereas 23.34% were identified via the NRS-2002, highlighting discrepancies in sensitivity between screening tools. These findings align with previous findings suggesting the superiority of the PG-SGA in detecting malnutrition

risk(Chen *et al*, 2023).

From a clinical perspective, the NCOM study will also provide more information for the improvement of patients' malnutrition and the effects of antitumor-related treatment. Malnutrition is associated with poor treatment tolerance, increased toxicity, and reduced survival rates. Malnourished patients experience higher rates of treatment-related complications, including chemotherapy-related gastrointestinal toxicity and myelosuppression, often leading to dose reductions or treatment delays(Li *et al*, 2024). Another study by the authors confirmed that malnutrition exacerbates chemotherapy-related side effects, emphasizing the need for good baseline nutritional status to mitigate toxicity and improve survival outcomes(Zhou *et al*, 2025). Addressing nutritional deficits early is crucial for optimizing patient well-being and enhancing treatment efficacy.

Our study has several strengths. As a prospective, multicenter cohort, it enables longitudinal assessment of nutritional status with comprehensive data collection, integrating validated screening tools, anthropometric measures, biochemical markers, and psychosocial assessments. This robust methodology allows for a detailed understanding of the link between nutrition, treatment response, and long-term survival. However, some limitations exist. First, self-reported dietary assessments may introduce recall bias, but this bias is partially mitigated by objective measures such as biochemical markers and anthropometry. Second, loss to follow-up is anticipated due to disease progression or dropout, although conservative sample size calculations account for this(Reeves *et al*, 2007; Schwedhelm *et al*, 2016). Third, the preliminary study is geographically limited to hospitals in Xi’an, potentially restricting generalizability. However, Xi’an is a major regional referral center attracting diverse cancer populations from Northwest China, which may increase its representativeness(Chen *et al*, 2022). Finally, the study does not include mechanistic investigations, such as molecular or metabolic pathway analyses, limiting its ability to explore the biological underpinnings of malnutrition in cancer progression. Future research should incorporate biomarker-driven mechanistic studies to address this gap and further elucidate the impact of malnutrition on cancer outcomes.

Conclusion

The NCOM study explores the impact of nutritional status on cancer outcomes through a

comprehensive, multicenter cohort. Preliminary findings highlight the high prevalence of nutritional risk and the importance of early detection. The findings of this study will inform evidence-based guidelines to optimize oncological care and improve patient outcomes.

Acknowledgments

We sincerely thank Xi'an Jiaotong University for providing essential support for this study. We are also grateful to all participating patients, healthcare providers from the involved hospitals, as well as the data collection and supervision teams for their commitment and contributions to the success of this research.

Author Contributions

HeXiang Yang and Yaxin Yu contributed equally to this work. They participated in the study design, data acquisition, analysis, and manuscript drafting. Haige Cao, Jinglin Li, Feng Liu, Jiahe Zhou, and Yuluyuan Tian assisted in data collection and preliminary analysis. Yilan Li contributed to data interpretation and manuscript revision. Xiaoqin Luo* supervised the study, provided critical revisions, and approved the final manuscript.

Ethical Approval and consent to participate

All methods and procedures were conducted in accordance with relevant guidelines and regulations, in line with the principles of the Declaration of Helsinki. Ethical approval for this study was obtained from the Institutional Review Board of Xi'an Jiaotong University (Approval No. 2022-1373). The study was registered at ClinicalTrials.gov (NCT06219083). Additionally, all participants were fully informed of the purpose and potential benefits of the study, and written informed consent was obtained prior to participation. Confidentiality of participant information was strictly maintained throughout the study.

Data availability statement

The authors declare that all the other data supporting the findings of this study are available within the article, its Supplementary Information files or from the corresponding author upon reasonable request.

Competing Interests

All the authors disclosed no relevant relationships.

Funding information

This work was funded by the Natural Science Basic Research Program of Shaanxi Province (Program No. 2020JQ-460).

References

Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, Filiberti A, Flechtner H, Fleishman SB, de Haes JC (1993) The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* **85**: 365–376, doi:10.1093/jnci/85.5.365.

Arends J, Bachmann P, Baracos V, Barthelemy N, Bertz H, Bozzetti F, Fearon K, Hütterer E, Isenring E, Kaasa S, Krznaric Z, Laird B, Larsson M, Laviano A, Mühlebach S, Muscaritoli M, Oldervoll L, Ravasco P, Solheim T, Strasser F, de van der Schueren M, Preiser J-C (2017) ESPEN guidelines on nutrition in cancer patients. *Clin Nutr Edinb Scotl* **36**: 11–48, doi:10.1016/j.clnu.2016.07.015.

Beirer A (2021) Malnutrition and cancer, diagnosis and treatment. *Memo - Mag Eur Med Oncol* **14**: 168–173, doi:10.1007/s12254-020-00672-3.

Bossi P, Delrio P, Mascheroni A, Zanetti M (2021) The Spectrum of Malnutrition/Cachexia/Sarcopenia in Oncology According to Different Cancer Types and Settings: A Narrative Review. *Nutrients* **13**: 1980, doi:10.3390/nu13061980.

Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, Jemal A Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin* **n/a**: doi:https://doi.org/10.3322/caac.21834.

Cao W, Chen H-D, Yu Y-W, Li N, Chen W-Q (2021) Changing profiles of cancer burden worldwide and in China: a secondary analysis of the global cancer statistics 2020. *Chin Med J (Engl)* **134**: 783–791, doi:10.1097/CM9.0000000000001474.

Chen N, Zhang X-Y, Ma L-L, Zhao G-D, Yan Y-X (2022) Trends of cancer mortality in Xi'an City, China: 2005–2020. *J Cancer Res Clin Oncol* **148**: 2781–2792, doi:10.1007/s00432-022-04046-6.

Chen X, Liu X, Ji W, Zhao Y, He Y, Liu Y, Li Q, Shi H, Cui J (2023) The PG-SGA outperforms the NRS 2002 for nutritional risk screening in cancer patients: a retrospective study from China. *Front Nutr* **10**: doi:10.3389/fnut.2023.1272420.

Divani A, Heidari ME, Ghavampour N, Parouhan A, Ahmadi S, Narimani Charan O, Shahsavari H (2022) Effect of cancer treatment on sleep quality in cancer patients: A systematic review and meta-analysis of Pittsburgh Sleep Quality Index. *Support Care Cancer Off J Multinatl Assoc Support Care Cancer* **30**: 4687–4697, doi:10.1007/s00520-021-06767-9.

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP (2007) Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* **335**: 806–808, doi:10.1136/bmj.39335.541782.AD.

Fu Z, Zhang R, Wang K-H, Cong M-H, Li T, Weng M, Guo Z-Q, Li Z-N, Li Z-P, Wang C, Xu H-

X, Song C-H, Zhuang C-L, Zhang Q, Li W, Shi H-P, INSCOC Study Group (2022) Development and validation of a Modified Patient-Generated Subjective Global Assessment as a nutritional assessment tool in cancer patients. *J Cachexia Sarcopenia Muscle* **13**: 343–354, doi:10.1002/jcsm.12872.

Garutti M, Noto C, Pastò B, Cucciniello L, Alajmo M, Casirati A, Pedrazzoli P, Caccialanza R, Puglisi F (2023) Nutritional Management of Oncological Symptoms: A Comprehensive Review. *Nutrients* **15**: 5068, doi:10.3390/nu15245068.

Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG (2009) Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* **42**: 377–381, doi:10.1016/j.jbi.2008.08.010.

Hébuterne X, Lemarié E, Michallet M, de Montreuil CB, Schneider SM, Goldwasser F (2014) Prevalence of malnutrition and current use of nutrition support in patients with cancer. *JPEN J Parenter Enteral Nutr* **38**: 196–204, doi:10.1177/0148607113502674.

Holdoway A, Donald M, Hodge A (2023) Supporting people to manage nutrition throughout their cancer journey. *Cancer Nurs Pract* **22**: 34–42, doi:10.7748/cnp.2023.e1830.

Huo Z, Chong F, Yin L, Li N, Liu J, Zhang M, Guo J, Fan Y, Zhang L, Lin X, Zhang H, Shi M, He X, Lu Z, Fu Z, Guo Z, Li Z, Zhou F, Chen Z, Ma H, Zhou C, Chen J, Wu X, Li T, Zhao Q, Weng M, Yao Q, Liu M, Yu H, Zheng J, Cui J, Li W, Song C, Shi H, Xu H, Investigation on Nutrition Status and Clinical Outcome of Common Cancers (INSCOC) Group (2023a) Comparison of the performance of the GLIM criteria, PG-SGA and mPG-SGA in diagnosing malnutrition and predicting survival among lung cancer patients: A multicenter study. *Clin Nutr Edinb Scotl* **42**: 1048–1058, doi:10.1016/j.clnu.2023.04.021.

Huo Z, Chong F, Yin L, Li N, Liu J, Zhang M, Guo J, Fan Y, Zhang L, Lin X, Zhang H, Shi M, He X, Lu Z, Fu Z, Guo Z, Li Z, Zhou F, Chen Z, Ma H, Zhou C, Chen J, Wu X, Li T, Zhao Q, Weng M, Yao Q, Liu M, Yu H, Zheng J, Cui J, Li W, Song C, Shi H, Xu H, Investigation on Nutrition Status and Clinical Outcome of Common Cancers (INSCOC) Group (2023b) Comparison of the performance of the GLIM criteria, PG-SGA and mPG-SGA in diagnosing malnutrition and predicting survival among lung cancer patients: A multicenter study. *Clin Nutr Edinb Scotl* **42**: 1048–1058, doi:10.1016/j.clnu.2023.04.021.

Jin S, Cong M, Zhang L, Wang Y, Qin D, Lu Q (2020) Validation of a simple diet self-assessment tool (SDSAT) in head and neck cancer patients undergoing radiotherapy. *Eur J Oncol Nurs Off J Eur Oncol Nurs Soc* **44**: 101702, doi:10.1016/j.ejon.2019.101702.

Kadakia KC, Symanowski JT, Aktas A, Szafranski ML, Salo JC, Meadors PL, Walsh D (2022) Malnutrition risk at solid tumor diagnosis: the malnutrition screening tool in a large US cancer institute. *Support Care Cancer* **30**: 2237–2244, doi:10.1007/s00520-021-06612-z.

Kaegi-Braun N, Schuetz P, Mueller B, Kutz A (2021) Association of Nutritional Support With

517 Clinical Outcomes in Malnourished Cancer Patients: A Population-Based Matched Cohort Study.
518 *Front Nutr* **7**: 603370, doi:10.3389/fnut.2020.603370.

519 Keller U (2019) Nutritional Laboratory Markers in Malnutrition. *J Clin Med* **8**: 775,
520 doi:10.3390/jcm8060775.

521 Kipouros M, Vamvakari K, Kalafati IP, Evangelou I, Kasti AN, Kosti RI, Androutsos O (2023)
522 The Level of Adherence to the ESPEN Guidelines for Energy and Protein Intake Prospectively
523 Influences Weight Loss and Nutritional Status in Patients with Cancer. *Nutrients* **15**: 4232,
524 doi:10.3390/nu15194232.

525 Li C, Zhang S, Liu Y, Hu T, Wang C (2024) Effects of nutritional interventions on cancer patients
526 receiving neoadjuvant chemoradiotherapy: a meta-analysis of randomized controlled trials. *Support*
527 *Care Cancer Off J Multinatl Assoc Support Care Cancer* **32**: 583, doi:10.1007/s00520-024-08780-
528 0.

529 Liu C, Lu Z, Li Z, Xu J, Cui H, Zhu M (2021) Influence of Malnutrition According to the GLIM
530 Criteria on the Clinical Outcomes of Hospitalized Patients With Cancer. *Front Nutr* **8**: 774636,
531 doi:10.3389/fnut.2021.774636.

532 McNair KM, Zeitlin D, Slivka AM, Lequerica AH, Stubblefield MD (2023) Translation of
533 Karnofsky Performance Status (KPS) for use in inpatient cancer rehabilitation. *PM R* **15**: 65–68,
534 doi:10.1002/pmrj.12741.

535 Moore SC, Lee I-M, Weiderpass E, Campbell PT, Sampson JN, Kitahara CM, Keadle SK, Arem
536 H, Berrington de Gonzalez A, Hartge P, Adami H-O, Blair CK, Borch KB, Boyd E, Check DP,
537 Fournier A, Freedman ND, Gunter M, Johannson M, Khaw K-T, Linet MS, Orsini N, Park Y, Riboli
538 E, Robien K, Schairer C, Sesso H, Spriggs M, Van Dusen R, Wolk A, Matthews CE, Patel AV (2016)
539 Association of Leisure-Time Physical Activity With Risk of 26 Types of Cancer in 1.44 Million
540 Adults. *JAMA Intern Med* **176**: 816–825, doi:10.1001/jamainternmed.2016.1548.

541 Muscaritoli M, Arends J, Aapro M (2019) From guidelines to clinical practice: a roadmap for
542 oncologists for nutrition therapy for cancer patients. *Ther Adv Med Oncol* **11**: 1758835919880084,
543 doi:10.1177/1758835919880084.

544 Nissim M, Rottenberg Y, Karniel N, Ratzon NZ (2024) Effects of aquatic exercise program versus
545 on-land exercise program on cancer-related fatigue, neuropathy, activity and participation, quality
546 of life, and return to work for cancer patients: study protocol for a randomized controlled trial. *BMC*
547 *Complement Med Ther* **24**: 74, doi:10.1186/s12906-024-04367-8.

548 Phillips CM, Chen L-W, Heude B, Bernard JY, Harvey NC, Duijts L, Mensink-Bout SM,
549 Polanska K, Mancano G, Suderman M, Shivappa N, Hébert JR (2019) Dietary Inflammatory Index
550 and Non-Communicable Disease Risk: A Narrative Review. *Nutrients* **11**: 1873,
551 doi:10.3390/nu11081873.

552 Qiu H, Cao S, Xu R (2021) Cancer incidence, mortality, and burden in China: a time-trend
553 analysis and comparison with the United States and United Kingdom based on the global

554 epidemiological data released in 2020. *Cancer Commun Lond Engl* **41**: 1037–1048,
555 doi:10.1002/cac2.12197.

556 Rasschaert M, Vandecandelaere P, Marechal S, D'hondt R, Vulsteke C, Mailleux M, De Roock
557 W, Van Erps J, Himpe U, De Man M, Mertens G, Ysebaert D (2024) Malnutrition prevalence in
558 cancer patients in Belgium: The ONCOCARE study. *Support Care Cancer* **32**: 135,
559 doi:10.1007/s00520-024-08324-6.

560 Reeves GK, Pirie K, Beral V, Green J, Spencer E, Bull D (2007) Cancer incidence and mortality
561 in relation to body mass index in the Million Women Study: cohort study. *BMJ* **335**: 1134,
562 doi:10.1136/bmj.39367.495995.AE.

563 Riboli E (2001) The European Prospective Investigation into Cancer and Nutrition (EPIC): Plans
564 and Progress. *J Nutr* **131**: 170S-175S, doi:10.1093/jn/131.1.170S.

565 Sandström N, Johansson M, Jekunen A, Andersén H (2023) Socioeconomic status and lifestyle
566 patterns in the most common cancer types-community-based research. *BMC Public Health* **23**: 1722,
567 doi:10.1186/s12889-023-16677-6.

568 Schuetz P, Fehr R, Baechli V, Geiser M, Deiss M, Gomes F, Kutz A, Tribolet P, Bregenzer T,
569 Braun N, Hoess C, Pavlicek V, Schmid S, Bilz S, Sigrist S, Brändle M, Benz C, Henzen C, Mattmann
570 S, Thomann R, Brand C, Rutishauser J, Aujesky D, Rodondi N, Donzé J, Stanga Z, Mueller B (2019)
571 Individualised nutritional support in medical inpatients at nutritional risk: a randomised clinical trial.
572 *Lancet Lond Engl* **393**: 2312–2321, doi:10.1016/S0140-6736(18)32776-4.

573 Schwedhelm C, Boeing H, Hoffmann G, Aleksandrova K, Schwingshackl L (2016) Effect of diet
574 on mortality and cancer recurrence among cancer survivors: a systematic review and meta-analysis
575 of cohort studies. *Nutr Rev* **74**: 737–748, doi:10.1093/nutrit/nuw045.

576 Snaith RP (2003) The Hospital Anxiety And Depression Scale. *Health Qual Life Outcomes* **1**: 29,
577 doi:10.1186/1477-7525-1-29.

578 Tang H, Wang R, Yan P, Zhang W, Yang F, Guo S, Li T, Yi L, Bai X, Lin S, Zhang Y, Shang L
579 (2023) Dietary Behavior and Its Association with Nutrition Literacy and Dietary Attitude Among
580 Breast Cancer Patients Treated with Chemotherapy: A Multicenter Survey of Hospitals in China.
581 *Patient Prefer Adherence* **17**: 1407–1419, doi:10.2147/ppa.s413542.

582 Webb N, Fricke J, Hancock E, Trueman D, Ghosh S, Winstone J, Miners A, Shepelev J, Valle JW
583 (2020) The clinical and cost-effectiveness of supplemental parenteral nutrition in oncology. *ESMO*
584 *Open* **5**: e000709, doi:10.1136/esmoopen-2020-000709.

585 Wu J, Yu C, Shivappa N, Hébert JR, Xu X (2023) Dietary inflammatory index and renal cancer
586 risk: a prospective study. *Food Funct* **14**: 9287–9294, doi:10.1039/d3fo02158k.

587 Wu Y, Xu J, Gao Y, Zheng J (2024) The relationship between health behaviors and quality of life:
588 the mediating roles of activities of daily living and psychological distress. *Front Public Health* **12**:
589 doi:10.3389/fpubh.2024.1398361.

590 Xiao Y, Wang H, Zhang T, Ren X (2019) Psychosocial predictors of physical activity and health-
591 related quality of life among Shanghai working adults. *Health Qual Life Outcomes* **17**: 72,
592 doi:10.1186/s12955-019-1145-6.

593 Yang S, Zhao K, Ding X, Jiang H, Lu H (2019) Prognostic Significance of Hematological
594 Markers for Patients with Nasopharyngeal Carcinoma: A Meta-analysis. *J Cancer* **10**: 2568–2577,
595 doi:10.7150/jca.26770.

596 Ye Y, Zeng K, Qin L, Luo J, Liu S, Miao J, Liang J, Yu Y, Zhao M, Zhang L (2024) Differential
597 Characteristics of Fatigue-Pain-Sleep Disturbance-Depression Symptom Cluster and Influencing
598 Factors of Patients With Advanced Cancer During Treatment: A Latent Class Analysis. *Cancer Nurs*
599 doi:10.1097/NCC.0000000000001316.

600 Yuan S, Chen J, Ruan X, Sun Y, Zhang K, Wang X, Li X, Gill D, Burgess S, Giovannucci E,
601 Larsson SC (2023) Smoking, alcohol consumption, and 24 gastrointestinal diseases: Mendelian
602 randomization analysis. *eLife* **12**: e84051, doi:10.7554/eLife.84051.

603 Zhang Z, Wan Z, Zhu Y, Zhang L, Zhang L, Wan H (2021) Prevalence of malnutrition comparing
604 NRS2002, MUST, and PG-SGA with the GLIM criteria in adults with cancer: A multi-center study.
605 *Nutr Burbank Los Angel Cty Calif* **83**: 111072, doi:10.1016/j.nut.2020.111072.

606 Zhou H-J, Deng L-J, Wang T, Chen J-X, Jiang S-Z, Yang L, Liu F, Weng M-H, Hu J-W, Tan J-Y
607 (2021) Clinical practice guidelines for the nutritional risk screening and assessment of cancer
608 patients: a systematic quality appraisal using the AGREE II instrument. *Support Care Cancer* **29**:
609 2885–2893, doi:10.1007/s00520-021-06094-z.

610 Zhou Q, Yang H, Wang X, Wang L, Yan X, Zhang B, Ma X, Li G, Li J, Zhang J, Yan Z, Bao N,
611 Li C, Ge P, Liu J, Luo X (2025) The dynamic effects of nutritional status on chemotherapy-related
612 toxicity in patients with non-Hodgkin's lymphoma. *Eur J Clin Nutr* 1–8, doi:10.1038/s41430-025-
613 01565-6.

614 Zhu C, Lian Z, Arndt V, Thong MSY (2024) Combined healthy lifestyle factors and psychosocial
615 outcomes among cancer survivors: a systematic review and meta-analysis. *J Cancer Surviv*
616 doi:10.1007/s11764-024-01705-0.

617