Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)

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Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)

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ABSTRACT

Background

With the prevalence of late-stage cancers at diagnosis remained more than 52.0%, the number of patients with advanced cancer in China is rapidly increasing. People living with advanced cancer have multidimensional needs and concerns requiring person-centred care. As services and policy evolve, it is essential to improve the quality of care by measuring outcomes of importance to patients and families. However, little evidence exists on patients' priorities of advanced cancer care in China, and there were no reliable and validated patient-reported outcome measures for use to measure the care needs and outcomes of patients with advanced cancers. The Integrated Palliative care Outcome Scale (IPOS) is a psychometrically sound and multidimensional measure that has been used worldwide for patients with advanced illnesses including cancer. IPOS is a brief and valid PROM that evaluates the most burdensome concerns and has been used with advanced cancer patients and adapted to many cultures.

Aim

To translate, cross-culturally adapt and validate the Chinese IPOS among adults with cancer.

Methods

Design

A sequential qualitative mixed-methods study was employed comprising a qualitative component followed by quantitative components. Rothrock guidance, COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) and Palliative care Outcome Scale family of measures Manual for cross-cultural adaptation and psychometric validation guided the translation, cross-cultural adaptation and validation phases of the study.

Phase 1: A systematic review was conducted in accordance with COSMIN, with quality assessment using the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures and COSMIN quality criteria for measurement properties. MEDLINE, EMBASE, PsycINFO, CINAHL, CNKI and WanFang were systematically searched from inception to May 2019, updated to August 2022. Supplemental searches were conducted in grey literature databases, Google scholar and hand-searching of reference lists.

Phase 2: Semi-structured in-depth qualitative interviews with advanced cancer patients and family members at an inpatient oncology ward in China were conducted between October 2019 to January 2020. Data collection continued until thematic saturation was achieved. Interviews were audio-recorded, transcribed verbatim and analysed utilising thematic analysis.

Phase 3: Chinese versions of IPOS Patient and IPOS Staff were translated and culturally adapted following the Rothrock guidance and the Palliative care Outcome Scale family of measures Manual for cross-cultural adaptation and psychometric validation. Five phases were included: (I) Conceptual definition; (II) Forward translation (translation from English to Chinese); (III)Backward translation (translation from Chinese to English); (IV) Expert review; (V)Cognitive debriefing.

Phase 4: A multi-centre validation study was conducted to test the psychometric properties of the Chinese Integrated Palliative care Outcome Scale - both (1) patient self-report and (2) staff proxy-report versions. We tested construct validity (factor analysis and correlational analysis), reliability (internal consistency, test-retest reliability and inter-rater reliability), and responsiveness (through longitudinal evaluation of change).

Results

Phase 1: From 10793 articles, 437 were selected for full-text review based on titles and abstracts. A total of 46 studies reporting 39 PROMs were retained. No articles were rated as "good quality" in more than four of the six stages of cross-cultural adaptation. At least

half of the required information on psychometric properties was missing for each measure. Based on COSMIN, none identified PROMs were valid across all properties nor appropriate to use.

Phase 2: Patients (n=20, median age 55.0, 60% female) and family members (n=20, median age 41.0, 45% female) described distinctive but highly interrelated concerns related to living with advanced cancer across five domains: (a) physical and psychological symptoms (e.g. pain and anxiety), (b) financial difficulties (e.g. debt and health insurance problems), (c) impacts on family (e.g. change of roles and burden on families), (d) coping and adapting to the disease (e.g. decision making and healthcare resource accessibility), and (e) plans to the future (e.g. attitudes toward dying and palliative care and unfulfilled wishes). A conceptual model showing the perspectives of patients and family members has been developed. Findings confirmed that advanced cancer has far-reaching implications for patients and family members in China, extending beyond physical and psychological problems into social (e.g., family issues), practical (e.g., financial difficulties and coping with cancer) needs and future plans.

Phase 3: One new item was developed, and changes were made, agreed upon by the expert review meeting. The comprehension and judgement difficulties identified in the pre-final patient and staff versions were successfully solved during the cognitive interviewing process. IPOS was well accepted by both patients and staff, none of the items in the Chinese versions of IPOS were inappropriate, and all questions was judged relevant and important.

Phase 4: Three hundred eight inpatient adults with advanced cancer were consecutively recruited from two medical oncology units in China. We confirm a three-factor structure (Physical Symptoms, Emotional Symptoms/Communication, and Practical Issues). Good convergent validity to hypothesised items and subscales of the Edmonton Symptom Assessment System is demonstrated. The Integrated Palliative care Outcome Scale shows good internal consistency ($\alpha = 0.83$) and acceptable to good test-retest reliability ($\kappa w=0.59$) and inter-rater reliability ($\kappa w=0.48$). Longitudinal validity in the form of responsiveness to change is good.

Conclusion

This novel study translated and culturally adapted the patient and staff versions of IPOS and demonstrated content validity and acceptability of the scale through expert review and cognitive interviews with patients and staff. The Chinese Integrated Palliative care Outcome Scale is a reliable and valid outcome measure for use in patients with advanced cancer and available in both patient self-report and staff proxy-report versions. It is suitable for assessing needs, symptoms and concerns in advanced cancer, monitoring the change of health status over time, determining the impact of healthcare interventions, and demonstrating the quality of care.

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PERSONAL CONTRIBUTION AND DECLARATION OF ORIGINALITY

During the study period, I conceived the study aim and objectives, developed the study phased design and conducted each phase in this project, including the translation, cross-cultural adaptation, development and refinement, and the psychometric testing of the measure. Within these study phases, I obtained all the ethical approvals for each phase and conducted all the qualitative interviews and relevant data collection, alongside with conducting the data analysis and interpretation. This thesis was written by me and presents my original thoughts and arguments, supervised and supported by my supervisors.

This thesis was conducted while I was registered as a PhD student at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care, King's College London, with supervision from Professor Richard Harding, Professor Charles Normand, Professor Ping Guo and Professor Wei Gao, and regular Thesis Progression Committee meetings with two external advisors: Professor Fliss Murtagh and Dr Sabrina Bajwah.

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I led the following four incorporated papers with co-authors' support and inputs. The following are specific contributions by each author for each incorporated publication.

PAPER 1: ***Houshen Li,*** *Ping Guo, Wei Gao, Richard Harding. Patient-reported outcome measures for advanced cancer in China: a systematic review of cross-cultural adaptation and psychometric properties* (**published**, Journal of cancer policy)

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PUBLICATIONS, PRESENTATIONS AND AWARDS

Publications incorporated into this thesis:

PAPER 1: Houshen Li, Ping Guo, Wei Gao, Richard Harding. *Patient-reported outcome measures for advanced cancer in China: a systematic review of cross-cultural adaptation and psychometric properties* (published, Journal of cancer policy) **[Chapter 4]**

PAPER 2: Houshen Li, Ping Guo, Gao Wei, Xiujie Cui, Yuhua Guo, Lin Lu, Yanxue Han, Furong Yin, Charles Normand, Richard Harding. *Towards person-centred care for people with advanced cancer and their families in China: what core outcomes matter? A qualitative study* (submitted to PLOS ONE and under review) **[Chapter 5]**

PAPER 3: Houshen Li, Ping Guo, Wei Gao, Xiujie Cui, Shubin Wang, Li Wang, Yuhua Guo, Lin Lu, Yanxue Han, Furong Yin, Charles Normand, Richard Harding. *Translation and Cross-cultural adaptation of the Chinese Version of Integrated Palliative care Outcome Scale: Expert Reviews and Cognitive Interviews* (manuscript, will be submitted to Health and Quality of Life Outcomes) **[Chapter 6]**

PAPER 4: Houshen Li, Ping Guo, Wei Gao, Xiujie Cui, Shubin Wang, Li Wang, Yuhua Guo, Lin Lu, Yanxue Han, Furong Yin, Charles Normand, Richard Harding. *Psychometric validation of the Chinese Version of Integrated Palliative care Outcome Scale* (manuscript, will be submitted to J of Pain and Symptoms Management) **[Chapter 7]**

Other publications during this PhD period:

Houshen Li, Yifan Cui, Nikolaos Efstathiou, Bo Li, Ping Guo. *Experiences of redeployed healthcare workers in the fight against COVID-19 in China: A qualitative study*. PLoS One. 2022 Aug 25;17(8):e0273429.

Omar Shamieh, Ghadeer Alarjeh, **Houshen Li**, Mahmoud Abu Naser, Fadi Abu Farsakh, Rashid Abdel-Razeq, Adib Edilbi, Ruba Al-Ani, Richard Harding, Ping Guo. *Care Needs and Symptoms Burden of Breast Cancer Patients in Jordan: A Cross-Sectional Study.* Int J Environ Res Public Health. 2022 Aug 30;19(17):10787.

Chunxin Lv, Wen Shi, Teng Pan, **Houshen Li**, Weixiong Peng, Jiayi Xu, Jinhai Deng. *Exploration of Aging-Care Parameters to Predict Mortality of Patients Aged 80-Years and Above with Community-Acquired Pneumonia.* Clin Interv Aging. 2022 Sep 20;17:1379-1391.

Xuchen Huang, **Houshen Li**, Xuhua Hu, Tongbo Yi. *Efficacy of Carbon Nanoparticles for Parathyroid Glands Protection During Total Thyroidectomy and Bilateral Central Lymph Nodes Dissection for Thyroid Cancer: A Systematic Review and Meta-Analysis.* Acta Medica Mediterranea, 2022, 38: 745

Pei Liu, **Houshen Li**, Weiqiang Chen, Fang Chen. *Analysis of the status quo and influencing factors of readiness for hospital discharge in elderly patients with hip arthroplasty*. 2022, 8(5):645-649. (written in Chinese)

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Houshen Li, Ping Guo, Wei Gao, Xiujie Cui, Shubin Wang, Li Wang, Yuhua Guo, Lin Lu, Yanxue Han, Furong Yin, Charles Normand, Richard Harding. *Translation and Cross-cultural adaptation of the Chinese Version of Integrated Palliative care Outcome Scale: Expert Reviews and Cognitive Interviews* [Poster presentation at the 2023 European Association for Palliative Care]

Houshen Li, Ping Guo, Gao Wei, Richard Harding. *Towards Person-centred Care for People with Advanced Cancer and their Families in China: What Core Outcomes Matter?* [Poster presentation at the 2021 European Association for Palliative Care]

Houshen Li, Ping Guo, Gao Wei, Richard Harding. *Patient-reported outcome measures in advanced cancer in China: a systematic review of cross-cultural adaptation and psychometric properties* [Poster presentation at the 2020 European Association for Palliative Care]

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GLOSSARY OF TERMS

Advanced cancer- Cancer that is unlikely to be cured or controlled with treatment. The cancer may have spread from where it first started to nearby tissue, lymph nodes, or distant parts of the body.[1]

Context- Context is anything external to the intervention, which may either impede or assist implementation or its consequences.[2]

Cross-cultural adaptation is a process that looks at both language (i.e., translation) and cultural adaptation (i.e., culturally relevant content) to utilize existing instruments in other cultural, language or geographic settings.[3]

Measures/Outcome measures-

> Measure- a standardised and validated patient-reported or proxy-reported measure designed to capture concerns important to patients, or in this study, people with dementia living in care homes.[4]
>
> Outcome measure- a standardised and validated measure of change in patient health status as a result of an intervention or health care delivered.[5]
>
> Patient-reported outcome measure (PROM)- an outcome measure completed by patients to measure their own perspectives of health status, functional status or wellbeing.[6]

Proxy-reported outcome measure- an outcome measure to measure concerns important to patients, but not completed by patients usually because they are too unwell or have significant cognitive impairment to self-report.[7]

Measurement properties-

Acceptability: whether patients (for patient-reported measures) or staff/health care professionals are prepared to and willing to use the measure, and its suitability for intended use in clinical practice. [8]

Availability: availability was added to capture the requirement for measures, and additional training and resources, to be easily and freely accessible.[9]

Comprehension: how patients or staff/health care professionals understand, interpret terms, and choose their responses.[9]

Feasibility: whether patients or staff/health care professionals are able to use the measure in their respective setting or context.[8]

Interpretability: the degree to which one can assign qualitative meaning, or clinical connotations, to a measure's score(s) or change in score(s).[8]

Reliability: the degree to which the measurement is free from measurement error.[10]

Responsiveness: the ability of a measure to detect change over time in the construct to be measured.[9]

Validity: the degree to which an instrument measures what it purports to measure.[8]

Palliative care- 'an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual'.[11, 12]

Translation- It is the act of transferring the linguistic entities from one language into their equivalents into another language.[13]

ABBREVIATIONS

ADAS- Advance Directive Attitude Survey

BFS-C- Chinese version of the Benefit Finding Scale

BPI- Brief Pain Inventory

CI- Confidence Interval

CDST- Clinical Decision Support Tool

CFA- Confirmatory factor analysis

ChPSQ-9- Nine-Item Chinese Patient Satisfaction Questionnaire

COREQ- Consolidated criteria for reporting qualitative studies

COSMIN- COnsensus-based Standards for the selection of health status Measurement INstruments

CPPCN- Cancer patients' palliative care needs questionnaire

CRC- Colorectal cancer

DALYs- Disability-adjusted life years

DCS- Decisional Conflict Scale

EORTC- European Organisation for Research and Treatment of Cancer

EFA- Exploratory factor analysis

ESAS- Edmonton Symptom Assessment System

FACT-C- Functional Assessment of Cancer Therapy – Colorectal

GDPR- General Data Protection Regulation

HADS- Hospital Anxiety and Depression Scale

IPOS- The Integrated Palliative Care Outcome Scale also referred to as the Integrated Patient care Outcome Scale

KPS- Karnofsky Performance scale

LMIC- Low- and Middle-Income Countries

MAX-PC- Chinese version of the Memorial Anxiety Scale for Prostate Cancer

MDASI- M. D. Anderson Symptom Inventory

MDASI-GI-C- Chinese Version of the M. D. Anderson Symptom Inventory Gastrointestinal Cancer Module

MiLS- Meaning in Life Scale

MPI-sC- Multidimensional Pain Inventory-Screening Chinese version

MQOL- McGill Quality of Life Questionnaire

MSAS- Memorial Symptom Assessment Scale

PNPC-sv- Problems and Needs in Palliative Care questionnaire-short version

POS- Palliative care Outcome Scale

PPI- Patient and Public Involvement

PRISMA- The Preferred Reporting Items for Systematic reviews and Meta-Analyses

PRO- Patient-reported outcome

PROMs- Patient-reported outcome measures

PTPQ- Prognosis and Treatment Perception Questionnaire

QLASTCM-Ga- Quality of life assessment scale for gastric cancer patients

QLQ-BM22- Quality of life assessment scale for bone metastases

QLQ-C15-PAL- Quality of life assessment scale in palliative cancer care patients

QLQ-C30- Quality of life assessment scale of cancer patients

QLQ-OES18- Quality of life assessment scale oesophageal cancer patients

QLQ-OV28- Quality of life assessment scale for ovarian cancer patients

QLQ-SWB27- Quality of life assessment scale for spiritual wellbeing

QoL- Quality of Life

QONCS- Quality of Oncology Nursing Care Scale

RMSEA- Root mean square error of approximation

SAIL- Spiritual Attitude and Involvement List

SCNS-SF34-C- Chinese version of the short-form Supportive Care Needs Survey questionnaire

SpIRIT- Spiritual Interests Related Illness Tool

SWBS–M- Spiritual Well-Being Scale-Mandarin version

TCM- Traditional Chinese medicine

TLI- Tucker-Lewis index

UK- United Kingdom

UWQOL-C- University of Washington Quality of Life Chinese Version

WHO- World Health Organisation

CHAPTER 1. BACKGROUND

1.1 INTRODUCTION

China is the most populous and one of the most rapidly aging nations in the world.[14, 15] Of the 202 million people aged 60 years or over in China, more than 100 million had at least one chronic non-communicable disease, of these more than 37 million had significant reductions in physical function.[16] In China, approximately 20,000 patients receive specialty palliative care each year, accounting for about 1% of individuals who need palliative care annually.[17] There are “significant imbalances” between palliative care providers and the need for services.

1.2 ADVANCED CANCER

1.2.1 Definition and disease presentation

Advanced cancer means that cancer is unlikely to be cured or controlled with treatment.[1] The cancer may have spread from where it first started to nearby tissue, lymph nodes, or distant parts of the body. Treatment may be given to help shrink the tumour, slow the growth of cancer cells, or to relieve symptoms.

Patients who are diagnosed with advanced cancer cope with a complex array of factors. These include complicated symptoms, prolonged anticancer treatments, side effects from treatment, dealing with the unfamiliar medical terms and the implications of living with an

uncertain prognosis.[18] Being diagnosed with a life-limiting illness often involves significant changes to the ways a person experiences and understands living and dying.[19]

The presentation of advanced cancer can vary depending on the type and location of cancer, as well as the stage and extent of spread. However, there are some common symptoms that may indicate advanced cancer.[20] Pain is a common symptom of advanced cancer, and it may be localized to the site of the cancer or may be widespread;
Fatigue: Fatigue is a feeling of tiredness or weakness that is not relieved by rest. It is a common symptom of advanced cancer and may be caused by the cancer itself or by the treatments used to treat it; Weight loss: Unexplained weight loss may be caused by a combination of factors, including a decrease in appetite, metabolic changes, and the cancer itself; Difficulty breathing: difficulty breathing due to the involvement of the lungs or the fluid in the chest; Cognitive changes, such as confusion, memory loss, or difficulty concentrating.

As the improvement in anticancer therapeutics, many of advanced cancer patients with ‘incurable’ cancer could be considered to have a chronic disease trajectory with cumulative morbidity from their disease and the administered therapies and second, the time to patient referral to palliative care may become longer.[21-23] The management of patients with advanced incurable cancer presents healthcare professionals with a number of challenges in enabling patients to live for extended periods of time with a good quality of life.

1.2.2 Advanced cancer burden

Globally an estimated 19.3 million new cancer cases and almost 10.0 million cancer deaths occurred in 2020.[24] With increasing incidence and mortality, cancer is the leading cause of death in China and is a major public health problem. Because of China's large population size, approximately one-fifth of the world population, these Chinese data contribute significantly to the global burden of cancer: almost 22% of global new cancer cases and close to 27% of global cancer deaths occur in China.[25] 4,292,000 new cancer cases and 2,814,000 cancer deaths were reported in 2015.[26] In addition, the prevalence of late-stage cancers at diagnosis remained at a high-level - more than 52.0% through 2016–17 in Chinese patients with five common cancers (lung, stomach, oesophagus, colorectum, and female breast).[27] According to the WHO Global Burden of Disease estimate 2012, nearly 45% of the disability-adjusted life years (DALYs) in China are attributable to health conditions among those aged 60 years or over.[28]

Cancer incidence is strongly correlated with age, with nearly 50% of individuals diagnosed with cancer aged over 70 years.[29] At any age, cancer can have a substantial impact on an individual's independence, as treatment side-effects can reduce the ability to maintain normal daily activities. Almost a quarter of those living with and beyond cancer report poor health or disability after primary cancer treatment. Individuals can experience side-effects of cancer treatment such as pain, breathlessness, and fatigue, as well as psychological problems including anxiety, depression and loss of confidence.[30] However older adults are at increased risk of the side-effects of some cancer-related treatments and common features of ageing may be aggravated by cancer treatment.[31] Older adults often lack the

physiological reserves required to effectively recover from acute toxicities. In turn, this leads to ongoing problems related to quality of life.[32] In addition, older adults are more likely to have poorer literacy and numeracy skills, with less access to transportation, social support, or financial resources compared to younger adults cancer survivors.[33] Consequently, older adults may find it difficult to self-manage symptoms, complex therapeutic routines, self-monitoring, self-assessment and interactions with healthcare providers and organizations.

While cancer is a substantial health challenge, in older age it is often diagnosed in the context of other health needs that can complicate diagnosis, treatment, and management.[34, 35] Over 75% of people with cancer report at least one other condition, and multimorbidity (defined here as the co-existence of two or more conditions) increases with age.[36] Older cancer survivors are more likely to have pre-existing conditions and to experience poorer physical functioning than younger people with cancer and frequently report long-term support needs for management of complex health conditions after cancer treatment.[31, 35, 37] The number of people living with multimorbidity is rising with an ageing population.[38] Further conditions are also likely to develop after- and perhaps as a consequence of cancer and its treatment. These include diabetes, cardiovascular disease, neuropathy, or renal impairment.[35, 36] Leach et al reported that older adults have an average of five long-term conditions, two of which develop after a cancer diagnosis.[39] The onset of these conditions may be a consequence of ageing, behavioural/genetic risk factors, or due to late/long-term effects of cancer treatments. Additional conditions may negatively impact cancer recovery, longevity, and reduce QoL.[31]

1.2.3 Social and cultural factors in advanced cancer in Chinese context

China is facing severe problems arising from uneven economic, political and social development, particularly between rural and urban areas and east and west.[40] In other words, the Chinese population is ageing rapidly while China is ill prepared to provide for and support such a large older population.

Currently, families provide fundamental social support for Chinese older people.[41] For example, adult children provide financial support by giving their parents money, or paying for their medical expenses; in rural areas, this includes material support such as food and clothing. Furthermore, families provide personal care and assist in the activities of daily living, as well as nursing care at home when older people are ill.[42] Families also provide psychological and emotional support, for example, through listening, accompanying, sharing or helping out in difficult situations.[43] In view of the traditional value of filial piety, the emotional and psychological satisfaction acquired in a harmonious and caring family cannot be replicated or replaced by any form of professional support or services.[44, 45] Indeed, as the moral foundation of the long-term care model for older people, filial piety is reinforced by Chinese laws, such as the Constitution of the People's Republic of China and 'Law of the People's Republic of China on the Protection of the Rights and Interests of Older People'.

However, informal care traditionally provided to older people at home by adult children will become increasingly unfeasible in the near future, when the parents of the first generation since the introduction of the One-Child policy start reaching old age and retirement.[46, 47] Rather, these single children will face the need to care for two parents and often four

grandparents without siblings with whom to share the responsibility, a problem sometimes referred to as the '4-2-1 problem'.[48] In light of this, a social service system for older people has taken initial shape, based on family care, supported by community services and supplemented by institutional services for seniors. Nonetheless, despite significant improvement, these social services still fall short of public needs.[41]

The current health care system is market-oriented, relying heavily on private funding and charging excessive fees. Consequently, it is generally hard for Chinese people to access and afford health care. For cancer patients, the excessive use of anticancer treatment is common, and curative interventions are continued either until patients are no longer able to endure the side effects or at the end of their disease trajectory.[17] Furthermore, when patients are close to death, resuscitative measures such as intracardiac injections and even cardio-pulmonary resuscitation at the moment of death are taken. However, despite advanced interventions close to and at the point of death, physicians fail to take advantage of the accessible analgesics to relieve patients' pain.

Most Chinese people believe that only dying patients need palliative care.[49] Affected by the traditional view that people with terminal illnesses have short life expectancies, patients and their families become desperate and find it difficult to accept palliative care emotionally. Until now, not many people are aware that palliative care can be helpful for patients diagnosed with cancer.[50]

1.3 PALLIATIVE CARE IN CHINA: CURRENT SITUATION AND CHALLENGES

China is the most populous nation in the world with the estimated total population at 1411.4 million people in 2016, according to the latest census figures reported by WHO.[51] The Chinese population is ageing dramatically. In 2013, there were 22.6 million people aged 80 years or over in the country, and by 2050 this number is expected to increase fourfold to 90.4 million- representing the world's largest population of this most elderly age group.[52] Of the 202 million people aged 60 years or over in China, more than 100 million had at least one chronic non-communicable disease, of these more than 37 million had significant reductions in physical function. Many had multiple chronic diseases at the same time. As the population ages further, chronic diseases such as ischaemic heart disease, cancer, stroke, arthritis and dementia are likely to increase. Since palliative care plays an important role through whole trajectory of all life limited disease,[53] the need for palliative care is huge in mainland China.

1.3.1 Definition and scope of palliative care

Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.[54]

Palliative care[55]:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- intends neither to hasten or postpone death;
- integrates the psychological and spiritual aspects of patient care;

- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patients' illness and in their own bereavement;
- uses a team approach to address the needs of patients and their families, including bereavement counselling, if indicated;
- enhance quality of life, and may also positively influence the course of illness;
- is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.

Palliative care is a global human right.[56] It enables patient and families to live well with progressive illness, improving their outcomes, achieving a "good death", and saving costs by reducing unplanned admissions and futile treatments [57-61]. However, only 58% of countries provide it, reaching only 10% of the 20 million people annually who require it [62] (80% of whom are in LMIC[63]). The development and delivery of appropriate care are hampered by death taboo,[64] and limited investment in palliative care research.[65] The need for palliative care in advanced cancer has drastically increased due to the increasing trend in cancer incidence and mortality. Advanced cancer brings psychological, economic/social, physical and spiritual concerns.[66] Burden may be greatest for family caregivers.[67]

The 2015 Quality of Death Index compiled by The Economist Intelligence Unit warned that ageing and booming populations would make palliative care a growing worldwide issue.[68] The Index was based on extensive research and interviews with more than 120 palliative-

care experts across the world. The rankings considered hospitals and hospice environments, staffing numbers and skills, affordability of care, and quality of care. China ranked 71st of 80 countries and was reported to be “facing difficulties from slow adoption of palliative care and a rapidly aging population”. Approximately 20,000 patients receive specialty palliative care each year in China, accounting for about 1% of individuals who need palliative care annually. There are “significant imbalances” between providers and the need for services.[69]

1.3.2 Palliative care education

Training for palliative care is rarely included in healthcare education curricula.[70] It was not until 1998 that the concept of end-of-life care was first included in a Chinese textbook in a chapter on community nursing. Two years later, the first book about palliative medicine was published in China.[71] Palliative care education has not achieved widespread acceptance however, with respect to either the medical educational system or gaining the official status that other medical specialties hold, such as oncology. Although some information about aspects of end-of-life care is delivered in schools of nursing, the lecturers are often not palliative care specialists, and the number of class hours is insufficient.[17]

1.3.3 Palliative care professionals

The shortage of professional palliative care staff is severe. Because of insufficient training and educational resources, most doctors have not been trained to use opioid analgesics appropriately. A survey of 201 doctors in China showed that 66% of medical practitioners

did not fully understand the dosage of morphine[72]. As a result, the consumption of morphine, the most widely used palliative painkiller worldwide, is very low in China. Moreover, communication skills of most physicians regarding palliative care are poor, as a result of medical education being centred on curative treatment of physical illnesses, which also leads to physicians feeling incompetent in dealing with mental health or emotional issues.[12, 73]

1.3.4 Service and policy development

In 1988, the first institute for hospice care was established in Tianjin. After that, palliative care units were established in university hospitals, provincial hospitals, municipal hospitals, and health centres in the community. The method of “cancer pain relief and palliative care” recommended by the World Health Organization was introduced by the Chinese National Health Ministry in 1992.[49] Since 2000, certification training to prescribe opioids has been available for all clinicians who care for cancer patients and required by the Chinese government. Regulations from the National Health Ministry, dating from 2006, allowed health centres in communities to register “a unit/department of hospice and palliative care” for the patients with advanced cancer and non-malignant diseases.[74] The document “The Guiding Principle of Clinical Application of Narcotic Analgesic Medications” from the National Health Ministry was published in 2007 and permits a physician to prescribe controlled/slow-release opioids, or transdermal fentanyl patches for 15 days per prescription time according to the requirements of the patient. Following these developments in palliative care, many hospices and/or departments of palliative care were started in urban areas. There are more than 200 hospices and palliative care units and more

than 10,000 health care professionals who work in the field of palliative medicine in China in 2011.[75]

However, absence of national strategies and guidelines are also major problems.[76] Since palliative care is generally not supported through the national health insurance, palliative care physicians have to seek other ways to generate income, which can be a big distraction and compromise on professionalism.

1.3.5 Opioid consumption

The regulation for opioid use has been changing with the policy of government.[71] Opioids were “limited in the quantity or supply” during the early years of new China, “planned quantities and supply” began to be the policy in the 1990s, and “supply according to needs on record” is the current policy. Opioid consumption has been increasing from 10 kg (morphine equivalents) in 1989 to 906 kg in 2008, and accounts for 2.33% of the global consumption of morphine equivalences. The consumption of morphine increased 90.6 times during the last 20 years, increasing their rank in consumption internationally from 146 in 2001 to 81 in 2007. Per capita consumption of morphine increased from 0.08 mg/year in 1989 to 0.68 mg/year in 2008, an increase of 851%.

1.4 PATIENT-REPORTED OUTCOME MEASURES FOR ADVANCED CANCER PATIENTS IN CHINA

Despite the range of symptoms and concerns cancer patients have and significant improvement in cancer care and palliative care provision and cancer registry infrastructure,

there is very limited evidence for holistic multidimensional assessment of advanced cancer care in China. This is a common problem in counties where palliative care is relatively new and not fully integrated into health systems.[77, 78] Lack of appropriate and psychometrically sound outcome measures, logistical and methodological challenges in advanced populations are primary reasons for the dearth of evidence in this field.[79] As cancer becomes the leading cause of death with serious health-related suffering,[80] it is essential that outcomes-focused quality care is provided at the end of life.

The most commonly used palliative care outcome measures in China are generic quality of life questionnaires.[12] However, patients with advanced cancer experience specific complex and burdensome symptoms and concerns (physical, psychological social and spiritual) needs varying according to cancer type, treatments and comorbidities.[81-83] A systematic review found evidence of poor validity and reliability in China for quality of life questionnaires applied to advanced disease, and no patient reported outcome measure (PROM) with adequate psychometric proprieties[12]. In China where palliative care is developing it could really help to have a valid tool to assess and manage palliative care symptoms and concerns for advanced cancer patients.

Symptom recognition by health professionals caring for advanced cancer patients is often inadequate.[84, 85] The optimal identification and appropriate management of symptoms in advanced cancer patients have the potential to facilitate symptom relief , improve the overall quality of life and meet patients' needs. The regularly use of PROMs has been advocated as an effective way to standardize cancer practice due to its association with improved symptom control, increased supportive care measures, and patient satisfaction.

Several patient-reported measures for cancer patients in China are widely used, despite limited or unclear validation data.[86] There is no standardised and national accepted outcome measurement tools for palliative care patients in China.

1.4.1 Definition of Patient-Reported Outcome Measures

PROMs are tools used to measure patient-reported outcome (PRO). PROMs are standardized, validated questionnaires that are completed by patients' during the perioperative period to ascertain perceptions of their health status, perceived level of impairment, disability, and health-related quality of life.[87] They allow the efficacy of a clinical intervention to be measured from the patients' perspective. Questionnaires are given to patients both pre and post operatively to allow comparison of outcomes pre and post procedure.[3] In addition to outcomes relating to interventions, PROMs measure patients' perceptions of their general health or their health in relation to a specific disease. PROMs are a means of measuring clinical effectiveness and safety.[88]

1.4.2 Benefit of using PROM

There is increasing recognition of the importance of involving patients and the public in in clinical research and within the wider context of development and evaluation of health care service delivery and quality improvement. Routine use of patient-reported outcome measures and feedback of results to clinicians can helps identify problems/concerns and improves outcomes for patients[89, 90],including pain management, physician-patient communication, and symptom detection and control; increase utilization of supportive care;

and increase patient involvement in care[91]. Using PROMs facilitates a systematic and comprehensive approach to patient assessment and identifies problems. Regularly collecting PROM data is an effective way to standardize practice and improve patient management.[92] PROMs are an assessment of health status and health-related quality of life that comes directly from the patient,[93] which carry significant potential to improve comprehensive cancer care.[94] There is a growing interest in integrating patient-reported outcomes into routine oncology practice for symptom monitoring[95]. The ideal outcome measurement scale is valid, reliable and responsive, which is a crucial component of research quality.[96]

However, the PROMs that perform best in advanced cancer patients in China have not yet been identified, which hampers clinical practice and research to evaluate the effectiveness of interventions for cancer care in China. The lack of an outcome measures hampers the delivery of structured, quality palliative care, audit, research and evaluation.

1.4.3 Developing a new measure or adapting an existing measure?

A range of existing QOL tools has been validated for use in cancer, but these are not always focused on the priorities of patients, and no instrument has been developed specifically for use in advanced cancer patients in China.

A pan-European survey of palliative care professionals identified over 100 different tools and suggested that users require the number of tools to be rationalised. Would it be appropriate to add a new tool to an already overcrowded marketplace? One reason for the

proliferation of QOL tools is the need to develop instruments that are specific to a given disease, stage of disease (newly diagnosed / relapsed / palliative) or treatment group (chemotherapy / radiotherapy / off treatment) – since there may be different issues relevant in different contexts. A possible solution is to use a core questionnaire (containing issues relevant at all stages) with supplementary modules for different tumour groups or stages. This approach has been specifically proposed for clinical QOL tools,[97] and has been adopted by the European Organisation for Research and Treatment of Cancer (EORTC) who have developed a core cancer questionnaire (EORTC-QLQ-C30) with modules for different tumour groups, treatments modalities and phases of disease.

Based on the results of this survey, the authors recommended that the number of tools be rationalised, and that new measurement tools are not developed but rather existing ones refined.[98] The decision was therefore taken to identify a comprehensive measure of symptoms and concerns with robust psychometric properties, and established for use in routine clinical care.

1.4.4 Cross-cultural adaptation of measures

As multicultural and multinational research projects have multiplied, the adaptation of health measurements to be used in other languages has also increased rapidly. Cross-cultural adaptation is a process that looks at both language (i.e., translation) and cultural adaptation (i.e., culturally relevant content) to utilize existing instruments in other cultural, language or geographic settings.[3]

Cross-cultural adaptation has been used for several years in the social field, in epidemiological and behavioural studies, and more recently in health sciences, especially with the growing research into health-related quality of life. In order to make worthwhile comparisons between countries in terms of population, services, quality, costs and outcomes of health services, researchers need an internationally agreed system to assess the validity and reliability of their instruments.[99]

There is research evidence that the nature of society and culture in Western countries differs from those of Asian countries, in terms of language, lifestyle and education. In addition, countries can differ according to public strategy, attitudes and socioeconomic conditions,[100] so it is important to translate questionnaires using cross-cultural adaptation in order to maintain the meaning and intention of the original items.[101] Empirical evidence shows that culture can influence a person's activities, thinking and behaviour. Accordingly, when researchers wish to assess health status and perceptions of quality of life and to compare results with those in the original setting, they need to ensure that the instrument used is culturally adapted.[102] Thus, if researchers have no appropriate HRQoL measure in their own language, they have two options: to develop a new measure or to modify one previously validated in another language, which is known as cross-cultural adaptation.[103]

The perception of QOL and the ways in which health problems are expressed vary from culture to culture.[104] Adaptation is oriented towards measuring a similar phenomenon in different cultures as if the transposition of a measure from its original cultural context is done by simple translation it is unlikely to be successful because of language and cultural

differences.[105] It is essentially the production of an equivalent instrument adapted to another culture. Cross-cultural comparison refers to the comparative study of a phenomenon across cultures to identify differences attributable to culture. It is possible only after the measurement tool has been adapted and is equivalent in both cultures. Thus, the cross-cultural adaptation of a measure is a prerequisite for the investigation of cross-cultural differences.

In conclusion, the adaptation of a pre-existing measure to the cultural context of a target population, as described above, has several advantages:[103]

- it provides a common measure for the investigation of HRQOL within different cultural contexts;
- it offers a standard measure for use in international studies, many of which are now being conducted;
- it allows comparisons between national/ cultural groups relying on a standard measure designed and adapted to measure the phenomenon cross-culturally;
- it allows the inclusion of immigrants avoiding the frequent bias of representing only the dominant culture of the country;
- it is less costly and time-consuming than generating a new measure. Nevertheless, it should be borne in mind that the cross-cultural adaptation of HRQOL also requires careful attention, involves numerous people and is time-consuming.

1.4.5 Psychometric properties of PROMs

Variations in healthcare quality can be addressed by improving the delivering outcomes-focused care.[106] Patient-reported outcome measures (PROMs), elements of patient-centred care, comprise standardised validated questionnaires that are completed by patients to measure their perceptions of their health status and wellbeing.[107] Routine use of PROMs in palliative care (i.e. capture, transfer, and feedback of patient-centred outcomes data in routine palliative care clinical practice) can improve symptom recognition, increase discussion of quality of life, increased referrals based on PROMs reporting, and improve emotional and psychological patient outcomes.[108, 109]

1.4.5.1 Reliability

Reliability is defined as the degree to which any measurement produces the same results on a recurrent basis.[110, 111] Reliability is a prerequisite for validity, but high reliability does not necessarily equate to high validity.[110] Bollen highlighted that reliability refers to the part of the measure that is free of random error.[111] Random error may be due to a participant's mood, the way a questionnaire is administered or the instructions given to participants.[110]

1.4.5.1.1 Test-retest reliability

Test-retest reliability is the degree to which test scores are consistent under the same conditions. One of the major challenges of test-retest reliability is how much time is acceptable between the first and second administration. If there is too much time between the two administrations, it may be likely that external circumstances influence responses for the second administration. Whereas, if there is too little time between the two

administrations it is possible that answers in the second administration will be similar to those in the first administration.[112]

1.4.5.1.2 Internal consistency reliability

Internal consistency is the extent to which items in a questionnaire correlate with each other, therefore measuring the same construct. Terwee et al. note that an internally consistent measurement is achieved through adequate definition of the construct being measured, satisfactory items and factor analytic techniques. There are a number of different ways to calculate internal consistency, namely Kuder-Richardson, split halves or Cronbach's alpha. However, Cronbach's alpha is most commonly used.

1.4.5.1.3 Inter-rater reliability

Inter-rater reliability is the degree of agreement between two or more raters who provide consistent estimates of the same behaviour.[113] Inter-rater reliability can be determined via two different methods, depending on whether a measure is categorical or continuous. If a measure is categorical, raters will check which category each observation will belong to and their percentage of agreement will be calculated. If a measure is continuous the correlation between the ratings of the two raters will be calculated.[113]

1.4.5.2 Validity

Validity is defined as the extent to which an instrument measures what it is meant to measure.[110, 114]

1.4.5.2.1 Face and content validity

Face and content validity aims to establish whether the items in a questionnaire represent all aspects of the construct that is to be measured.[110] Content validation of an instrument is usually determined via interviews with individuals from the targeted population and/or experts in the field to ensure items and other elements are representative of and relevant to construct being measured.[115]

1.4.5.2.2 Criterion-related validity

Criterion validity is the degree to which the instrument correlates with other instruments, usually a 'gold standard' that measures the same variables.[112, 116] Criterion validity consists of two types 1) concurrent validity (which involves correlating the scale with a gold standard) and 2) predictive validity (which involves establishing the predictive power of the measure on some future criterion).

1.4.5.2.3 Construct validity

Construct validity is the extent to which a measurement measures the intended construct.[116] It is determined by testing hypotheses which were established in advance, such as expected correlations between measures or expected differences in scores between known groups.

1.5 THEORETICAL STANDPOINT

Polit et al describe two paradigms in nursing research, the positivist and the naturalistic.[117] However, this may be an oversimplification of these paradigms. Other academia describe four such paradigms each with its own epistemology, ontology and methods; positivism, postpositivism, interpretivism and critical theory.[118, 119] For the purposes of this study two paradigms were employed: postpositivism and interpretivism.

Ontologically in the interpretive paradigm reality is seen as subjective, open to change and that there is no ultimate truth.[118] Epistemologically there are multiple interpretations of reality and there is no ultimate way of knowing. Qualitative research methods are used. The researcher interacts with the research participants and the findings are a result of the interactive process with a focus on understanding. The individualised, holistic nature of the person in the context of their environment is important to the researcher who seeks to understand this complexity.[119]

In contrast the postpositivist paradigm seeks an objective reality, believing that there is an overarching objective truth.[118] However, unlike positivism, there is an acknowledgement that reality can never be fully known and that attempts at measurement are limited by understanding.[117] Post-positivists try to establish a 'probable' truth.[118, 120] Quantitative methods are commonly used with goals of prediction and explanation. However, as with the positivist tradition, the researcher remains separate from the research participants and seeks statistical analyses that produce generalisations.[121] Unlike

positivists, however, qualitative methods are also used to provide confirmation of and depth to the quantitative methods.[117]

In this study, interpretive inquiry was employed in the service of cross-cultural adaptation and item refinement of the IPOS with the hallmarks of postpositivism in terms of finding the palliative care needs could be measured. It was hoped that this approach would consider the individual and holistic nature of relationships by providing valid and reliable indicators of the palliative care needs of advanced cancer patients in China. This was the initial focus of the quest to adapt a measure. However, it became clear during the interpretive inquiry that these palliative care needs could not be considered outside of the Chinese context. These affected the advanced cancer patients' palliative care needs, resulting not only in the formation of needs measures but also of cultural impacts to be considered alongside.

Inevitably, trying to measure palliative care needs is difficult and striving for an objective tool may reduce the phenomena to a measure that detracts from the deeper meaning of complex palliative care needs. The ability to measure something as invisible, varied and multidimensional as the needs predictably means that it will be reduced to a series of symptoms or issues. However, these symptoms or issues are only 'indicators' of something that is much deeper and felt at a personal level by the participants. The measure is not the 'palliative care needs' itself but an indicator of the phenomena.

Clearly, each paradigm had its own contribution to make to the development of knowledge about palliative care needs. The interpretive enquiry concentrated on the advanced cancer parents' subjective experiences of their relationships clarifying the details and processes

present. An analysis of these factors enabled a synthesis, to distil common indicators to measure palliative care needs. In keeping with a postpositivist approach, the measures were used with researcher observation methods to give added verification and confirmation to the findings. It is hoped that the measure will be of use in both practice and research in China.

CHAPTER 2. AIM AND OBJECTIVES

2.1 AIM

To translate, cross-culturally adapt and validate the Chinese IPOS among adults with cancer

2.2 OBJECTIVES

Phase 1 Patient-Reported Outcome Measures in Advanced Cancer in China: A Systematic Review

Objective 1. To identify PROMs reported in the peer review literature for adult advanced cancer patients in China

Objective 2. To appraise the quality of development, cross-cultural adaptation and /or validation of the reported PROMs

Objective 3. To identify which PROMs have adequate psychometric properties for use among advanced cancer patients in China.

Phase 2 Determine Face and Content Validity of the IPOS

Objective 4. To identify palliative care needs among adults living with advanced cancer in China and their families

Objective 5. To determine optimal implementation of the IPOS among stakeholders i.e. patients and families

Phase 3 Refinement, Translation and Cross-cultural Adaptation of IPOS

Objective 6. To conceptually map the qualitative data of symptoms and concerns from patients and families onto the existing IPOS and refine the items for the Chinese IPOS

Objective 7. To conduct cognitive interviews among patient and families and refine the final Chinese IPOS for validation

Phase 4 Psychometric Testing of the Chinese IPOS

Objective 8. To assess the validity, reliability and responsiveness of the Chinese IPOS (patient and staff versions) among patients with advanced cancer, family members and health professionals in China.

CHAPTER 3. METHODS

3.1 OVERVIEW OF STUDY DESIGN AND METHODS

The diversity of the population worldwide suggests a great need for cross-culturally validated research instruments or scales. [122-124] Psychometrics is the scientific study—including the development, interpretation, and evaluation of the accuracy, dependability and consistency of a tool.[125, 126] Psychometric testing could be described as 'the degree to which the performance of the items on a translated or culturally adapted PROM instrument is an adequate reflection of the original version of the PROM' .[127] Psychometric properties of the newly translated and adapted instruments are context-specific attributes rather than fixed properties and therefore must be assessed in relation to the specific population and context.[112] An instrument that has demonstrated satisfactory measurement properties in one population is not necessarily appropriate for use in other populations.[128] The validation of the IPOS into Chinese population enabled the generalisability of its implantation, as well as allowing comparisons between countries.

A sequential mixed-methods study was employed comprising a qualitative component followed by quantitative components. Rothrock guidance (Figure 1), COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) and Palliative care Outcome Scale family of measures Manual for cross-cultural adaptation and psychometric validation guided the translation, cross-cultural adaptation and validation phases of the study.[126, 129-131] An overview of the study design can be found in Figure 2.

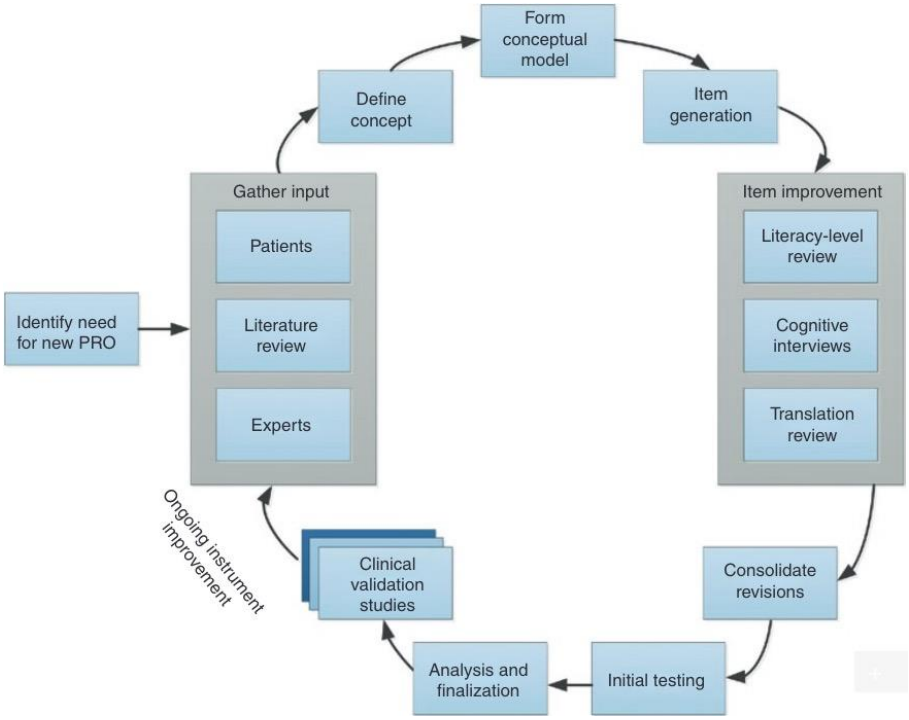

Figure 1. Patient-reported outcome (PRO) instrument development process. (Rothrock et al. 2011)

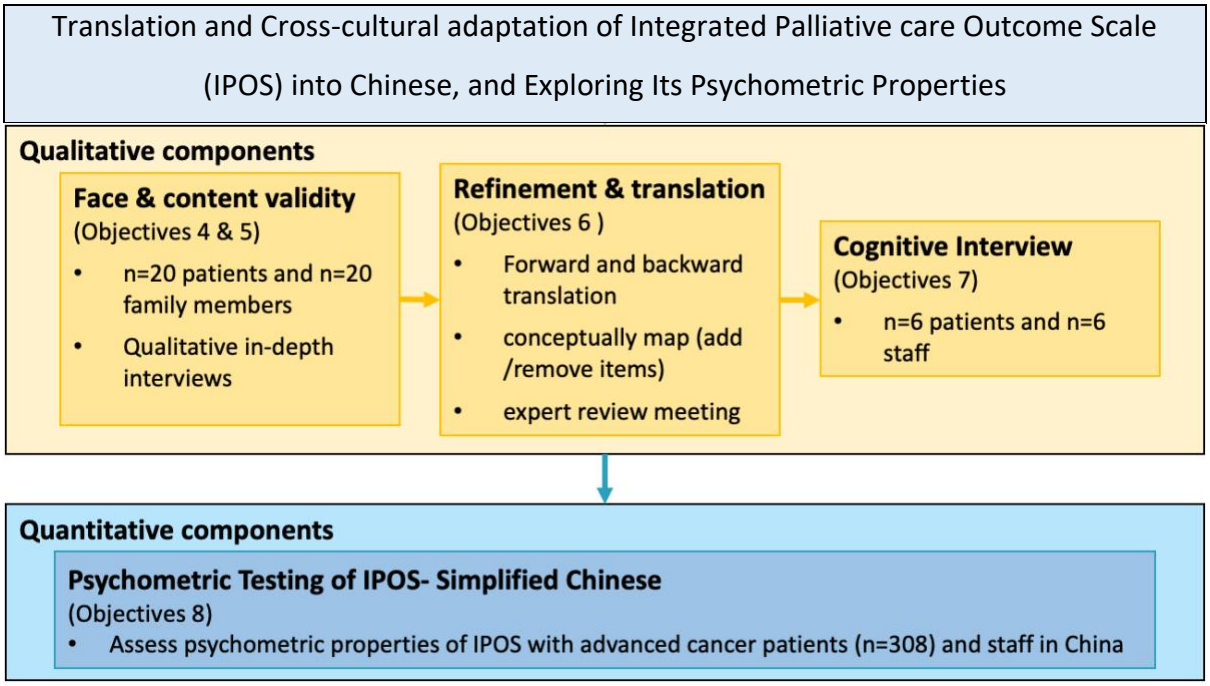

Figure 2. The flow diagram of study design

Phase 1: A systematic review was conducted in accordance with COSMIN, with quality assessment using the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures and COSMIN quality criteria for measurement properties to critically appraise, compare and summarise the quality of the measurement properties and examine their potential for use in clinical settings. MEDLINE, EMBASE, PsycINFO, CINAHL, CNKI and WanFang were systematically searched from inception to May 2019, updated to August 2022. Supplemental searches were conducted in grey literature databases, Google scholar and hand-searching of reference lists.

Phase 2: Semi-structured in-depth qualitative interviews with advanced cancer patients and family members at an inpatient oncology ward in China were conducted between October 2019 to January 2020 to explore palliative care needs and experience of people living with advanced cancer in China. This qualitative study followed the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) taxonomy and guidance for relevance and comprehensiveness of PROMs.[127, 132] Data collection continued until thematic saturation was achieved. Interviews were audio-recorded, transcribed verbatim and analysed utilising thematic analysis.

Phase 3: Cross-cultural adaptation and psychometric testing create a version of the original scale in a target language that is conceptually equivalent to the source instrument and psychometrically valid to allow for data pooling and cross-national and cross-cultural comparisons.[133] Chinese versions of IPOS Patient and IPOS Staff were translated and culturally adapted following the Rothrock guidance and the Palliative care Outcome Scale family of measures Manual for cross-cultural adaptation and psychometric validation.[129,

130] Five phases were included: (I) Conceptual definition; (II) Forward translation (translation from English to Chinese); (III)Backward translation (translation from Chinese to English); (IV) Expert review; (V)Cognitive debriefing.

Phase 4: A multi-centre validation study was conducted to test the psychometric properties of the Chinese Integrated Palliative care Outcome Scale - both (1) patient self-report and (2) staff proxy-report versions to ensure that the new IPOS - Chinese demonstrates the measurement properties needed to obtain reliable and valid results from its application. We tested construct validity (factor analysis and correlational analysis), reliability (internal consistency, test-retest reliability and inter-rater reliability), and responsiveness (through longitudinal evaluation of change).

3.2 STUDY SETTING AND SITES

This study was conducted in the medical oncology wards in two hospitals in Chaoyang, Liaoning Province and Shenzhen, Guangdong Province, China. Both hospitals are Class A tertiary comprehensive hospitals committed to delivering best quality clinical care, innovative scientific research and rigorous medical education, with 1408 and 1429 inpatient beds separately.

The study sites are:

1. Chaoyang Central Hospital (Liaoning)
2. Peking University Shenzhen Hospital (Guangdong)

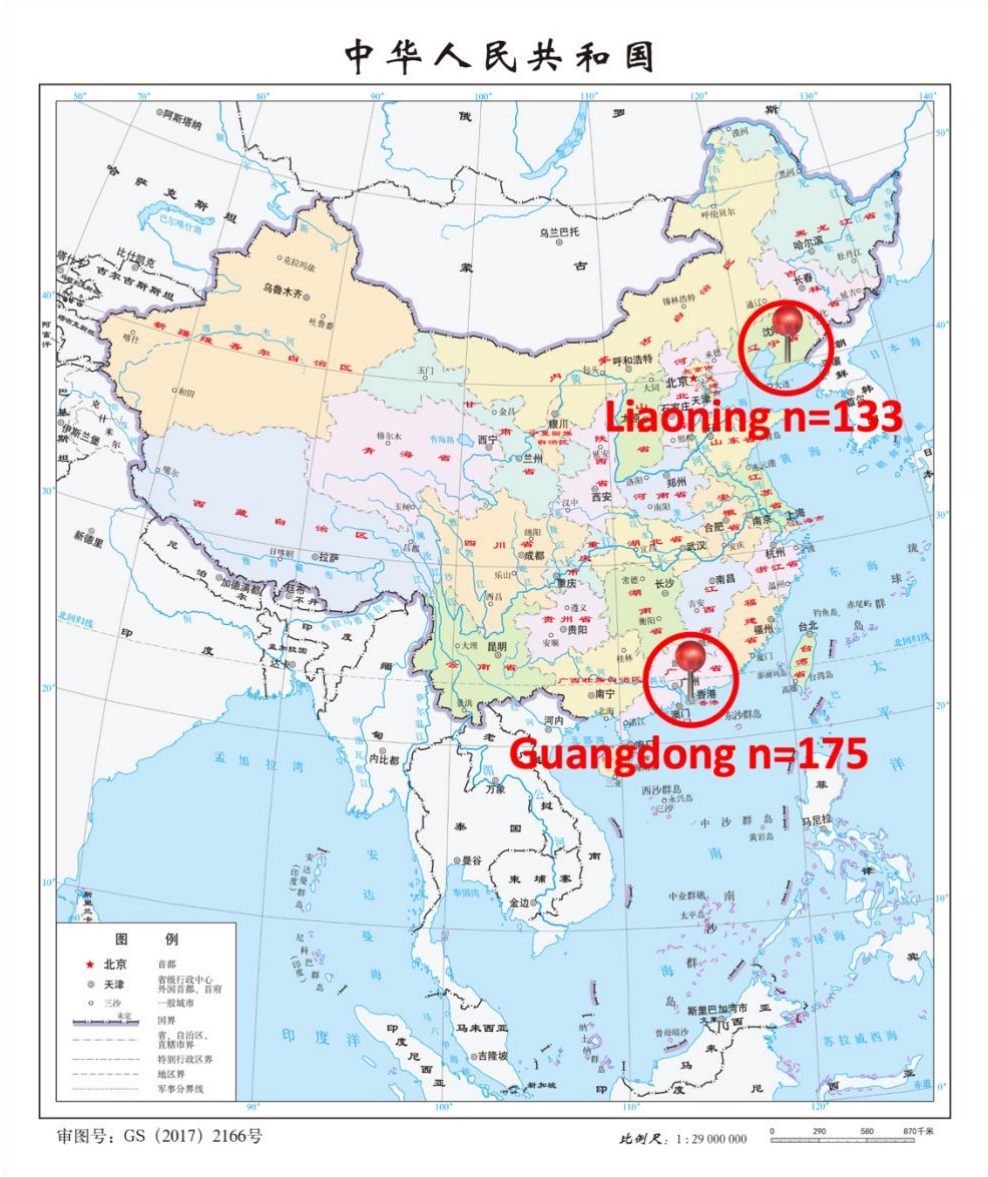

Figure 3. Locations of the two study sites in China

3.3 PART 1: PATIENT-REPORTED OUTCOME MEASURES IN ADVANCED CANCER IN CHINA: A SYSTEMATIC REVIEW (OBJECTIVES 1-3)

An overview of the method of the systematic review is presented below. The details of the method, results and discussion are reported in incorporated paper 1 in Chapter 6.

3.3.1 Background

The number of patients with advanced cancer in China is rapidly increasing. As services and policy evolve, it is essential to improve the quality of care by measuring outcomes of importance to patients and families. However, it is unclear whether there are currently measures with sound psychometric properties recommended for use with advanced cancer patients in China.

3.3.2 The aim of the systematic review

This review aimed to systematically identify patient-centred measures for advanced cancer patients in China and critically appraise their measurement properties. The objectives are to 1) identify PROMs reported in the peer review literature that has been tested with advanced cancer patients in China; 2) appraise the development, cross-cultural adaptation and /or validation methods and findings of the reported PROMs.

3.3.3 Study design

A systematic review was conducted in accordance with COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN), with quality assessment using the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures and COSMIN quality criteria for measurement properties. MEDLINE, EMBASE, PsycINFO, CINAHL, CNKI and WanFang were systematically searched from inception to May 2019,

updated to August 2022. Supplemental searches were conducted in grey literature databases, Google scholar and hand-searching of reference lists.

3.3.4 Study eligibility criteria

Inclusion criteria: i) Studies reporting on the development, validation and/or cross-cultural translation and revalidation of instruments measuring patient health status designed to be completed by patients with advanced cancer or a proxy. ii) Studies examining one or more measurement properties of an instrument in advanced adult cancer patients (stated to be at a terminal stage, Stage III or IV, or no longer responding to curative treatment) in China. iii) Studies published in English or Chinese. iv) Full-text articles.

Exclusion criteria: i) Studies only report PROM data without reporting measurement properties. ii) Studies of unstructured tools. iii) Studies on individuals with a non-cancer diagnosis or early-stage cancer diagnosis. iv) Editorials, reviews and conference abstracts.

3.3.5 Study selection

Following deduplication, search returns were initially titles and abstracts screened, and then full manuscripts of all studies were retrieved. The first reviewer (HL) screened these, with discussion on inclusion or exclusion decided where necessary with a second reviewer (PG). Discussions focussed on the exclusion of the overseas-born Chinese population and the early cancer stage. Discrepancies were resolved through discussion with the reach team and the consensuses were reached. The process is presented in a PRISMA flow diagram.[134]

3.3.6 Data extraction

To assess the quality of cross-cultural adaptation (where relevant), the following information was extracted in each step of standardised process of cross-cultural adaptation described by Beaton et al: stage I – forward translation, stage II – synthesis, stage III – backward translation, stage IV – expert committee review, stage V – pretesting and stage VI – submission.[135] Data on the following measurement properties were extracted: content validity, construct validity, internal consistency, test-retest reliability, responsiveness, floor and ceiling effect and interpretability based on Terwee et al.[136] Additional data were extracted where available, including age, gender, diagnosis, cancer stage, and completion time.

3.3.7 Data synthesis

Tools were categorised by domain measured. The categories were adapted from Categories of End-of-Life Care and Recommended Measures Online Toolkit.[137, 138] The following analyses were conducted. Cross-cultural adaption (CCA) process was evaluated based on the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures described by Beaton et al.[135] We assessed the quality of each stage of cross-cultural adaption with quality criteria adapted from Oliveira et al, which is the recommended methodologically evaluates the quality of each step of translation and cross-cultural adaptation, such as the number of translators required, adequate sample size, test-retest interval, etc.[139] (see Table 1)

Table 1. Quality criteria of the cross-cultural adaptation process

Stage	Rating	Quality criteria
I: Forward translation	+	Translations conducted by two or more independent translators
	?	Doubtful translation process (e.g. translators' background or awareness status about the tool are different from the recommended, translation conducted by one translator)
	−	Translation conducted by two non-independent translators
	0	No information on the forward translation process
II: Synthesis	+	Synthesis conducted by the same two or more translators from stage I
	?	Doubtful synthesis process (e.g. different translators or professionals from stage I)
	0	No information on the synthesis process
III: Back-translation	+	Back-translation made by two or more independent translators for whom English is the first language and who are naive to the instrument
	?	Doubtful back-translation process (e.g. English is not the translators' first language, or they are aware of the instrument, back-translation conducted by one translator only)
	−	Back-translation made by two non-independent translators
	0	No information on back-translation process
IV: Expert committee review	+	An expert committee is reported, and participants' roles clearly indicated. The committee reviews all documents
	?	Doubtful expert committee review (e.g. there is no mention of participants' roles)
	−	The committee reviews only one or some documents

Stage	Rating	Quality criteria
	0	No information on expert committee
V: Pretesting	+	Pre-test was conducted in 30 or more subjects from the target population
	?	Doubtful design (e.g. there is no mention of the number of subjects tested, target population not described)
	−	Pre-test was conducted in less than 30 subjects
	0	No information on the pre-test
VI: Submission	+	All reports and forms were submitted to the developer of the instrument or central committee for appraisal
	?	Doubtful submission process (e.g. the reports and forms were received by others instead of the developer of the instrument or central committee)
	0	No information on submission process

Measurement properties were assessed against criteria based on Terwee et al. as follows (see Table 2).[136] In addition, Content Validity Index (CVI), i.e. rating of item relevance by content experts[140]: threshold for validity ≥ 80%. Construct validity (for studies using classical test theory) threshold of comparative fit index (CFI) or Tucker-Lexis index (TLI) or comparable measure > 0.95 or Root Mean Square Error of Approximation(RMSEA) < 0.06 or Standardised Root Mean Residuals(SRMR) < 0.08.[136]

Table 2. Quality criteria for measurement properties of health status questionnaires

Property	Definition	Quality criteria
1. Content validity	The extent to which the domain	+ A clear description is provided of the measurement aim, the target population, the

Property	Definition	Quality criteria
	of interest is comprehensively sampled by the items in the questionnaire	concepts that are being measured, and the item selection AND target population and (investigators OR experts) were involved in item selection; ? A clear description of above-mentioned aspects is lacking OR only target population involved OR doubtful design or method; - No target population involvement; 0 No information found on target population involvement.
2. Internal consistency	The extent to which items in a (sub)scale are intercorrelated, thus measuring the same construct	+ Factor analyses performed on adequate sample size (7 ∗ # items and ≥100) AND Cronbach's alpha(s) calculated per dimension AND Cronbach's alpha(s) between 0.70 and 0.95; ? No factor analysis OR doubtful design or method; − Cronbach's alpha(s) <0.70 or >0.95, despite adequate design and method; 0 No information found on internal consistency.
3. Construct validity	The extent to which scores on a particular questionnaire relate to other measures in a manner that is consistent with theoretically derived hypotheses	+ Specific hypotheses were formulated AND at least 75% of the results are in accordance with these hypotheses; ? Doubtful design or method (e.g., no hypotheses); − Less than 75% of hypotheses were confirmed, despite adequate design and methods; 0 No information found on construct validity.

Property	Definition	Quality criteria
	concerning the concepts that are being measured	
4. Reliability	The proportion of the total variance in the measurements which is due to "true" differences	+ ICC or weighted Kappa ≥ 0.70; ? Doubtful design or method (e.g., time interval not mentioned); - ICC or weighted Kappa < 0.70, despite adequate design and method; 0 No information found on reliability.
5.Responsiveness	The ability of a questionnaire to detect clinically important changes over time	+ SDC or SDC < MIC OR MIC outside the LOA OR RR > 1.96 OR AUC ≥ 0.70; ? Doubtful design or method; − SDC or SDC ≥ MIC OR MIC equals or inside LOA OR RR ≤ 1.96 OR AUC < 0.70, despite adequate design and methods; 0 No information found on responsiveness.
6. Floor and ceiling effects	The number of respondents who achieved the lowest or highest possible score	+ ≤15% of the respondents achieved the highest or lowest possible scores; ? Doubtful design or method; − >15% of the respondents achieved the highest or lowest possible scores, despite adequate design and methods; 0 No information found on interpretation.
7. Interpretability	The degree to which one can assign qualitative meaning to quantitative scores	+ Mean and SD scores presented of at least four relevant subgroups of patients and MIC defined; ? Doubtful design or method OR less than four subgroups OR no MIC defined; 0 No information found on interpretation.

MIC = minimal important change; SDC = smallest detectable change; LOA = limits of agreement; ICC = Intraclass correlation coefficient; SD, standard deviation.
+ = positive rating; ? = indeterminate rating; − = negative rating; 0 = no information available.

3.4 PART 2: DETERMINE FACE AND CONTENT VALIDITY OF THE ENGLISH IPOS IN CHINA (OBJECTIVES 4-5)

3.4.1 Background

With increasing incidence and mortality, cancer has become one of the leading causes of death in China and a significant public health problem. People living with advanced cancer have multidimensional needs and concerns requiring person-centred care. However, little evidence exists on patients' priorities of advanced cancer care in China, and there is no ideal outcome measure that captures the breadth of needs and concerns of patients with advanced cancer in China.

3.4.2 The aim of the qualitative study

To identify the main symptoms, needs, concerns and priority outcomes for patients with advanced cancer and family members and devise a model for person-centred advanced cancer care in China.

3.4.3 Study design

A grounded theory methodological orientation was used to inductively explore participants' experiences and needs to develop a theoretical framework for advanced cancer patients in China. Our work was informed by the Consolidated Criteria for Reporting Qualitative Research (COREQ).[141, 142] As the purpose of the research was to identify the main symptoms, needs, concerns and priority outcomes for patients with advanced cancer and family members in China, a qualitative, descriptive design was employed. Qualitative studies do not seek to quantify data but, by careful analysis and interpretation, use the data as a means of increasing understanding. Semi-structured in-depth qualitative interviews with advanced cancer patients and family members were conducted at an inpatient medical oncology ward at Chaoyang Central Hospital in China.

3.4.4 Participants and recruitment

Advanced cancer patient participants and family participants were enrolled from an inpatient medical oncology ward in Chaoyang Central Hospital, a university teaching hospital in Liaoning Province, China. The target advanced cancer patients were determined by local medical team. The PhD fellow then approached the eligible cancer patient for enrolment by using maximum variation sampling[143] participants were purposively selected. The Staff, on the other hand, were selected by the PhD fellow as the PhD fellow visits the wards (oncology and general surgery). Each participant approached was given the information sheet, and the principal investigator introduced the study and answer any questions from

participants regarding the study. The participants signed a consent form if they are willing to take part in this study.

For qualitative interview, saturation is more important than sample size [144]. Saturation is the point in the data collection process after which no relevant information in line with the objectives is elicited. No rule can be provided to determine either the sample size or number of iterations needed to reach saturation in PRO instrument development. The sample needed to achieve saturation depends on the concept of interest and how it is perceived by patients from the target population. Heterogeneous patient samples and complex concepts generally require larger samples sizes.[145-150] 20 advanced cancer patients and 20 family members are expected to be considered sufficient to reach a point of data saturation. Therefore, 20 patients with advanced cancer and 20 family members (total of 40 participants) were purposively recruited and interviewed.

Eligible patient participants were adults (at least 18 years old), diagnosed with stage III or IV cancer or being the main carer of a relative with stage III or IV cancer, able to give informed consent, and judged to be physically and mentally well enough to participate by their clinical staff, and able to speak Mandarin. Eligible family participants were the main carer of a relative with stage III or IV cancer. We defined a diagnosis of stage III-IV cancer In line with the Chinese Society of Clinical Oncology clinical guidelines for the diagnosis and treatment.[151] The purposive maximum variation sampling frame took account of age, gender, marital status, patient's primary diagnosis, and duration of disease to reflect the diversity of possible experiences. Families were recruited independently of the patients and

interviewed separately. Patients and family members did not have to match unless the family members expressed a strong willingness to participate.

3.4.5 Data collection

A trained oncology research nurse (Yanxue Han) was based at the study site and was responsible for approaching eligible patients and families in the inpatient ward. 48 hours were given to the approached eligible patients and family members when they could take careful consideration on whether to participate or not. Face-to-face, semi-structured in-depth interviews were conducted in the participants' preferred setting (e.g., a private ward or office) between October 2019 and January 2020. The interviewer (PhD fellow) had extensive experience in cancer palliative care and qualitative research and had no pre-existed relationship at the time of consenting and interviewing. A topic guide was developed from a review of evidence on experiences of palliative care needs in cancer patients and their families and refined by the research team (see Appendix 9 and Appendix 10).

Interviews commenced with demographic questions followed by open questions exploring patients' experience of illness, the experience of healthcare, preferences, and ideas about the future. Participants were asked to tell stories based on their personal experience, from the point they were diagnosed with cancer, or their families were diagnosed with cancer. The participants are encouraged to tell stories following the prompts and questions being asked in the way they prefer, with minimum interruption from the interviewer. At the end of the interviews, the interviewer used open questions to explore particular issues further and offer participants opportunities to add/ change anything. Interviews are transcribed

professionally, checked by the researcher, and returned to the respondent for change or approval before analysis. Field notes were made during each interview. No one else presented besides the participants and the interviewer.

Data collection continued until data saturation was reached (i.e. no new themes were identified in line with the study aim), which was informed by diarised emergent themes. All interviews were conducted in Mandarin and digitally audio recorded, anonymised, transcribed verbatim by researchers, and translated from Mandarin into English. The research team reviewed the transcripts to check the accuracy of translations. The transcripts were not returned to participants for comments or corrections. In addition, we used the Karnofsky Performance Scale (KPS) to measure patients' functional status.[152, 153]

3.4.6 Data management

The interviews were anonymised, and any identifiable references was removed in accordance with the General Data Protection Regulation 2016 (GDPR) and research governance, and requirements in China. Participants could not be identifiable in any report or publication. Personal information was kept confidential and secure at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, King's College London, UK and Chaoyang Central Hospital, China; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets.

Research data (e.g. audio recordings), transcripts and personal demographic/clinical information will be stored or accessed by the research team for 7 years after the study has ended. After this period, all data will be permanently deleted or destroyed. The research team removed participants' data from the research records when they withdraw from the study.

Only the study team including principal investigator, supervisors and clinical leaders who assist the delivery of study can have accesses to the study materials. Anonymised data may also be used in future research studies and teaching by appropriately qualified researchers, trained and supervised by the research team. The research findings were presented in an anonymous way (for example, removing names and using identification code). No data was able to be linked to back to an individual taking part in the interview.

3.4.7 Data analysis

Thematic analysis was performed. Interview transcripts were read repeatedly and coded each transcript line by line by the PhD fellow after importing data into NVivo (Version 10, QSR International Pty Ltd. 2019), creating a coding frame of themes generated directly from the interview data. A combined analysis of interviews involving both patients and family caregivers was undertaken to comprehensively investigate the patients' concerns while capturing the insights provided by patients and their caregivers. Transcribing, translating, and analysing the data occurred simultaneously as the data collection proceeded to refine the topic guide. Interview data were categorised and compared, enabling the identification of common themes and sub-themes. We used constant comparison in our analysis to

ensure that the thematic analysis represented all perspectives. A list of themes and sub-themes were created, then examined for overlapping themes merged under descriptive labels and themes containing few quotations. Throughout this process, the data were consistently analysed to gain insight into the relationship between themes. To ensure open discussion of qualitative data collection and analysis throughout the project, the research team had regular meetings throughout the study. Besides, demographic data were descriptively analysed using SPSS (Version 26.0. Armonk, NY: IBM Corp). Participants' feedback on the findings was not obtained.

3.5 PART 3: TRANSLATION AND CROSS-CULTURAL ADAPTATION OF INTEGRATED PALLIATIVE CARE OUTCOME SCALE (IPOS) (OBJECTIVES 6-8)

3.5.1 Background

Despite the burden of advanced cancer in China, there were no reliable and validated patient-reported outcome measures for use to measure the care needs and outcomes of patients with advanced cancers.

The Integrated Palliative Care Outcome Scale (IPOS; also referred to as the Integrated Patient care Outcome Scale) is intended to provide multidimensional perspectives on a patient's situation, including physical, psychological, social, emotional, and spiritual concerns and needs.[7] It is a new development, integrating the most important questions from POS, POS-S and the APCA African POS. It has been welcomed by patients and professionals as a more streamlined measure which is brief, yet which still captures their

most important concerns. The POS team has currently endorsed 14 translations with over 10,000 registered POS users in over 100 countries in the world. Besides, IPOS has been translated into 7 languages with another 13 underway. Clinical Decision Support Tool (CDST) provides a straightforward guide to help support clinical care and improve evidence-based outcomes for patients with progressive illness and their families, addressing four areas of clinical uncertainty.

IPOS is available, in both a patient (self-report) and a staff (proxy rating) version (IPOS Patient and IPOS Staff, respectively) for reporting outcome measures. [7] IPOS Patient version should be used when patients are able to answer the questions, while the staff version allow proxy report when the patient is unable to self-report[154]. The IPOS is comprised of 10 questions addressing patients' concerns: symptoms, anxiety or low mood, family anxieties, overall feeling of being at peace, information needs, and practical concerns. The first question is an open question concerning patients' main challenges. The second question is in the form of a list of 10 common symptoms and includes space for three free options of individual symptoms to be added if needed. The questions are scored using a 0–4 Likert scale, with numerical and descriptive labels.[155] Although there have been several IPOS validation study conducted internationally, no study has yet attempted to validate IPOS to establish sound its psychometric properties (validity, reliability and responsiveness) in China [156-160].

3.5.2 The aim of the Part 3

To translate and cross-culturally adapt IPOS to the Chinese context in advanced cancer care.

3.5.3 Rationale for cross-cultural adaptation

There has been a growing interest in cross-culturally adaptation and validation of health-related PROMs.[161] Cross-cultural adaptation is a process that ensures equivalence in meaning in a target language.[162] The cross-cultural adaptation process is important when an instrument is used in a different language, setting and time to reduce the risk of introducing bias into a study.[163] In addition, patients experience and needs can be measured through some set of items in a questionnaire.[164] In studies where a phenomenon is measured with questionnaires, comparison of results between cultures and groups may be a challenge. In particular comparison was difficult if the adaptation process has been flawed. It is therefore important that each item is adapted appropriately. Standardized sequential procedures and guidelines was reported to support the translation of assessments.[165-168] Besides, a well-conducted cross-cultural adaptation is critical to ensure a good methodological quality of cross-cultural validation.[169] Evaluation of PRO items through cognitive interview is considered standard practice in the development of psychometrically sound PRO instruments.[170]

3.5.4 Study design and analysis plan

Process of translation and adaptation of instruments were adapted for use for the translation.[171] Refinement of the original IPOS was undertaken following the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) taxonomy and guidance for relevance and comprehensiveness of PROMs to ensure content

validity,[172-174] and Rothrock guidance on the development of valid PROMs in five phases (modified from the Rothrock guidance and The Palliative care Outcome Scale family of measures Manual for cross-cultural adaptation and psychometric validation):[130, 175] Phase I: Conceptual Definition; Phase II: Forward Translation (translation from the original English to Chinese); Phase III: Backward Translation (translation from Chinese to English); Phase IV: Expert Review; Phase V: Cognitive debriefing. The methods for each of these five phases are described below.

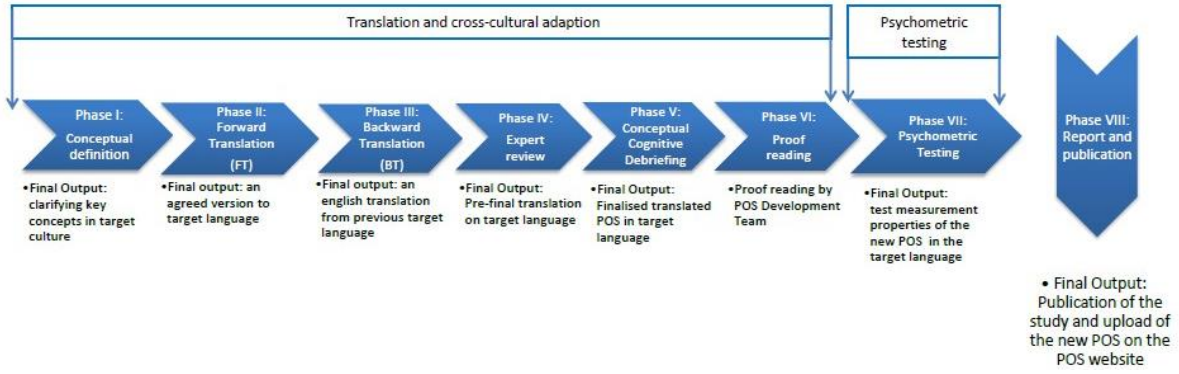

Figure 4. Translation, Cross-Cultural Adaption and Psychometric Testing Process

Phase I: Conceptual Definition: In-depth Interviews with Patients and Families

The first stage of IPOS cross-cultural adaptation was to gather information from key stakeholders, to define concepts and construct a conceptual model to underpin the item refinement and establish the face and content validity of the new IPOS.[130, 176] This is important because the new IPOS need to reflect palliative care concepts appropriate and to avoid certain concepts are not recognised or meaningless in the Chinese culture.[103] Adhering to COSMIN guidance,[172-174] interviews were conducted with advanced cancer patients to explore experience, needs and priorities for people living with advanced cancer

in China, as well as their brief opinions regarding the implement of IPOS. To ensure that the IPOS was relevant not only on patient level but also family level, main caregivers of advanced cancer patients were also interviewed regarding priorities from families' perspectives. 20 patients living with advanced cancer and 20 main caregivers of advanced cancer patients were recruited from Chaoyang Central Hospital, a large university affiliated teaching hospital in Northeast China, by research nurses. Interviews explored experience, needs and priority outcomes for people living with advanced cancer, as well as their perspectives of the implement of IPOS in China's clinical settings. Interviews were analysed using thematic analysis.[177, 178] Further details regarding the purposive sampling frame, inclusion and exclusion criteria, recruitment, conduct of the interviews and analysis, which formed the conceptual model will be published separately.

Phases II – III: Translation

The forward translation (phase II) was performed by two persons whose first language is Chinese and fluent in English, one with medical oncology and palliative care knowledge and one naive in medicine. A third person, independent and naive in health care, acted as a mediator in a consensus discussion. This group generated a preliminary Chinese version of IPOS. The backward translation (phase III) was carried out by two persons whose first language is English and fluent in Chinese working independently. A third person, with knowledge of palliative care, was involved as mediator in consensus discussions. This group generated a back-translated version of the preliminary Chinese version of IPOS ready for expert review.

Phase IV: Expert review

Expert review was performed by researchers, oncology clinicians, nurses, and patient and public involvement (PPI) members from the UK and China. The meeting commenced with presentations in both English and Chinese providing an overview of IPOS, and their development and use in palliative care in research, teaching and clinic work. Following this, the findings from the in-depth interviews with patients and families were presented including themes and subthemes from the primary interview data to inform discussions of priority items for inclusion and potential missing items.

Discussion commenced with reviewing each item before moving into exploring priorities that were not emphasised in the original IPOS informed by the qualitative research findings, which led to new item generation. The following aspects of items were discussed and comments were raised: 1. Conceptual: degree to which a concept of the IPOS measure items exists in both cultures and the meaning is the same; 2. Semantic: sentence structure, colloquialisms or idioms which ensure the meaning of the text or idea of the items; 3. Experiential: items seeking to capture experience of daily life often vary in different countries and cultures; 4. Content equivalence: relevance or pertinence of the text or idea of the items in each culture.

The research team carefully reviewed the comments after the meeting. We agreed minor changes to wording for better comprehension should be made and restructure and reformat certain items were needed. At this stage, IPOS was finalised for cognitive interviews.

Phase V: Cognitive interviews

Cognitive interviewing or testing of a tool involves processes of 'think aloud' and 'verbal probing' to determine the acceptability and accessibility of the format and structure of a tool, interpretation of items, how responses are formulated, and whether any key concepts have been missed.[179] Registered nurses at an oncology ward recruited patients and staff based on the inclusion criteria, ask these individuals whether they are interested in participating, and provide an information sheet about the cognitive interviews. The contact details of those interested were passed on to and approached by the interviewer. Inclusion criteria for advanced cancer patients: 1. Diagnosed with advanced cancer (Stage III-IV), 2. Over 18 years of age, 3. Possess mental capacity to give informed consent as determined by the treating clinician, 4. Possess sufficient fluency in spoken Chinese. Inclusion criteria for staff: 1. Able to give the informed consent, 2. Available to participate in the study, 3. Have been caring for advanced cancer patients for at least six months or more. See Appendix 11 and Appendix 12 for topic guide of the cognitive interviews.

Increasing the sample size in cognitive interviews can increase the number of problems detected.[180] Although every cognitive interview pre-test study must decide how many interviews need to be conducted, there is little theory or empirical research to guide the choice of sample size, practitioners generally rely on the examples of other studies and their own experience or preferences[181]. Based on a recent published study which aims to translate and cultural adapt IPOS into French(five patients and five staff were

recruited)[182], six in-patients with advanced cancer and six staff members within the study site participated to the cognitive interview.

Interviews were audio recorded and comments captured by the researcher. Interview data was verbatim transcript and part that is considered important for the aim of the study was translated. NVivo 12 data software package was used for data analysis (https://www.qsrinternational.com/nvivo/home) and results were reported in accordance with the consolidated criteria for reporting qualitative studies (COREQ)[183]. Each subject first completes the questionnaire and is then asked about their thoughts on what was meant by each item and their response. Both the meaning of the items and responses were explored. Cognitive interviewing or testing of a tool involved processes of 'think aloud' and 'verbal probing' to determine the acceptability and accessibility of the format and structure of a tool, interpretation of items, how responses are formulated, and whether any key concepts have been missed.

Interviews were analysed using inductive thematic analysis. All the questions and answers were checked in terms of wording, acceptability, ambiguous meaning, as well as format (including electronic or paper format) and layout issues. Any difficulties emerged during the filling of IPOS or in the discussion with participants were considered as a possible issue and code to be reviewed by the project steering group (PhD student, supervisors, local clinicians). The categories used to perform the analysis following Tourangeau's[184]: comprehension (what does the respondent believe the question to be asking), retrieval (Could they recall the information required by the question? Was the time frame suitable?), judgement (Is the respondent able to make an evaluation based on the information

recalled?), response (Is the respondent able to map their internally generated answer to a response option?) and others, (including additional comments, the questionnaire overall impression, questions to be removed, layout issues). All cognitive interview data of patient and staff participants were tabulated by item and participant, reviewed by the research team, and consensus reached regarding whether any change should be implemented. Chinese IPOS was refined further informed by findings (Chapter 6) from cognitive interviews.

All document describing each phase of the process, as well as any questions, were sent to the supervisors to proofread and endorse before psychometric testing.

3.6 PART 4: PSYCHOMETRIC TESTING OF IPOS - CHINESE (OBJECTIVE 9)

3.6.1 Background

Outcome measures amenable for palliative care patients in China have been lacking. The Integrated Palliative care Outcome Scale is a brief and valid PROM that evaluates the most burdensome concerns and has been used with advanced cancer patients and adapted to many cultures.

3.6.2 The aim of validation study

To evaluate the psychometric properties (validity, reliability, and responsiveness to change) of the Integrated Palliative care Outcome Scale in advanced cancer patients in China.

3.6.3 Study design

A multi-centre validation study was conducted to test the psychometric properties of the Chinese Integrated Palliative care Outcome Scale - both (1) patient self-report and (2) staff proxy-report versions. We tested construct validity (factor analysis and correlational analysis), reliability (internal consistency, test-retest reliability and inter-rater reliability), and responsiveness (through longitudinal evaluation of change).

3.6.4 Population and settings

Patients with advanced cancer were consecutively recruited from two inpatient medical oncology units in two university-affiliated hospitals in China within three days of admission. Staff caring for participating patients were also recruited.

The sample size for psychometric testing depends on the types of psychometric approaches that was used. The more complete the psychometric approaches for evaluation of the translated instrument the more confidence was generated in its reliability and validity properties. In general, it is highly recommended to use at least 10 subjects per item of the instrument scale and item analysis and exploratory factor analysis[185-188]. Power analysis based on the number of degrees of freedom, an alpha level (0.05 or 0.01), and a desired power (80% or above) can also be calculated[189, 190]. Comrey and Lee[191] provided the following guidance: 100 = poor, 200 = fair, 300 = good, 500 = very good, ≥1000 = excellent. In this study, we aim to recruit 300 patients and their attending physicians or nurses.

Inclusion criteria for patient participants were: >18 years old, inpatients diagnosed with advanced cancer (stage III-IV), capacity to give written informed consent as determined by the treating clinician, and able to speak and read Chinese. Exclusion criteria for patient participants included: too unwell or without the mental capacity to give informed consent for themselves as determined by the treating clinician or unable to understand written and verbal communication in Chinese. Inclusion criteria for staff participants were: with a key clinical role in caring for patient participants and the experience of delivering care for patients with advanced cancer for at least six months. Staff participants scored the research measures independently of the corresponding patient participant.

3.6.5 Data collection

Demographic data (e.g., age, gender, marital status, and primary diagnosis) were collected through self-report and electronic medical record review at baseline. There were two time points of data collection: 0-3 days and 5-7 days after admission (Table 1). At Timepoint 1 (T1), the patients were asked to self-complete the IPOS patient version (3-day recall period, with assistance as required from research nurses) and ESAS, and their allocated nurse completed the IPOS staff version, KPS, and ESAS. At Timepoint 2 (T2), IPOS patient version and global change question 'Has your condition changed?' were collected for patient participants. For staff participants, the IPOS staff version and KPS were collected. The testing and reporting of the measurement properties of the Chinese IPOS followed the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) recommendations.[192, 193]

3.6.6 Measures used

Integrated Palliative care Outcome Scale (IPOS)[194]

IPOS is a 10-question, 17-item brief PROM addressing symptoms, information needs, practical concerns, anxiety, low mood, family anxieties and overall feeling of being at peace with persons living with life-threatening illnesses. It is scored on a 5-point Likert scale (0–4), with higher scores indicating an overwhelming presence of symptoms and needs not addressed. Patients may also list their main problems and concerns and any additional symptoms. The seven-day patient version recommended for use in community-based services was used in this study. An earlier study identified Physical Symptoms, Emotional Issues and Support (Social issues and Quality of Care) as three sub-scales of IPOS.

The Edmonton Symptom Assessment System (ESAS)[195]

ESAS consists of nine visual analogue scales, scored from 0-10, including pain, shortness of breath, nausea, depression, activity, anxiety, wellbeing, drowsiness and appetite. Initially, ESAS was developed to measure the most common symptoms in cancer patients. Higher scores indicate worse symptoms. The ESAS has been validated for assessing the symptoms of patients with an advanced progressive illness in China.

Karnofsky Performance Status (KPS)[196]

A single score between 0% and 100% (in 10% steps) is based on a patient's ability to perform common tasks relating to activity, work and self-care. A KPS score of 100% signifies normal physical abilities with no complaints and no evidence of disease. Decreasing numbers indicate reduced performance status. The Australia-modified Karnofsky Performance Status (AKPS) has been adapted and validated for advanced illness but is not available in China.[197]

Global change question

Single item asking patient participants to report an overall change in their symptoms and concerns: 'Over the last three days, has your condition changed/ would you say that things have got better /worse / there has been no change?'. A single global 'change' question is recommended for assessing the responsiveness of patient-reported outcome measures.[198]

3.6.7 Data analysis

Descriptive and multivariate analyses were carried out to present participant characteristics and to assess data distribution, internal consistency, reliability, validity and internal responsiveness of Chinese IPOS using IBM SPSS Statistics 28.0 and R 3.6.0 (Bell Laboratories, Oakland). Participant characteristics were summarised as percentages of the total participants. Mean or median with standard deviation or range of values were presented where relevant.

Reliability

Internal consistency was evaluated using Cronbach's alpha for IPOS total scores and subscales, with a Cronbach's alpha between 0.70 and 0.95, indicating good internal consistency without homogeneity.[136]

Test-retest reliability was calculated between the repeated IPOS – Chinese in stable patients — those who, at Time Point 2, were asked the question: “Over the last three days has your condition changed? ” and answered “no” to the question. Inter-rater reliability was assessed between independent patient and staff ratings at each time point. Cohen’s weighted kappa was calculated, and the Spearman correlation was calculated to test the association between patient/ staff ratings. For interpretation, the Landis and Koch[199] and Fleiss’[200] criteria of $k > 0.4$ for fair to good and $k > 0.75$ for substantial to excellent agreement were used.

Validity

Structural validity

Exploratory factor analysis (EFA) was used to initially evaluate the dimensions of the measure. The EFA was conducted using the principal components extraction method with varimax oblique rotation. The number of factors was determined by Scree plot and Kaiser’s criterion of an Eigen value>1.[201, 202] A factor loading greater than 0.30 was considered significant. The EFA output was used to inform the confirmatory factor analysis (CFA). The

CFA model fit was assessed using fit indices. We used robust maximum likelihood estimation to accommodate the ordinal nature of the data[203]. The fit of each solution was evaluated using chi-square, ratio of chi-square and degrees of freedom, confirmatory fit index, Tucker-Lewis index (TLI), Standardised Root Mean Squared Residual (SRMR), and root mean square error of approximation (RMSEA)[204]. Contrasting models were compared regarding fit indices, standardised parameter estimates, and local strains (low loadings, high standard error)[205]. The following thresholds were used to indicate a good fitting model: RMSEA < 0.05, CFI > 0.95, TLI > 0.95 and SRMR < 0.08.[8, 206] The modification indices command was used to identify any further factor loadings or covarying error terms that would improve model fit; these were then added to the model. Correlation coefficients were used to assess the correlation of factors. Parameters described by Evans et al. were used to classify weak (<0.4), moderate (0.4 – 0.6) and strong (>0.6) correlations.

Convergent validity was tested by correlating individual IPOS items and subscales with respective items and subscales from ESAS,[207] using Spearman's correlation coefficients (r)[208] with associated p-values, where r between 0 and 0.200 indicated weak, 0.20 – 0.40 low, 0.40 – 0.60 moderate and 0.60 – 0.80 strong relationship given statistical significance. We hypothesised high correlations (r > 0.60) of identical or near-identical single items relating to the physical and psychological symptoms from ESAS and IPOS and moderate correlations ($0.40 \leq r < 0.60$) between total ESAS scores (which includes only symptoms) and subscale scores (not covering the spectrum of spiritual and family issues covered by the IPOS) and total IPOS scores (including domains beyond symptoms).

Responsiveness to change

Responsiveness was assessed by observing changes in IPOS scores over time. Changes in POS scores were examined (total score and for each item) between the first and second assessments.

We checked for responsiveness to change by comparing IPOS - Chinese scores at timepoint 1 and timepoint 2 using the Wilcoxon signed-rank test, among patients who indicate that their clinical condition has changed at Time Point 2. We compared mean changes and respective standard deviations of change descriptively in the six categories of change given by the global change rating (ranging from much better to much worse with a “do not know”-category).

Interpretability

More than 15% of respondents recorded the highest (4) or lowest (0) possible value would be described as having a ceiling or floor effect, calculated by the percentage frequency of the extreme score in each item achieved at T1.[136]

Feasibility

Completion time was recorded by research nurses. Means, standard deviations and ranges of completion time were calculated.

3.7 ETHICAL CONSIDERATION AND APPROVALS

Systematic review: Ethical approval was not required due to the nature of the study design.

Qualitative study: Ethical approval was obtained from King's College London Research Ethics Committee (HR-18/19-12556) and Chaoyang Central Hospital Research Ethics Committee (Chaoyang Central Hospital Research Ethics Committees, approved on 8 October 2019). Research data were managed by the research team according to the General Research Data regulations and KDPR. Informed consent was obtained from all participants prior to the interview participation.

Validation study: Ethical approval was obtained from King's College London Research Ethics Committee (HR-20/21-18713), Chaoyang Central Hospital (Chaoyang Central Hospital Research Ethics Committees, approved on 8 October 2019) and Peking University Shenzhen Hospital (Peking University Shenzhen Hospital Research Ethics Committees, approved on 15 July 2020). All participants completed informed consent forms before engaging in the intervention and evaluation.

The principal investigator had a study launch meeting with all staff, describe the aims of the study and the sampling frame of the recruitment. The medical staff then approached people and gave an outline of the study to patients or families. The principal investigator asked if the medical staff were interested to be a participant. If patients, families and medical staff are interested in this study, the principal investigator then received contact details and went to see the patients or families and gave them information and consent with 48 hours to

decide before the interview starts. The principal investigator attended the clinic daily to collect contact details and visited patients, families and staff. For those who agree, consent was taken after 48 hours when the interview was conducted.

Any personal information and patients' medical records were accessed before they have consented to take part in this study. The principal investigator obtained consent from patients, families and medical staff individually. Patients were also be informed that the decision they made to be involved or refuse participation in the study not in any way to be influenced the care and treatment they received currently, nor in the future. And we had made a clear statement in our patient information sheets that states the patients' medical or legal rights were not affected if they chose not to participate. Participants were also reassured in information sheets that they were free to withdraw from the study at any time, without providing a reason.

Potential participants who met the study criteria were identified by the medical staff, who made the first approach regarding the study. Patients were provided a copy of information sheet. Patients were also informed that the decision they made had no effect on the care they received currently, nor in the future. The PhD fellow prepared a sheet in an envelope in advance. This sheet included two options for the potential participants to choose one of them: (1) I am happy to be contacted by the PhD fellow; (2) I am not happy to be contacted by the PhD fellow. This sheet provided the space for the patient to add their name. The potential participants were offered (at least 48 hours) to think about the study participation and to decide.

Then PhD fellow contacted the participants who indicated their willingness to take participant in the study, and also provided more information on the study and gave them the opportunity to ask further questions. After this, the PhD fellow obtained written informed consent of the study.

Each participant approached was given the information sheet, and the principal investigator introduced the study and answered any questions from participants regarding the study. Participants was not contacted on sooner than 24 hours later to ensure they have sufficient time to consider participation. The participants signed a consent form if they are willing to take part in this study.

The participants could withdraw at any time during the study without giving any reason. If participants withdraw during the study, we removed their data from the research records according to their wishes. Even though the study has been completed, the participants still can request to withdraw their data 6 months (30th November 2020) after the study completed. After the time, they may no longer withdraw their data from the study.

i) Explain how the nature of the research could induce psychological stress or anxiety or produce humiliation or cause harm or negative consequences beyond the risks encountered in normal life.

According to the principles of biomedical ethics, the researcher should apply strategies to maximise the benefit for participants and minimise the harm. In this study, there were no invasive intervention so that no physical harm occurred. However, to discuss the experience

of disease with patients and family members in the in-depth interview could remind patients distress and the cause potentially psychological harm. The possible risks participants were exposed to is that patients were reminded issues relating to their illness and families were reminded of the experience of taking care of the patients.

The proposal and the intent of the study were explained to the participants before informed consent. Participants were reminded that they could withdrawal at any time point of this study and advised they may refuse to answer any particular question, whether in the interview or on the questionnaires. If they feel uncomfortable about anything, they could inform the researcher or clinic team immediately and may ask for the interview to pause or stop. There is no obligation of participants to be part of this study and their care and treatment received was not affected if they decline or withdrawal the study.

The PhD fellow approached the participant for further arrangement of consulting with a multidisciplinary team if they require additional support. An urgent issue was raised if participants disclose any ideation of self-harm or other risks of others. The researcher informed and discussed with the clinical leaders in the study site and supervisors at Kings College London by email or phone for the decision whether to continue the study or not.

The medical team in oncology unit in Chaoyang Central Hospital and Peking University Shenzhen Hospital could provide immediate support including psychological support, financial support and information queries by clinicians and volunteers for participants that require it. In addition, there were an opportunity for participants to speak to their care team

to address any distress. The principal investigator helped participants to arrange the support anytime should this be the case.

To discuss the experience and issues in terms of illness with patients or families in the in-depth interview might remind patients' and families' current challenge of living with distress and the implications for future they are likely to be distressed by. This might induce psychological stress or anxiety for patients and families.

Qualitative research and questionnaires with palliative care patients and carers identified that while distress is extremely rare, reported benefits are common. The process of sharing thoughts in an interview was experienced as therapeutic. Furthermore, the benefit of being involved in an interview was not limited to a personal level. The patients and carers felt empowered by contributing to research with the purpose of improving services, which meant that their views mattered. Although the interview with patients or carers might evoke emotional reactions, most participants all wish to continue the interview and expressed grateful after the interview. Therefore, we believed that the benefit of this interview with patients, carers and medical staff outweighed the risk.

The study was anonymised, and any potentially identifiable information was removed in accordance with the General Data Protection Regulation 2016 (GDPR) and Tort Law of the People's Republic of China (2009) in reporting, transcripts and any publications. The names were stored separately from data. The research finding was presented in an anonymous way (for example, removing names and using an identification code). No data were able to be linked back to any individual taking part in the interview.

CHAPTER 4. RESULTS 1-SYSTEMATIC REVIEW

4.1 INTRODUCTION TO CHAPTER

This chapter presents findings from a systematic review which aimed to address study objective one to three:

Objective 1. To identify PROMs reported in the peer review literate that psychometric properties has been tested for advanced cancer patients in China

Objective 2. To appraise the quality of development, cross-cultural adaptation and /or validation of the reported PROMs

Objective 3. To identify which PROMs have adequate psychometric properties for recommending clinical use among advanced cancer patients in China.

4.2 SUMMARY OF THE RESULTS

From 9289 articles, 429 were selected for full-text review based on title and abstract. A total of 46 studies reporting 39 PROMs were retained. Data regarding to quality of cross-cultural adaptation and psychometric test process was extracted. Personal communications with lead authors were initiated in two papers when inconsistencies in age[209] and gender[210] were identified in the full-text articles. Correct data was entered into the data extraction form after both lead authors confirmed the requested information. No articles were rated as "good quality" in more than two of the six stages of cross-cultural adaptation. At least half of the required information on psychometric properties was missing for each measure. Based on COSMIN, none of the identified PROMs were valid across all properties.

Collecting information using PROMs is a critical component of evaluating the complex needs of advanced cancer patients clinically and in research. As there are currently no contextually appropriate and psychometrically sound PROMs that measure the multidimensional concerns of advanced cancer patients in China, there is an urgent need for further high-quality methodological studies to properly evaluate and strengthen measurement properties.

Details of the method, results and discussion of the systematic review can be found in the incorporated publication presented below.

Li H, Guo P, Gao W, Normand C, Harding R. Patient-reported outcome measures for advanced cancer in China: A systematic review of cross-cultural adaptation and psychometric properties. J Cancer Policy. 2022 Nov 24;35:100371. doi: 10.1016/j.jcpo.2022.100371.

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Patient-reported outcome measures for advanced cancer in China: A systematic review of cross-cultural adaptation and psychometric properties

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ABSTRACT

Background: The number of patients with advanced cancer in China is rapidly increasing. As services and policy evolve, it is essential to improve the quality of care by measuring outcomes of importance to patients and families by identifying patient-reported outcome measures (PROMs) for use with advanced cancer patients in China, and critically appraising their cross-cultural adaptation process and measurement properties.

Methods: A systematic review was conducted in accordance with COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN), with quality assessment using the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures and COSMIN quality criteria for measurement properties. MEDLINE, EMBASE, PsycINFO, CINAHL, CNKI and WanFang were systematically searched from inception to May 2019, updated to August 2022. Supplemental searches were conducted in grey literature databases, Google scholar and hand-searching of reference lists.

Results: From 10793 articles, 437 were selected for full-text review based on titles and abstracts. A total of 46 studies reporting 39 PROMs were retained. No articles were rated as "good quality" in more than four of the six stages of cross-cultural adaptation. At least half of the required information on psychometric properties was missing for each measure. Based on COSMIN, none identified PROMs were valid across all properties nor appropriate to use.

Conclusion: There is currently no contextually appropriate and psychometrically sound PROMs for advanced cancer patients in China. The psychometric literature suggest that adaptation of existing measures is the potential solution.

Policy summary: Developing outcome measures for advanced cancer patients in China is invaluable to improve audit, clinical services and assess the quality of care, for research purposes and secure funding. Future research in measures' development, refinement and cross-cultural adaptation in this field is urgently needed.

1. Background

China is the most populous nation in the world and is rapidly ageing. The 176 million elderly adults (aged 65 years or older) in China at the end of 2019 accounted for 13% of the total population [1]. The proportion of the population aged at least 60 years is projected to increase from 12.4% in 2010 to 28% in 2040 [2]. China had an estimated 4,292,000 new cancer cases and 2,814,000 cancer deaths in 2015 (and is the leading cause of death), representing 22% of all incident globally, 27% of global cancer deaths [3].

Advanced cancer brings psychological, socioeconomic, physical and spiritual concerns [4]. Palliative care enables patients and families to live well with progressive illness, improving their outcomes and saving costs [5–9]. Approximately 0.7% of hospitals in China offer palliative care, and only 10% of patients have access to palliative care [10]. It is essential to ensure that investment in access to palliative care is pursued with a focus on care quality. Quality care is person-centred with the multidimensional assessment of patients and families to identify their more burdensome symptoms and concerns [11] and is measurable by determining the change in patient health status [12]. Patient reported outcome measures (PROMs) are the instruments or tools to measure patient reported outcomes (PROs), which are directly reported by

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patients to measure their perception of their well-being and functional status [13]. Using PROMs facilitates a systematic and comprehensive approach to patient assessment and identifies problems, standardises practice and improves patient management using data directly from the patient and their families [14,15]. PROMs offer significant potential to improve comprehensive cancer care [16], especially in symptoms recognition [17,18]. There is growing interest in integrating patient-reported outcomes into routine oncology practice for symptom monitoring [19].

The cross-cultural adaptation refers to the process of reaching equivalence between the original and target versions of the PROMs for use in new languages [20]. It is significant to establish face and content validity of PROMs in order to promote effective communication and quality of care as illness and healthcare have different meaning in different cultures, religions and languages [21]. The ideal outcome measurement scale should be valid, reliable and responsive, facilitating the delivery of structured, quality palliative care, audit, research and evaluation [22]. A systematic review identified a small evidence base for palliative care in Greater China and the use of single domain measures [23]. However, it is unclear whether there are currently measures with sound psychometric properties recommended for use with advanced cancer patients in China.

This review aimed to systematically identify patient-centred measures for advanced cancer patients in China and critically appraise their measurement properties. The objectives are to 1) identify PROMs reported in the peer review literature that has been tested with advanced cancer patients in China; 2) appraise the development, cross-cultural adaptation and /or validation methods and findings of the reported PROMs.

2. Methods

This systematic review was performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [24], COSMIN [25–27] methodologies for systematic reviews of PROMs, Guidelines for the process of cross-cultural adaptation of self-report measures [28], and the Peer Review of Electronic Search Strategies (PRESS) Guidelines [29].

2.1. Search strategy

The six following electronic databases were systematically searched from inception to May 2019, updated in August 2022: MEDLINE, EMBASE, PsycINFO and CINAHL (English-language literature); CNKI and WanFang (Chinese literature).

Supplementary searches were conducted by hand searching reference lists, grey literature for policy and practice references [30] (OpenGery and Global Health), and Google Scholar [31,32]. Endnote was used to manage references.

The search strategy (Appendix 1) was in accordance with COSMIN [25–27] methodology for systematic reviews of PROMs. Search terms were adapted according to Terwee et al. [33] to ensure sensitive search filters for three constructs (1) patient-reported outcome measurement, (2) Chinese population, (3) advanced cancer. Terms within each group were combined with a Boolean 'OR' command and searched in a combination using a Boolean 'AND' command. Before commencing the searches, the strategies were reviewed and checked against the Peer Review of Electronic Search Strategies (PRESS) Guidelines [29], with advice from an information specialist.

2.2. Inclusion/ exclusion criteria

Inclusion criteria: i) Studies reporting on the development, validation and/or cross-cultural translation and revalidation of instruments measuring patient health status designed to be completed by patients with advanced cancer or a proxy. ii) Studies examining one or more measurement properties of an instrument in advanced adult cancer patients (stated to be at a terminal stage, Stage III or IV, or no longer responding to curative treatment) in China. iii) Studies published in English or Chinese. iv) Full-text articles.

Exclusion criteria: i) Studies only report PROM data without reporting measurement properties. ii) Studies of unstructured tools. iii) Studies on individuals with a non-cancer diagnosis or early-stage cancer diagnosis. iv) Editorials, reviews and conference abstracts.

2.3. Study selection

Following deduplication, search returns were initially titles and abstracts screened, and then full manuscripts of all studies were retrieved. The first reviewer (HL) screened these, with discussion on inclusion or exclusion decided where necessary with a second reviewer (PG). Discussions focussed on the exclusion of the overseas-born Chinese population and the early cancer stage. Discrepancies were resolved through discussion with the reach team and the consensuses were reached. The process is presented in a PRISMA flow diagram [34].

2.4. Data extraction

To assess the quality of cross-cultural adaptation (where relevant), the following information was extracted in each step of standardised process of cross-cultural adaptation described by Beaton et al.: stage I – forward translation, stage II – synthesis, stage III – backward translation, stage IV – expert committee review, stage V – pretesting and stage VI – submission [28]. Data on the following measurement properties were extracted: content validity, construct validity, internal consistency, test-retest reliability, responsiveness, floor and ceiling effect and interpretability based on Terwee et al. [35] Additional data were extracted where available, including age, gender, diagnosis, cancer stage, and completion time (Table 1).

2.5. Data synthesis

Tools were categorised by domain measured. The categories were adapted from Categories of End-of-Life Care and Recommended Measures Online Toolkit [36,37]. The following analyses were conducted. Cross-cultural adaption (CCA) process was evaluated based on the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures described by Beaton et al. [28] We assessed the quality of each stage of cross-cultural adaption with quality criteria adapted from Oliveira et al., which is the recommended methodologically evaluates the quality of each step of translation and cross-cultural adaptation, such as the number of translators required, adequate sample size, test-retest interval, etc [38]. (see Appendix 2).

Measurement properties were assessed against criteria based on Terwee et al. as follows (see Appendix 3) [35]. In addition, Content Validity Index (CVI), i.e. rating of item relevance by content experts [39]: threshold for validity $\geq$ 80%. Construct validity (for studies using classical test theory) threshold of comparative fit index (CFI) or Tucker-Lexis index (TLI) or comparable measure > 0.95 or Root Mean Square Error of Approximation(RMSEA) < 0.06 or Standardised Root Mean Residuals(SRMR) < 0.08 [35].

Research ethics committee/ institutional review board approvals were not required as this was a systematic review of pre-existing evidence.

3. Results

3.1. Paper selection

A total of 10793 articles were identified (including 6964 found in May 2019, with an additional 3829 in February 2021). Full-text reviews were conducted for 437. A total of 46 studies were retained in the review

Table 1
Summary of included studies.

Study	Year	Place of study sites	Measure	No. of domains	No. of items	N	Age (Mean±SD, Range) years
Au et al. [41]	2011	Hong Kong	SCNS-SF34-C	5	34	348	53.74 ± 9.91, 27–81
Chen et al. [42]	2019	Mainland China	MDASI-GI-C	2	25	527	54.9 ± 11.2, 25–81
Cheng et al. [43]	2009	Hong Kong	MSAS	3	32	370	54.2 ± 11.9, 21–84
Chie et al. [44]	2010	Taiwan	EORTC QLQ-OES18	4	18	95	61 ± 12 for the off-treatment group 58 ± 12 for the on-treatment group
Chie et al. [45]	2010	Taiwan	EORTC QLQ-OV28	7	28	96	54 ± 12
Cui et al. [46]	2014	Mainland China	MQOL	4	17	531	45–60 years: 27.3% 60–74 years: 30.9% 75 years or older: 32.8%
Fu et al. [47]	2018	Mainland China	MSAS	3	32	359	53.69 ± 11.76,22–80
Ger et al. [48]	1999	Taiwan	BPI-T		0–10 numeric scales for item rating with 0 being 'no pain' and 10 being 'pain as bad as you can imagine'	534	55.1 ± 15.1, 12–80
Han et al. [49]	2017	Mainland China	SCNS-SF34-C	5	34	861	51.66 ± 12.75
He et al. [50]	2020	Mainland China	SAIL	3	25	258	48.34 ± 13.17, 18–76
Hu et al. [51]	2015	Mainland China	MQOL	4	16	126	48.9 ± 15.8, 20–84
Hu et al. [52]	2003	Taiwan	MQOL-Taiwan	4	16	64	47.77 ± 16.23
Huang et al. [53]	2017	Mainland China	MAX-PC	3	18	254	68.25 ± 7.61, 42–89
Lai et al. [54]	2009	Taiwan	MPI-sC	4	8	106	58.4 ± 15.4
Lam et al. [55]	2008	Hong Kong	MSAS	4	32	256	59.0 ± 9.78, 27–75
Lam et al. [55]	2008	Hong Kong	CMSAS	3	14	256	59.0 ± 9.78, 27–76
Lam et al. [56]	2015	Hong Kong	DCS	5	16	471	54.4 ± 9.9, 29–86
Lee et al. [57]	2017	Taiwan	UWQOL-C	2	13	211	59.4 ± 13.4, 30–91
Li et al. [58]	2016	Mainland China	C-HADS	2	14	641	54.6 ± 12.9, 18–88
Li et al. [40]	2013	Hong Kong, Taiwan	SCNS-SF34-C	5	34	360 (Hong Kong) 263 (Taiwan)	65.7 ± 11.1, 27–90 (Hong Kong) 58.4 ± 11.2, 23–82(Taiwan)
Li et al. [59]	2019	Mainland China	QONCS	5	28	612	56.17 ± 10.90, 22–80
Li et al. [60]	2007	Mainland China	MDASI-TCM		26	317	55.36 ± 11.82
Lin et al. [61]	2015	Taiwan	C-SpIRIT	5	33	260	55.89 ± 10.86, 20–65
Lou et al. [62]	2014	Mainland China	FACIT-AI	4	13	69	26–88
Luo et al. [63]	2014	Mainland China	EORTC QLQ-C15-PAL	10	15	187	59.1 ± 10.8
Luo et al. [64]	2015	Mainland China	EORTC QLQ-BM22	4	22	121	30–88 (58.00 ± 10.77)
Luo et al. [65]	2014	Mainland China	EORTC IN-PATSAT32	4	32	119	58, 23–88
Quan et al. [66]	2016	Mainland China	QLASTCM-Ga		43	240	59.3 ± 11.7, 27–92
Sun et al. [67]	2020	Mainland China	EORTC QLQ-SWB27	4	27	270	Female 61.64 ± 12.69 Male 57.79 ± 12.52

(*continued on next page*)

Table 1 (*continued*)

Study	Year	Place of study sites	Measure	No. of domains	No. of items	N	Age (Mean±SD, Range) years
Tang et al. [68]	2017	Taiwan	SWBS–M	2	20	243	58.6 ± 15.21, 16–92
Tang et al. [69]	2021	Mainland China	DADDS-C	2	15	256	50.73 ± 11.35
Tao et al. [70]	2021	Mainland China	Spiritual Coping Questionnaire	7 dimensions and 2 subscales	26	442	18–83 (52.03 ± 12.14)
Wang et al. [71]	1996	Mainland China	BPI-C		0–10 numeric scales for item rating with 0 being 'no pain' and 10 being 'pain as bad as you can imagine'	147	54 ± 18–86
Wang et al. [72]	2015	Mainland China	BFS-C	6	17	658	47.52 ± 8.23, 25–70
Wang et al. [73]	2019	Hong Kong	PNPC-sv	8	33	174	< 60 y = 109,62.66% > 60 y = 65, 37.4%
Wang et al. [74]	2004	Mainland China	MDASI-C	2	19	249	51, 18–77
Wong et al. [75]	2008	Hong Kong	ChPSQ-9	2	9	222	55.6 ± 12.37
Wong et al. [76]	2012	Hong Kong	FACT-C	5	36	536 (76.1% CRC, 23.9% Polyps)	63.9 ± 11.2
Wu et al. [77]	2020	Mainland China	CPPCN	6	36	198	57.6 ± 12.4, 22–82
Xia et al. [78]	2017	Mainland China	C-MiLS	5	25	251	44.4 ± 13.43
Yan et al. [79]	2022	Mainland China	ADAS	3	13	213	60–83 (65.43 ± 4.698)
Yin et al. [80]	2020	Mainland China	PTPQ	4	12	198	55.90 ± 10.82
Zhang et al. [81]	2016	Mainland China	EORTC QLQ-C15-PAL	10	15	243	59
Zhang et al. [82]	2022	Mainland China	Symptom assessment scale for patients with advanced cervical cancer undergoing concurrent chemoradiotherapy	6	23	171	26–78 (53.06 ± 9.65)
Zhang et al. [83]	2016	Mainland China	EORTC QLQ-BM22	4	22	221	60 ± 11.28, 29–88
Zhao et al. [84]	2000	Mainland China	EORTC QLQ-C30	3	30	191	42.2 ± 14.3, 18–78
Zheng et al. [85]	2021	Mainland China	Quality Care Questionnaire- Palliative Care	4	32	289	56.08 ± 11.91

ADAS: Advance Directive Attitude Survey; BFS-C: Chinese version of the Benefit Finding Scale; BPI: Brief Pain Inventory; ChPSQ-9: Nine-Item Chinese Patient Satisfaction Questionnaire; CPPCN: Cancer patients' palliative care needs questionnaire; DCS: Decisional Conflict Scale; EORTC: European Organisation for Research and Treatment of Cancer; FACT-C: Functional Assessment of Cancer Therapy – Colorectal; HADS: Hospital Anxiety and Depression Scale; MAX-PC: Chinese version of the Memorial Anxiety Scale for Prostate Cancer; MDASI: M. D. Anderson Symptom Inventory; MDASI-GI-C: Chinese Version of the M. D. Anderson Symptom Inventory Gastrointestinal Cancer Module; MiLS: Meaning in Life Scale; MPI-sC: Multidimensional Pain Inventory-Screening Chinese version; MQOL: McGill Quality of Life Questionnaire; MSAS: Memorial Symptom Assessment Scale; PNPC-sv: Problems and Needs in Palliative Care questionnaire-short version; PTPQ: Prognosis and Treatment Perception Questionnaire; QLASTCM-Ga: Quality of life assessment scale for gastric cancer patients; QLQ-BM22: Bone Metastases; QLQ-C15-PAL: Quality of Life in palliative cancer care patients; QLQ-C30: Quality of Life of Cancer Patients; QLQ-IN-PATSAT32: Satisfaction with In-Patient Cancer Care; QLQ-OES18: Oesophageal patients; QLQ-OV28: Ovarian patients; QLQ-SWB27: Spiritual Wellbeing; QONCS: Quality of Oncology Nursing Care Scale; SAIL: Spiritual Attitude and Involvement List; SCNS-SF34-C: Chinese version of the short-form Supportive Care Needs Survey questionnaire; SpIRIT: Spiritual Interests Related Illness Tool; SWBS–M: Spiritual Well-Being Scale-Mandarin version; TCM: Traditional Chinese medicine; UWQOL-C: University of Washington Quality of Life Chinese Version.

(see Fig. 1).

3.2. Summary of results

The retained 46 studies reported 39 PROMs (see Table 1 and more detailed information in the appendix 4): 30 studies conducted in Mainland China, eight in Hong Kong, and nine in Taiwan (one study [40] in both Hong Kong and Taiwan). All measures were developed for paper completion. Of the 15 PROMs developed for a single type of cancer, four were colorectal, three breast, two cervical, one oesophageal, one prostate, one ovarian, one gastric, one head and neck and one hepatocellular. With respect to disease stage of study participants, in 22 publications 100% were advanced, in 18 over 50% (50%–87.8%) participants were advanced, and six less than 50%. The number of domains measured ranged from 2 to 13, the number of items ranging from 8 to 36, with completion time from 2 to 30 min.

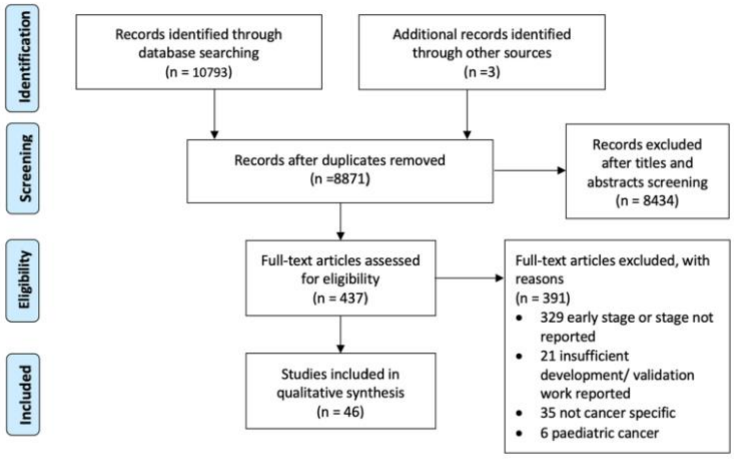

Fig. 1. Flow chat of studies selection.

3.3. PROM domains

Included PROMs were categorised in the Table 2 in accordance with Toolkit of Instruments to Measure End-of-Life Care [36,37]. We identified 18 measures of quality of life, six measures of physical symptoms, six measures of emotional and cognitive symptoms, five measures of spirituality, two measures of satisfaction and quality of care measure, one measure of continuity of care measure and one measure of advance care planning. No measure was found in the functional status category.

3.4. Quality of cross-cultural adaptation (CCA) process

Of the 46 studies included in this review, three reported PROM development in China, and 43 reported PROMs initially developed in other countries cross-culturally adapted to the Chinese population. (See Table 3) The quality of CCA was evaluated against Quality criteria [38] of the cross-cultural adaptation process and reported in Table 3. Of the 43 eligible articles, 33 (76.7%) reported some information on the translation and adaptation process, while 10 reported no details of the CCA process.

Forward translation and back translation were the most tested stages, with 31 and 30 articles respectively completing these aspects of translation. In contrast, only one of the articles reported any reports or forms submitted to the developer of the instrument or central committee for appraisal. In the forward translation stage, 13 articles were rated as "+" (translations conducted by two or more independent translators) and 18 as "?" (doubtful translation process) where translators' background or awareness status about the tool is different from the recommended, translation conducted by one translator mainly due to translation conducted by one translator. All the studies that completed the backward translation stage were rated as "?" (doubtful back-translation process, e.g. English is not the translators' first language, or they are aware of the instrument, back-translation conducted by one translator only). Expert committee review stage was described in 16 studies, of which 11 were all rate as "?" (doubtful expert committee review) because committee experts' roles were not clearly indicated, or the committee only reviewed part of documents generated in previous stages. Of the 21 articles that described pretesting, only three was rated as "+", while eight as "?" (doubtful design) where there is no mention of the number of subjects tested, target population not described) and ten studies did not meet the recommended sample size (> 30). No articles were rated as "+" in more than four stages of the cross-cultural adaptation process.

See Appendix 2 for Quality criteria of the cross-cultural adaptation process.

Table 2
Categorisation of the PROMs.

Domain (as recommended by the Toolkit [36,37])	PROMs
Quality of life	CPPCN, EORTC IN-PATSAT32, EORTC QLQ-BM22, EORTC QLQ-C15-PAL, EORTC QLQ-C30, EORTC QLQ-OES18, EORTC QLQ-OV28, MDASI-C, MDASI-GI-C, MDASI-TCM, UWQOL-C, FACIT-AI, FACT-C, MQOL (Mainland, Taiwan), PNPC-sv, QLASTCM-Ga, Quality Care Questionnaire-Palliative Care, SCNS-SF34-C (Mainland, HK, Taiwan)
Physical symptoms	MSAS-Ch, MSAS-SF, CMSAS, BPI, (Mainland, Taiwan), MPI-sC, Symptom assessment scale for patients with advanced cervical cancer undergoing concurrent chemoradiotherapy
Emotional and cognitive symptoms	BFS-C, C-HADS, DADDS-C, MAX-PC, PTPQ, SAIL
Continuity of care	DCS
Spirituality	C-MiLS, C-SpIRIT, QONCS, SCQ, SWBS–M
Satisfaction and quality of care	ChPSQ-9, Quality Care Questionnaire- Palliative Care
Functional status	–
Advance care planning	ADAS

3.5. Measurement properties

The properties are summarised in Table 4.

3.6. Validity

Content validity was tested and met the criteria for acceptability in 21/46 (45.7%) studies. CVI (content validity index) was used to determined content validity, which using ratings of item relevance by content experts.

Construct validity testing was carried out in 44/46 (95.6%) of the studies, reporting 39/39 (100%) PROMs. In all, 24/44 (54.5%) studies were rated as "+", 18/44 (40.9%) as "?", two (0.05%) as "-" and two (0.05%) as "0".

Table 3
Quality of cross-cultural adaptation process.

PROMs	Study	Place of study sites	Forward translation	Synthesis	Backward translation	Expert committee review	Pretesting	Submission
ADAS	Yan et al.[79]	Mainland China	?	?	?	?	?	0
BFS-C	Wang et al. [72]	Mainland China	?	0	?	0	0	0
BPI	Wang et al. [71]	Mainland China	?	0	?	0	0	0
	Ger et al.[48]	Taiwan	?	0	?	–	0	0
C-HADS	Li et al.[58][a]	Mainland China	?	+	?	0	0	0
C-SpIRIT	Lin et al.[61]	Taiwan	+	0	0	+	0	0
ChPSQ-9	Wong et al. [75]	Hong Kong	0	0	0	0	0	0
DADDS-C	Tang et al. [69]	Mainland China	?	?	?	0	?	0
DCS	Lam et al. [56]	Hong Kong	?	0	?	?	0	0
EORTC IN-PATSAT32	Luo et al.[65]	Mainland China	0	0	0	0	0	0
EORTC QLQ-BM22	Zhang et al. [83]	Mainland China	0	0	0	0	0	0
	Luo et al.[64]	Mainland China	?	0	?	0	0	0
EORTC QLQ-C15-PAL	Luo et al.[63]	Mainland China	0	0	0	0	0	0
	Zhang et al. [81][a]	Mainland China	+	+	?	0	–	0
EORTC QLQ-C30	Zhao et al. [84]	Mainland China	+	+	?	0	–	0
EORTC QLQ-OES18	Chie et al. [44]	Taiwan	0	0	0	0	?	0
EORTC QLQ-OV28	Chie et al. [45]	Taiwan	0	0	0	0	?	0
EORTC QLQ-SWB27	Sun et al.[67]	Mainland China	?	0	?	0	0	0
FACIT-AI	Lou et al.[62]	Mainland China	+	?	?	?	?	0
FACT-C	Wong et al. [76]	Hong Kong	0	0	0	0	0	0
MAX-PC	Huang et al. [53]	Mainland China	?	+	?	+	–	0
MDASI-C	Wang et al. [74]	Hong Kong	?	+	?	?	?	0
MDASI-GI-C	Chen et al. [42]	Mainland China	?	0	?	0	0	0
MDASI-TCM	Li et al.[60]	Mainland China	0	0	0	0	0	0
MPI-sC	Lai et al.[54]	Taiwan	?	0	?	0	0	0
MQOL	Cui et al. [46][b]	Mainland China	0	0	0	0	0	0
	Hu et al.[51]	Mainland China	?	0	?	0	0	0
	Hu et al.[52]	Taiwan	?	0	?	+	–	0
MSAS	Lam et al. [55]	Hong Kong	0	0	0	0	0	0
	Cheng et al. [43]	Hong Kong	?	0	?	?	–	0
	Lam et al. [55]	Hong Kong	?	0	?	0	0	0
	Fu et al.[47]	Mainland China	?	0	?	?	+	0
PNPC-sv	Wang et al. [73]	Hong Kong	+	+	?	0	–	0
PTPQ	Yin et al.[80]	Mainland China	+	+	?	0	–	0
QLASTCM-Ga	Quan et al. [66]	Mainland China	0	0	0	0	0	0
QONCS	Li et al.[59]	Mainland China	+	+	?	?	+	0
Quality Care Questionnaire-Palliative Care	Zheng et al. [82]	Mainland China	+	+	?	+	?	?
SAIL	He et al.[50]	Mainland China	+	+	?	+	+	0
SCNS-SF34-C	Au et al.[41]	Hong Kong	?	0	?	?	0	0
	Li et al.[40][a]	Hong Kong, Taiwan	+	+	?	?	–	0
	Han et al. [49]	Mainland China	+	+	?	?	–	0
SCQ	Tao et al.[70]	Mainland China	+	+	?	?	?	+
SWBS–M	Tang et al. [68]	Taiwan	0	0	0	0	0	0
UWQOL-C	Lee et al.[57]	Taiwan	+	+	?	0	–	0

[a] CCA process was reported in another publication: C-HADS [86], SCNS-SF34-C [49], EORTC QLQ-C15-PAL [84].
[b] The MQOL has been translated into Chinese, and its cross-cultural validity and reliability have been tested in Hong Kong and Taiwan [46], but no psychometric properties have been reported in Mainland China.

Table 4
Quality of measurement properties.

PROMs	Study	Content validity	Internal consistency	Construct validity	Test-retest reliability	Responsiveness	Floor and ceiling effects	Interpretability
ADAS	Yan et al. [79]	+	+	?	0	0	0	?
BFS-C	Wang et al. [72]	0	+	+	+	0	0	0
BPI-C	Wang et al. [71]	0	–	+	0	0	0	0
	Ger et al. [48]	0	+	+	–	0	0	?
C-HADS	Li et al. [58]	0	+	+	0	0	0	0
C-MiLS	Xia et al. [78]	+	+	+	0	0	0	0
C-SpIRIT	Lin et al. [61]	+	+	+	0	0	0	0
ChPSQ-9	Wong et al. [75]	0	+	+	0	0	0	0
CPPCN	Wu et al. [87]	+	+	?	0	0	0	0
DADDS-C	Tang et al. [69]	0	+	?	0	0	0	0
DCS	Lam et al. [56]	0	+	+	0	0	0	0
EORTC IN-PATSAT32	Luo et al. [65]	0	+	?	0	0	0	0
EORTC QLQ-BM22	Zhang et al. [83]	0	–	?	0	0	0	0
	Luo et al. [64]	0	+	?	0	0	0	0
EORTC QLQ-C15-PAL	Luo et al. [63]	0	–	?	0	0	0	0
	Zhang et al. [81]	0	+	–	0	0	0	0
EORTC QLQ-C30	Zhao et al. [84]	0	–	?	0	0	0	0
EORTC QLQ-OES18	Chie et al. [44]	0	–	0	0	0	?	0
EORTC QLQ-OV28	Chie et al. [45]	0	–	0	0	0	?	0
EORTC QLQ-SWB27	Sun et al. [88]	+	+	?	0	0	0	0
FACIT-AI	Lou et al. [62]	+	+	?	0	0	0	0
FACT-C	Wong et al. [76]	0	–	+	0	0	–	0
MAX-PC	Huang et al. [53]	+	+	+	+	0	0	0
MDASI-C	Wang et al. [74]	0	+	+	0	0	0	?
MDASI-GI-C	Chen et al.	0	+	?	0	0	0	0
MDASI-TCM	Li et al. [60]	0	+	+	+	0	?	0
MPI-sC	Lai et al. [54]	+	+	+	0	0	0	0
MQOL	Cui et al. [46]	0	0	+	0	0	0	?
	Hu et al. [51]	+	–	+	–	0	0	0
	Hu et al. [52]	+	–	+	0	0	0	0
MSAS	Lam et al. [55]	0	0	+	0	0	0	?
	Cheng et al. [43]	+	+	+	–	0	+	?
	Lam et al. [55]	0	0	+	0	0	0	?
	Fu et al. [47]	+	+	+	+	0	0	?
PNPC-sv	Wang et al.	+	+	?	0	0	0	0
PTPQ	Yin et al. [89]	+	+	?	0	0	0	0

(continued on next page)

Table 4 (*continued*)

PROMs	Study	Content validity	Internal consistency	Construct validity	Test-retest reliability	Responsiveness	Floor and ceiling effects	Interpretability
QLASTCM-Ga	Quan et al.[66]	+	+	+	+	–	0	0
QONCS	Li et al. [90]	+	+	?	+	0	0	0
Quality Care Questionnaire- Palliative Care	Zheng et al.[85]	+	+	?	+	0	0	0
SAIL	He et al. [91]	+	+	?	+	0	0	0
SCNS-SF34-C	Au et al. [41]	0	+	+	0	0	–	0
	Li et al. [40]	0	+	+	0	0	0	0
	Han et al. [49]	0	+	–	0	0	+	0
SCQ	Tao et al. [70]	+	+	?	+	0	0	0
SWBS–M	Tang et al.[68]	0	+	+	0	0	0	?
Symptom assessment scale for patients with advanced cervical cancer undergoing concurrent chemoradiotherapy	Zhang et al.[82]	+	+	?	+	0	0	0
UWQOL-C	Lee et al. [57]	+	–	+	+	0	0	0

3.7. Reliability

Internal consistency was tested in 44/46 (95.7%) studies, reporting 38/39 (97.4%) PROMs. Three of these had inadequate sample size (< 100) and seven reported Cronbach's alpha(s) < 0.7 in some subscales, which led to a "-" rating in all these ten studies.

Test-retest reliability testing was carried out in 14/46 (30.4%) of the studies. Of those three (21.4%) were rated as "-" due to ICC values < 0.7 in some subscales.

3.8. Responsiveness

Only one study [17] (2.17%) analysed responsiveness. Standardised response means (SRM) was calculated using a paired t-test to assess clinically meaningful changes.

3.9. Floor and ceiling effects

Floor and ceiling effects were tested in seven out of 46 (15.2%) studies. Of those two (28.6%) reported that ≤ 15% of the respondents achieved the highest or lowest possible scores. Three studies claimed floor and ceiling effects testing was conducted, but no detailed information was reported, therefore rating was "?".

Interpretability was tested in eight (17.4%) studies of those all were rated as "?" because Minimal important change (MIC) was not reported.

4. Discussion

A total of 46 studies, including 39 PROMs, were included in this review. None of the PROMs addressed all four domains of concern to patients with advanced cancer (i.e. physical, psychological, social and spiritual), and none were valid across all psychometric properties. No articles were rated "+ " in more than four stages of the cross-cultural adaptation process, demonstrating weak equivalence between the original language version and Chinese. The quality of measurement properties varied greatly. Content validity was tested and reported satisfaction in 21 (45.7%) studies. Internal consistency was tested in 44 (95.7%) studies, including 38 (97.4%). Responsiveness was only analysed in one study. Based on COSMIN, none identified PROMs were valid across all properties nor appropriate to use. Despite the incomplete information in the identified studies, results of this review suggest researchers and physicians working with advanced cancer patients in China have to choose the available measures without adequate psychometric properties, which risk unethical research and wasted resources [92].

None of the studies on measurement properties in this review achieved a rating of good quality in all characteristics. Internal consistency and construct validity were widely assessed in the included studies. In contrast, high proportion the information on properties per measure in each included study is missing and evidence is particularly limited in test-retest reliability, responsiveness, floor and ceiling effects and interpretability and greatly variations were observed in the methodological quality. Since accurate and reproducible measurements are prerequisites for an adequate instrument, acceptable validity and reliability is essential. There is a clear need of re-evaluation of some particular properties of measures with poor psychometric testing quality in future research. There is currently no ideal outcome measure for use in advanced cancer patients in China as the COSMIN recommends PROMs with evidence for sufficient content validity and at least low-quality evidence for sufficient internal consistency can be trusted [26,27,93].

Given that multidimensional unmet needs are associated with increased healthcare costs and increased distress, which can reduce survival, measures should ensure that all relevant dimensions are assessed efficiently [94,95]. For the quality-of-life scale, the only scale that met this standard was QLASTCM-Ga, which is specifically for gastric cancer patients in mainland China. There was no other quality of life scale that met standards for other cancer types in Hong Kong and Taiwan. Similarly, the only emotional and cognitive symptom scale that met standards was MAX-PC, which measures anxiety in prostate cancer patients in mainland China. MSAS met standards for use in the mainland and Hong Kong for evaluating physical symptoms, while MPI-sC met standards for use in Taiwan to measure pain in patients with advanced cancer. For scales measuring spirituality domain, C-MiLS met standards for use in mainland China and C-SpIRIT in Taiwan. Further research is needed to promote the use of multidimensional measures in China for clinical trials to measure treatment effects and in clinical practice to identify and prioritise problems, facilitate communications, monitor changes and treatment responses, staff training, and in clinical audit and governance.

When measuring non-tangible concepts, such as palliative care needs for advanced cancer patients, the methodological challenge in content validation is longstanding what matters and what should be measured.

Most of the included studies used CVI to establish face and content validity, which is the widely used method of quantifying content validity for multiitem scales [96]. An alternative method to establish face and content validity is qualitative methods, which were used in none of the included studies. Rigorous and transparent qualitative methodology is one of the most suitable methods for assessing content validity [97]. Qualitative analyses of the content validity of a measure assess not only the opinions of the measure under consideration but also the target population's conceptualisation intended to be assessed in order to have a better understanding of what matters to the participants and a firmer conclusion as to the content validity. Qualitative content validation can be established with the stakeholders who have first-hand and personal experience, which allow researchers to observe individuals with different background and how the construct of interest manifests itself in different individuals [98]. As there was no study reporting content validity qualitatively in advanced cancer patients in China, qualitative work amongst this population is needed to allow data from different perspectives and different methodologies.

5. Strengths and limitations

This systematic review summarised and critically appraised the psychometric measurement properties of existing PROMs used among advanced cancer patients in China, which provided the first robust and transparent evaluation of patient-reported measures for advanced cancer patients in China. The strengths of this systematic review are the comprehensive search strategy which found more than 10000 articles for potential inclusion and 46 papers were systematically appraised and compared, and the use of the COSMIN methodology.

This review also has several limitations. First, the search was restricted to databases in English or in Mainland China as the authors had no access to databases in Hong Kong and Taiwan. In addition, it was sometimes unclear if specific criteria on the COSMIN checklist were not performed or not reported on. Therefore, we had to use other evaluation criteria that were not suggested by COSMIN to assess the quality of measurement properties.

6. Conclusion

Collecting information using PROMs is a critical component of evaluating the complex needs of advanced cancer patients clinically and in research. As there are currently no contextually appropriate and psychometrically sound PROMs that measure the multidimensional concerns of advanced cancer patients in China, there is an urgent need for further high-quality methodological studies to properly evaluate and strengthen measurement properties. Developing outcome measures for advanced cancer patients in China is invaluable: to improve audit, clinical services and assess the quality of care, for research purposes and secure funding. A potential solution is adapting existing measures that have sound psychometric properties.

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Declaration of Competing Interest

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Appendix 1. Search strategy

1. ("Terminal Care" or "Palliative Care" or "Hospice Care" or "Terminally Ill Patients" or "Hospice Patients").hw. OR (palliati* or terminal or terminally ill* or end stage disease* or end of life or hospice* or advanced cancer or metasta* or late stage* or advanced stage* or advanced illness or incur* or end-stage).af.
2. (adenoma* or anticarcinogen* or blastoma* or cancer* or carcinogen* or carcinom* or carcinosarcoma* or chordoma* or germinoma* or gonadoblastoma* or hepatoblastoma* or hodgkin* or leukemi* or lymphangioma* or lymphangiomyoma* or lymphangiosarcoma* or lymphom* or malignan* or melanom* or meningioma* or mesenchymoma* or mesonephroma* or metasta* or neoplas* or neuroma* or nsclc or oncogen* or oncolog* or paraneoplastic or plasmacytoma* or precancerous or sarcoma* or teratocarcinoma* or teratoma* or tumor* or tumour*).ab,kw,ti.
3. (intermethod comparison or data collection method or validation study or feasibility study or pilot study or psychometry or reproducibility or observer variation or discriminant analysis or validity).hw. or (reproducib* or audit or psychometr* or clinimetr* or clinometr* or observer variation or reliab* or valid* or coefficient or internal consistency or (cronbach* and (alpha or alphas)) or item correlation or item correlations or item selection or item selections or item reduction or item reductions or agreement or precision or imprecision or precise values or test-retest or (test and retest) or (reliab* and (test or retest)) or stability or interrater or inter-rater or intrarater or intra-rater or intertester or inter-tester or intratester or intratester or interobserver or inter-observer or intraobserver or intraobserver or intertechnician or inter-technician or intra-technician or intratechnician or interexaminer or inter-examiner or intraexaminer or intraexaminer or interassay or inter-assay or intraassay or intra-assay or interindividual or inter-individual or intraindividual or intra-individual or interparticipant or inter-participant or intraparticipant or intraparticipant or kappa or kappas or coefficient of variation or repeatab* or ((replicab* or repeated) and (measure or measures or findings or result or results or test or tests)) or generaliza* or generalisa* or concordance or (intraclass and correlation*) or discriminative or known group or factor analysis or factor analyses or factor structure or factor structures or dimensionality or subscale* or multitrait scaling analysis or multitrait scaling analyses or item discriminant or interscale correlation or interscale correlations or ((error or errors) and (measure* or correlat* or evaluat* or accuracy or accurate or precision or mean)) or individual variability or interval variability or rate variability or variability analysis or (uncertainty and (measurement or measuring)) or standard error of measurement or sensitiv* or responsive* or (limit and detection) or minimal detectable concentration or interpretab* or (small* and (real or detectable) and (change or difference)) or meaningful change or minimal important change or minimal important difference or minimally important change or minimally important difference or minimal detectable change or minimal detectable difference or minimally detectable change or minimally detectable difference or minimal real change or minimal real difference or minimally real change or minimally real difference or ceiling effect or floor effect or item response model or irt or rasch or differential item functioning or dif or computer adaptive testing or item bank or cross-cultural equivalence).ab,kw,ti.

4. (China or Chinese or Mandarin or Cantonese).ab,kw,ti.
5. (addresses OR biography OR case reports OR comment OR directory OR editorial OR festschrift OR interview OR lectures OR legal cases OR legislation OR letter OR news OR newspaper article OR patient education handout OR popular works OR congresses OR consensus development conference OR consensus development conference, nih OR practice guideline).pt. NOT (animals NOT humans).hw.
6. 1 AND 2 AND 3 AND 4
7. 6 NOT 5

Appendix 2. Quality criteria of the cross-cultural adaptation process

Stage	Rating	Quality criteria
I: Forward translation	+	Translations conducted by two or more independent translators
	?	Doubtful translation process (e.g. translators' background or awareness status about the tool are different from the recommended, translation conducted by one translator)
	−	Translation conducted by two non-independent translators
	0	No information on the forward translation process
II: Synthesis	+	Synthesis conducted by the same two or more translators from stage I
	?	Doubtful synthesis process (e.g. different translators or professionals from stage I)
	0	No information on the synthesis process
III: Back-translation	+	Back-translation made by two or more independent translators for whom English is the first language and who are naive to the instrument
	?	Doubtful back-translation process (e.g. English is not the translators' first language, or they are aware of the instrument, back-translation conducted by one translator only)
	−	Back-translation made by two non-independent translators
	0	No information on back-translation process
IV: Expert committee review	+	An expert committee is reported, and participants' roles clearly indicated. The committee reviews all documents
	?	Doubtful expert committee review (e.g. there is no mention of participants' roles)
	−	The committee reviews only one or some documents
	0	No information on expert committee
V: Pretesting	+	Pre-test was conducted in 30 or more subjects from the target population
	?	Doubtful design (e.g. there is no mention of the number of subjects tested, target population not described)
	−	Pre-test was conducted in less than 30 subjects
	0	No information on the pre-test
VI: Submission	+	All reports and forms were submitted to the developer of the instrument or central committee for appraisal
	?	Doubtful submission process (e.g. the reports and forms were received by others instead of the developer of the instrument or central committee)
	0	No information on submission process

Appendix 3. Quality criteria for measurement properties of health status questionnaires

Property	Definition	Quality criteria
1. Content validity	The extent to which the domain of interest is comprehensively sampled by the items in the questionnaire	+ A clear description is provided of the measurement aim, the target population, the concepts that are being measured, and the item selection AND target population and (investigators OR experts) were involved in item selection; ? A clear description of above-mentioned aspects is lacking OR only target population involved OR doubtful design or method; - No target population involvement; 0 No information found on target population involvement.
2. Internal consistency	The extent to which items in a (sub)scale are intercorrelated, thus measuring the same construct	+ Factor analyses performed on adequate sample size (7 * # items and $\geq$100) AND Cronbach's alpha(s) calculated per dimension AND Cronbach's alpha(s) between 0.70 and 0.95; ? No factor analysis OR doubtful design or method; − Cronbach's alpha(s) $<$ 0.70 or $>$ 0.95, despite adequate design and method; 0 No information found on internal consistency.
3. Construct validity	The extent to which scores on a particular questionnaire relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured	+ Specific hypotheses were formulated AND at least 75% of the results are in accordance with these hypotheses; ? Doubtful design or method (e.g., no hypotheses); − Less than 75% of hypotheses were confirmed, despite adequate design and methods; 0 No information found on construct validity.
4. Reliability	The proportion of the total variance in the measurements which is due to "true" differences	+ ICC or weighted Kappa $\geq$ 0.70; ? Doubtful design or method (e.g., time interval not mentioned); - ICC or weighted Kappa $<$ 0.70, despite adequate design and method; 0 No information found on reliability.
5. Responsiveness	The ability of a questionnaire to detect clinically important changes over time	+ SDC or SDC $<$ MIC OR MIC outside the LOA OR RR $>$ 1.96 OR AUC $\geq$ 0.70; ? Doubtful design or method; − SDC or SDC $\geq$ MIC OR MIC equals or inside LOA OR RR $\leq$ 1.96 OR AUC $<$ 0.70, despite adequate design and methods; 0 No information found on responsiveness.
6. Floor and ceiling effects	The number of respondents who achieved the lowest or highest possible score	+ $\leq$15% of the respondents achieved the highest or lowest possible scores; ? Doubtful design or method;

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(*continued*)

Property	Definition	Quality criteria
7. Interpretability	The degree to which one can assign qualitative meaning to quantitative scores	− >15% of the respondents achieved the highest or lowest possible scores, despite adequate design and methods; 0 No information found on interpretation. + Mean and SD scores presented of at least four relevant subgroups of patients and MIC defined; ? Doubtful design or method OR less than four subgroups OR no MIC defined; 0 No information found on interpretation.

MIC = minimal important change; SDC = smallest detectable change; LOA = limits of agreement; ICC = Intraclass correlation coefficient; SD, standard deviation. + = positive rating; ? = indeterminate rating; − = negative rating; 0 = no information available.

Appendix 4. Summary of included studies

Study	Year	Place of study sites	Measure	No. of domains	No. of items	Completion time (min)	N	Age (Mean±SD, Range) years	Gender % female	Diagnosis	Cancer stage
Au et al. [41]	2011	Hong Kong	SCNS-SF34-C	5 (physical and daily living needs, psychological needs, patient care and support needs, health systems and information needs, sexuality needs)	34	10	348	53.74 ± 9.91, 27–81	100%	Breast cancer	43.4% advanced stages (III or IV)
Chen et al. [42]	2019	Mainland China	MDASI-GI-C	2 (symptom severity and interference subscales)	25	20–30	527	54.9 ± 11.2, 25–81	37.0%	Gastric 151 (28.7%) Colon 126 (23.9%) Rectal 138 (26.2%) Hepatobiliary 65 (12.3%) Pancreatic 25 (4.7%) Esophageal 22 (4.2%)	Stage I 0 Stage II 25(4.7%) Stage III 112 (21.3%) Stage IV 390 (74.0%)
Cheng et al. [43]	2009	Hong Kong	MSAS	3 (physical symptom subscale score, psychological symptom subscale score, global distress index)	32		370	54.2 ± 11.9, 21–84	52.20%	22% head and neck cancer 22% breast cancer 21% colorectal cancer	Stage I= 11.6% Stage II= 21.1% Stage III= 28.4% Stage IV= 34.6% unknown= 4.3%
Chie et al. [44]	2010	Taiwan	EORTC QLQ-OES18	4 (dysphagia, eating problems, reflux, pain)	18		95	61 ± 12 for the off-treatment group 58 ± 12 for the on-treatment group		Oesophageal cancer	Most patients were in advanced (III or IV) stages at diagnosis
Chie et al. [45]	2010	Taiwan	EORTC QLQ-OV28	7 (abdominal/ gastrointestinal symptoms, peripheral neuropathy, other chemotherapy side effects, hormonal/ menopausal, body image, attitude to disease and treatment, and sexual function)	28		96	54 ± 12	100%	Ovarian cancer	Most patients were in advanced (III or IV) stages at diagnosis
Cui et al. [46]	2014	Mainland China	MQOL	4 (physical, psychological, existential, support)	17		531	45–60 years: 27.3% 60–74 years: 30.9% 75 years or older: 32.8%	44.10%	Cancer	Stage IV
Fu et al. [47]	2018	Mainland China	MSAS	3 (physical symptom, psychological symptom, global distress)	32	5	359	53.69 ± 11.76,22–80	47.40%	29.0% Colorecta cancer 27.9% Gastric cancer 20.6% Breast cancer 13.6% Lung cancer 8.9% Others	Stage I= 1.7% Stage II= 5.6% Stage III= 9.2% Stage IV= 78.6% Unknown= 5.0%
Ger et al. [48]	1999	Taiwan	BPI-T		0–10 numeric scales for item rating with 0 being 'no pain' and 10 being 'pain as		534	55.1 ± 15.1, 12–80	36%	18% lung cancer 11% colon and rectum cancer 9% liver cancer 8% stomach cancer 7% breast cancer 6% uterus cervix cancer 41% others	61% advanced

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(*continued*)

Study	Year	Place of study sites	Measure	No. of domains	No. of items	Completion time (min)	N	Age (Mean±SD, Range) years	Gender % female	Diagnosis	Cancer stage
					bad as you can imagine'						
Han et al. [49]	2017	Mainland China	SCNS-SF34-C	5 (physical and daily living needs, psychological needs, patient care and support needs, health systems and information needs, sexuality needs)	34		861	51.66 ± 12.75	43.30%	25.9% gastrointestinal tract cancer 23.7% nasopharynx cancer	71.2% advanced
He et al. [50]	2020	Mainland China	SAIL	3 (connectedness with oneself, connectedness with the environment, connectedness with the transcendent)	25		258	48.34 ± 13.17, 18–76	37.6%	solid tumours, 213 (82.6%)	Stage IV= 188, 72.9%
Hu et al. [51]	2015	Mainland China	MQOL	4 (physical, psychological, existential, and support)	16		126	48.9 ± 15.8, 20–84	44.40%	41.3% Thoracic cancer 25.4% Digestive cancer 7.9% Head and neck cancer 17.5% Genitourinary cancer 7.9% Others	Stage I= 4.8% Stage II= 19.5% Stage III= 24.3% Stage IV= 39.7% Undiagnosed= 11.7%
Hu et al. [52]	2003	Taiwan	MQOL-Taiwan	4 (physical, psychological, existential, and support)	16	30	64	47.77 ± 16.23	37.50%	39.1% haematological cancer 18.8% gastrointestinal tract cancer 15.6% lung cancer 6.3% gynaecological organs cancer	
Huang et al. [53]	2017	Mainland China	MAX-PC	3 (general prostate cancer anxiety, anxiety related to prostate-specific antigen testing, fear of recurrence)	18		254	68.25 ± 7.61, 42–89	0%	Prostate Cancer	22.4% locally advanced 33.8% advanced
Lai et al. [54]	2009	Taiwan	MPI-sC	4 (pain severity, pain interference with life activities, affective distress, life control)	8		106	58.4 ± 15.4	46.20%	Breast cancer Lung cancer Head and neck cancer Gastrointestinal cancer	advanced cancer
Lam et al. [55]	2008	Hong Kong	MSAS	4 (global distress index, physical symptom distress score, psychological symptom distress score, total MSAS)	32	6	256	59.0 ± 9.78, 27–75	34%	Colorectal cancer	20% were undergoing palliative radiation therapy/ chemotherapy 20% were undergoing symptomatic care
Lam et al. [55]	2008	Hong Kong	CMSAS	3 (physical symptom, psychological symptom, total CMSAS)	14		256	59.0 ± 9.78, 27–76	34%	Colorectal cancer	20% were undergoing palliative radiation therapy/ chemotherapy 20% were undergoing symptomatic care
Lam et al. [56]	2015	Hong Kong	DCS	5 (informed, values clarity, support, uncertainty, effective decision)	16	5	471	54.4 ± 9.9, 29–86	100%	Breast cancer	Stage 0 = 24.0% Stage I= 25.5% Stage II= 22.9% Stage III= 10.3% Stage IV= 19.3%
Lee et al. [57]	2017	Taiwan	UWQOL-C	2 (physical function, social-emotional function)	13	2–4	211	59.4 ± 13.4, 30–91	7.60%	51.7% oral cavity cancer 48.3% laryngeal cancer	Stage I= 20.4% Stage II= 23.7% Stage III= 23.7% Stage IV= 32.2%
Li et al. [58]	2016	Mainland China	C-HADS	2 (anxiety, depression)	14		641	54.6 ± 12.9, 18–88	49.60%	10.9% Breast cancer 14.5% Ovarian and cervical cancer 23.7% Oesophageal and gastric cancer 13.4% Colorectal cancer 9.2% Liver cancer	Stage III= 56.8% Stage IV= 43.2%

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Study	Year	Place of study sites	Measure	No. of domains	No. of items	Completion time (min)	N	Age (Mean±SD, Range) years	Gender % female	Diagnosis	Cancer stage
										13.7% Lung cancer 11.9% Others	
Li et al. [40]	2013	Hong Kong, Taiwan	SCNS-SF34-C	5 (physical and daily living needs, psychological needs, patient care and support needs, health systems and information needs, sexuality needs)	34		360 (Hong Kong) 263 (Taiwan)	65.7 ± 11.1, 27–90 (Hong Kong) 58.4 ± 11.2, 23–82 (Taiwan)	36.9% (Hong Kong); 43% (Taiwan)	Colorectal cancer	81.2% do not receive active treatment
Li et al. [59]	2019	Mainland China	QONCS	5 (support and confirmation, spiritual care, belonging, value, respect)	28		612	56.17 ± 10.90, 22–80	297 (48.5%)	Lung cancer 108 (17.6%) Stomach cancer 76 (12.4%) colorectal cancer 73 (11.9%) oesophageal cancer 59 (9.6%) breast cancer 58 (9.5%) cervical cancer 51 (8.3%) liver cancer 48 (7.8%) lymphoma 21 (3.4%) bladder cancer 17 (2.8%) pancreatic cancer 15 (2.5%) endometrial cancer 14 (2.3%) nasopharyngeal cancer 13 (2.1%) ovarian cancer 12 (2.0%) prostate cancer 11 (1.8%) other cancers 36 (6.0%)	advanced
Li et al. [60]	2007	Mainland China	MDASI-TCM		26	5	317	55.36 ± 11.82		23.66% Lung cancer 20.82% Breast cancer 15.14% Colorectal cancer 12.93% Lymphoma	Stage I= 14.29% Stage II= 16.03% Stage III= 23.69% Stage IV= 45.99%
Lin et al. [61]	2015	Taiwan	C-SpIRIT	5 (related to beliefs/religion, positive attitudes toward life, love to/from others, seeking for the meaning of life, peaceful mind)	33	3–7	260	55.89 ± 10.86, 20–65	56.92%	24.62% breast cancer 23.85% head and neck cancer 11.92% oral cancer	Stages II and III= 23.85% Stage IV= 45.77%
Lou et al. [62]	2014	Mainland China	FACIT-AI	4 (daily life, upper oesophageal, the volume of ascitic fluid, ascitic complications)	13	3.03 ± 1.22 min	69	26–88	46 (66.7%)	Gastric cancer 16, ovarian cancer 12, liver cancer 12, bowel cancer 12, pancreatic cancer 5, lung cancer 4, breast cancer 2, peritoneal mesothelioma 2, Hodgkin lymphoma 1, unknown 3	advanced
Luo et al. [63]	2014	Mainland China	EORTC QLQ-C15-PAL	10 (physical functioning, emotional functioning, fatigue, pain, nausea and vomiting, dyspnoea, insomnia, appetite loss, constipation and one single-item QOL scale)	15		187	59.1 ± 10.8	57.20%	32.1% lung cancer 9.6% breast cancer 8.6%gastric cancer 5.3% Colorectal cancer	advanced
	2015	Mainland China	EORTC QLQ-BM22	2 symptom scales (painful sites and	22		121	30–88 (58.00 ± 10.77)	67/121	Lung 51(42.1), Breast 26(21.5),	advanced

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Study	Year	Place of study sites	Measure	No. of domains	No. of items	Completion time (min)	N	Age (Mean±SD, Range) years	Gender % female	Diagnosis	Cancer stage
Luo et al. [64]				pain characteristics) and 2 functional scales (functional interference and psychosocial aspects).						Gastrointestinal 6 (5.0), Kidney 2(1.7), Prostate 2(1.7), Bone marrow 1(0.8), Bladder 1(0.8), Other 29(24.0), missing 3 (2.5)	
Luo et al. [65]	2014	Mainland China	EORTC IN-PATSAT32	4(unity of the body and spirit, correspondence between man and universe, specific module, general module)	32		119	58, 23–88	56.30%	cancer	advanced
Quan et al. [66]	2016	Mainland China	QLASTCM-Ga		43		240	59.3 ± 11.7, 27–92	37.50%	gastric cancer	advanced
Sun et al. [67]	2020	Mainland China	EORTC QLQ-SWB27	4(existential, relationships with others, relationship with someone or something greater, relationship with self)	27	10	270	Female 61.64 ± 12.69 Male 57.79 ± 12.52	66.8%		advanced
Tang et al. [68]	2017	Taiwan	SWBS-M	2 (religious well-being, existential well-being)	20		243	58.6 ± 15.21, 16–92	44%	cancer	advanced
Tang et al. [69]	2021	Mainland China	DADDS-C	two domains: better relationship with healthcare providers, preparation for end of life	15		256	50.73 ± 11.35	226 (88.3%)	Breast 186 (72.7%), Lung 20 (7.8), Gastrointestinal 26 (10.2%), Others 24 (9.4%)	Stage III and IV
Tao et al. [70]	2021	Mainland China	Spiritual Coping Questionnaire	7 dimensions and 2 subscales: positive spiritual coping (person, society, environment, transcendent) and negative spiritual coping (person, society, transcendent)	26	5–15 min	442	18–83 (52.03 ± 12.14)	161/442	Lung cancer 135, Gastrointestinal cancer 147, Head and Neck cancer 47, Lymphoma 28, Reproductive System cancer 17, Breast cancer 14, Others 54	Stage III 137, Stage IV 305
Wang et al. [71]	1996	Mainland China	BPI-C		0–10 numeric scales for item rating with 0 being 'no pain' and 10 being 'pain as bad as you can imagine'		147	54 ± 18–86	42%	33% lung cancer 27% GI tract cancer 10% breast cancer 7% genitourinary cancer 4% gynaecological cancer 19% others	49.3% advanced
Wang et al. [72]	2015	Mainland China	BFS-C	6 (acceptance of life's imperfections, becoming more cognizant of the role of other people in one's life, and developing a sense of purpose in life)	17		658	47.52 ± 8.23, 25–70	100%	Breast cancer	Stage III= 33.7%
Wang et al. [73]	2019	Hong Kong	PNPC-sv	8 domains: daily activities (3 items), physical (9 items), autonomy (4 items), social (5 items), psychological (5 items), spiritual (4 items), financial (2	33	11	174	< 60 y = 109,62.66% > 60 y = 65, 37.4%	39.7%	Lung cancer 54 (31.0%) Nasopharynx cancer 30 (17.2%) Colorectal cancer 29 (16.7%) Gynaecological cancer 32 (18.4%) Liver cancer 5 (2.9%)	Stage III= 70 (40.2%) Stage IV= 104 (59.8%)

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Study	Year	Place of study sites	Measure	No. of domains	No. of items	Completion time (min)	N	Age (Mean±SD, Range) years	Gender % female	Diagnosis	Cancer stage
				items) and informational (1 item)						Breast cancer 4 (2.3%) Oesophageal cancer 3 (1.7%) Oral cancer 6 (3.4%) Others 11 (6.4%)	
Wang et al. [74]	2004	Mainland China	MDASI-C	2 (general symptom severity factor, gastrointestinal factor)	19	20	249	51, 18–77	54	25% Gastrointestinal cancer 24% Breast cancer 21% Lung cancer	Stage I= 21% Stage II = 29% Stage III= 29% Stage IV= 21%
Wong et al. [75]	2008	Hong Kong	ChPSQ-9	2 (doctor-related issues and nurse-related issues)	9		222	55.6 ± 12.37	18.50%	hepatocellular carcinoma	87% advanced
Wong et al. [76]	2012	Hong Kong	FACT-C	5 (physical well-being, social/ family well-being, emotional well-being, functional well-being, colorectal cancer subscale)	36		536 (76.1% CRC, 23.9% Polyps)	63.9 ± 11.2	41.80%	CRC, Polyps	Among patients diagnosed with CRC, 23.5% were currently undergoing adjuvant or palliative CRC treatment
Wu et al. [77]	2020	Mainland China	CPPCN	6 (physical needs, psychological needs, environmental needs, social support needs, disease-related knowledge needs and information needs)	36		198	57.6 ± 12.4, 22–82	37.0%	Lung cancer 45 ovarian cancer 14 pancreatic cancer 24 stomach cancer 29 bowel cancer 20 liver cancer 35 breast cancer 31	advanced
Xia et al. [78]	2017	Mainland China	C-MiLS	5(acceptance and adaptation, life perspective, self-control, relationship, purpose in life)	25	8–12	251	44.4 ± 13.43	54.20%	40.64% Breast cancer 22.71% Lung cancer 21.51% Gastric cancer 12.35% Colorectal cancer 2% Gynaecologic cancer 0.8% Nasopharyngeal cancer	Stage I= 9.16% Stage II = 16.73% Stage III= 35.86% Stage IV= 38.25%
Yan et al. [79]	2022	Mainland China	ADAS	3 (opportunity for treatment choices, effect of advance directives on the family, effect of an advance directive on treatment)	13	3–5 min	213	60–83 (65.43 ± 4.698)	111 (52%)	Cancer	Stage III (n = 156, 73.2%) Stage IV (n = 57, 26.8%)
Yin et al. [80]	2020	Mainland China	PTPQ	4 (understand the importance and help of the prognosis, evaluate the quality of the prognostic information provided by the doctor, treatment and prognostic information preferences, prognosis and end-of-life discussions)	12		198	55.90 ± 10.82	41.9%	lung cancer 44 (22.22%) gastric cancer 36 (18.18%) CRC 31 (15.66) oesophageal cancer 26 (13.13%) gynaecological cancer 33 (16.67%) others 28 (14.14%)	Stage III= 98 (49.49%) Stage IV= 100 (50.51%)
Zhang et al. [81]	2016	Mainland China	EORTC QLQ-C15-PAL	10 (physical functioning, emotional functioning, fatigue, pain, nausea and vomiting, dyspnoea, insomnia, appetite loss, constipation and one single-item qol scale)	15		243	59	56.20%	10.7% Gastric cancer 38.8% Lung cancer (7.1% Liver cancer 5.1% Rectal cancer 13.3% Breast cancer 3.6% Cervical cancer 2.6% Head and neck cancer 1.0% Brain neoplasm/ spinal cord neoplasm 1.5% Pancreatic cancer 1.5%	advanced

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Study	Year	Place of study sites	Measure	No. of domains	No. of items	Completion time (min)	N	Age (Mean±SD, Range) years	Gender % female	Diagnosis	Cancer stage
Zhang et al. [82]	2022	Mainland China	Symptom assessment scale for patients with advanced cervical cancer undergoing concurrent chemoradiotherapy	6 domains: psychological symptom group (5 items), nutritional symptom group (4 items), intestinal symptom group (5 items), urinary system related symptom group (3 items), sexual symptom group (2 items), and somatic symptom group (4 items)	23		171	26–78 (53.06 ± 9.65)	100%	Cholangiocarcinoma 14.8% Other cervical cancer	Stage IIB-IVA
Zhang et al. [83]	2016	Mainland China	EORTC QLQ-BM22	4 (painful sites, pain characteristics, functional interference, psychosocial aspects)	22		221	60 ± 11.28, 29–88	55.20%	41.2% Lung cancer 19.9% Brest cancer 5.0% Gastrointestinal cancer 1.8% Renal cell cancer 4.1% Prostate cancer 0.9% Multiple myeloma cancer 5.4% Bladder cancer 19.4% Others 2.3% Unknown	Stage IV
Zhao et al. [84]	2000	Mainland China	EORTC QLQ-C30	3 (global health, functional scales, symptom scales)	30		191	42.2 ± 14.3, 18–78	100%	gestational trophoblastic disease patients (n = 68), ovarian cancer patients (n = 105), and patients with other types of gynaecological cancer (n = 18).	Stage III= 40%
Zheng et al. [85]	2021	Mainland China	Quality Care Questionnaire-Palliative Care	4 (communication with medical staff, discussing the goals and plans of treatment and care, support and evaluation of overall care, continuity of care)	32	6–20 min	289	56.08 ± 11.91	129/289	Lung cancer 75, gastric cancer 27, colorectal cancer 28, liver cancer 13, breast cancer 48, gynaecological cancer 21, pancreatic cancer 35, others 42	Stage IV

ADAS: Advance Directive Attitude Survey; BFS-C: Chinese version of the Benefit Finding Scale; BPI: Brief Pain Inventory; ChPSQ-9: Nine-Item Chinese Patient Satisfaction Questionnaire; CPPCN: Cancer patients' palliative care needs questionnaire; DCS: Decisional Conflict Scale; EORTC: European Organisation for Research and Treatment of Cancer; FACT-C: Functional Assessment of Cancer Therapy – Colorectal; HADS: Hospital Anxiety and Depression Scale; MAX-PC: Chinese version of the Memorial Anxiety Scale for Prostate Cancer; MDASI: M. D. Anderson Symptom Inventory; MDASI-GI-C: Chinese Version of the M. D. Anderson Symptom Inventory Gastrointestinal Cancer Module; MiLS: Meaning in Life Scale; MPI-sC: Multidimensional Pain Inventory-Screening Chinese version; MQOL: McGill Quality of Life Questionnaire; MSAS: Memorial Symptom Assessment Scale; PNPC-sv: Problems and Needs in Palliative Care questionnaire-short version; PTPQ: Prognosis and Treatment Perception Questionnaire; QLASTCM-Ga: Quality of life assessment scale for gastric cancer patients; QLQ-BM22: Bone Metastases; QLQ-C15-PAL: Quality of Life in palliative cancer care patients; QLQ-C30: Quality of Life of Cancer Patients; QLQ-IN-PATSAT32: Satisfaction with In-Patient Cancer Care; QLQ-OES18: Oesophageal patients; QLQ-OV28: Ovarian patients; QLQ-SWB27: Spiritual Wellbeing; QONCS: Quality of Oncology Nursing Care Scale; SAIL: Spiritual Attitude and Involvement List; SCNS-SF34-C: Chinese version of the short-form Supportive Care Needs Survey questionnaire; SpIRIT: Spiritual Interests Related Illness Tool; SWBS–M: Spiritual Well-Being Scale-Mandarin version; TCM: Traditional Chinese medicine; UWQOL-C: University of Washington Quality of Life Chinese Version.

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4.3 CONCLUSION AND NEXT STEP

There are currently no contextually appropriate and psychometrically sound PROMs that measure the multidimensional concerns of advanced cancer patients in China. Developing outcome measures for advanced cancer patients in China is invaluable: to improve audit, clinical services and assess the quality of care, for research purposes and secure funding. The psychometric palliative care literature suggests adaptation of existing measures is the preferred response. There is an urgent need to adapt and validate existing tools to facilitate research and patient-centred clinical practice in China. The systematic review informs the next step to identify palliative care needs among adults living with advanced cancer in China and their families and determine optimal implementation of the IPOS among stakeholders.

CHAPTER 5. RESULTS 2-QUALITATIVE INTERVIEWS

5.1 INTRODUCTION TO CHAPTER

This chapter presents findings from a qualitative study which aimed to address study objective four to five:

Objective 4. To identify palliative care needs among adults living with advanced cancer in China and their families

Objective 5. To determine optimal implementation of the IPOS among stakeholders i.e. patients and families

5.2 SUMMARY OF THE RESULTS

Patients (n=20, median age 55.0, 60% female) and family members (n=20, median age 41.0, 45% female) described distinctive but highly interrelated concerns related to living with advanced cancer across five domains: (a) physical and psychological symptoms (e.g. pain and anxiety), (b) financial difficulties (e.g. debt and health insurance problems), (c) impacts on family (e.g. change of roles and burden on families), (d) coping and adapting to the disease (e.g. decision making and healthcare resource accessibility), and (e) plans to the future (e.g. attitudes toward dying and palliative care and unfulfilled wishes). A conceptual model showing the perspectives of patients and family members has been developed. Findings confirmed that advanced cancer has far-reaching implications for patients and family members in China, extending beyond physical and psychological problems into social

(eg. family issues), practical (eg. financial difficulties and coping with cancer) needs and future plans.

This study advances the understanding of patients' and family members' experience in the context of advanced cancer care in China and presents a novel multidimensional conceptual model of person-centred care, which reflected the priorities of patients and family members. This insight is a critical first step in the delivery of more person-centred care for patients with advanced cancer and family members in China.

5.3 SAMPLE CHARACTERISTICS

53 eligible patients and 77 family members were approached using purposive sampling and introduced about the study referring the participants' information sheet. 22 patients contacted the researcher for interest of participation, of those two patients withdrew because one refused to be recorded and another did not want to sign the consent form. 21 family members contacted the researcher for interest of participation, of those one family member patients withdrew because he worried participating the study could affect her wife's treatment. As a result, a total of 40 interviews were carried out (20 patients and 20 family members) at participants' preferred place and time. No repeated interviews were conducted. Interviews lasted 20-60 minutes.

Demographic/ clinical information for patients and family member participants are shown in Table 3.

Table 3. Sample characteristics. For patients (n=20) and family members (n=20)

Variable	Patients		Family members	
	n	%	n	%
Age	Median 55.0	8.3, 36-75 (SD, range)	Median 41.0	SD, range 13.5, 24-72
Gender				
Male	8	40.0	11	55.0
Female	12	60.0	9	45.0
Marital status				
Single	0	0	4	20.0
Married	18	90.0	16	80.0
Divorced	1	5.0	0	0
Widowed	1	5.0	0	0
Education				
Primary school	4	20.0	1	5.0
Junior high school	11	55.0	8	40.0
High school	4	20.0	4	20.0
Undergraduate	1	5.0	6	30.0
Postgraduate	0	0	1	5.0
Employment Status				
Employed full-time	0	0	7	35.0
Employed part-time	0	0	2	10.0
Self employed	1	5.0	7	35.0
Retired	7	35.0	1	5.0
Not employed	12	60.0	3	15.0
Participant’s relationship to patients				
Spouse	-	-	6	30.0
Child	-	-	14	70.0
Patient’s diagnosis				
Breast cancer	9	45.0	7	35.0
Lung cancer	4	20.0	6	30.0

Gastric cancer	1	5.0	2	10.0
Rectal cancer	2	10.0	1	5.0
Colon cancer	2	10.0	2	10.0
Prostate cancer	1	5.0	0	0
Sarcoma	1	5.0	0	0
Endometrial cancer	0	0	1	5.0
Hypopharyngeal cancer	0	0	1	5.0
Patient's stage				
III	6	30.0	6	30.0
IV	14	70.0	14	70.0
Patient's age at onset	Median	9.8, 30-75	Median	9.4, 42-74
	54.5	(SD, range)	59.0	(SD, range)
Time since diagnosis (years)				
< 1	12	60.0	12	60.0
≥1 & ≤5	3	15.0	4	20.0
> 5	5	25.0	4	20.0
Patient's KPS	Median	SD, range	Median	SD, range
	85.0	6.0, 70-90	80.0	7.6, 60-90
60	0		1	5.0
70	1	5.0	2	10.0
80	9	45.0	12	60.0
90	10	50.0	5	25.0

KPS: Karnofsky Performance Score

5.4 QUALITATIVE FINDINGS

These qualitative interview data highlighted and accentuated the dynamic nature of their experiences, which was characterised by distinctive but highly interrelated qualities across

the illness experience: (a) physical and psychological symptoms, (b) financial difficulties, (c) impacts on family (d) practical impacts and coping and (e) plans to the future.

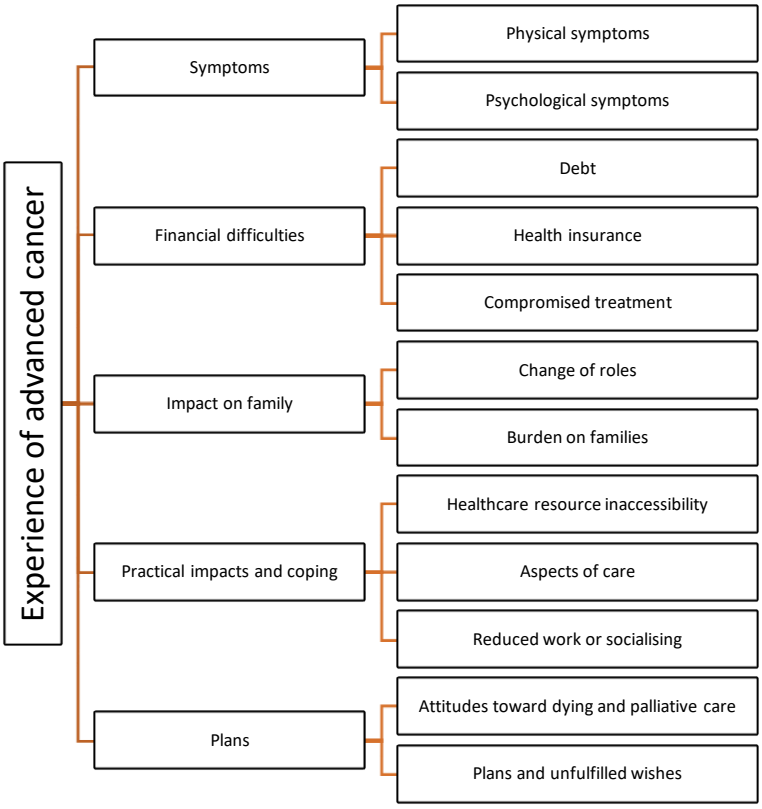

Figure 5. Themes and subthemes: living with advanced cancer in China

5.4.1 Theme 1: Symptoms

Physical symptoms

Participants reported a wide range of physical symptoms and most frequently mentioned fatigue or pain. One of the most notable physical symptoms was cancer pain, which is often the most tangible sign of disease they and their families perceive. Respondents reported that they experienced pain as a highly stressful condition that adversely affects all aspects of

their life. Pain was associated with difficulties, the negative thoughts, a range of functional limitations and the coping behaviours they adopted.

*"I have suffered from pain for 7 or 8 days in the hospital after my third chemotherapy. I feel pain. It is like burning inside of my body. I just thought maybe I wanted to suicide. I'm sweating all over my face…It is unbearable as a man." (*Patient 8, Male, 52, Lung cancer)

Fatigue is the most frequently reported symptom from participants. Participants reported they were less mobile than previously, and their physical fitness deteriorated. The tiredness and lost control of their bodies fell more often and stumbled. In many cases the loss resulted in feeling of need of seat or rest or simply remaining sleep.

"He was weak. Since he was given the medicine, he has suffered from weakness. His feet were quite dragging and a little hard to lift… He couldn't move at all when he was sick, and he was always sleeping. I did not notice this. He has not left the bed for 40 days." Family 7, Daughter of lung cancer patient, 43

Psychological symptoms

Some respondents described emotional reactions to the initial cancer diagnosis, including feelings of anxiety and distress. Patients often felt they were on an emotional rollercoaster, experiencing peaks and troughs at key times of stress and uncertainty in the cancer trajectory.

"I feel anxious… I dare not sleep. It is not that I am not going to sleep. It is I am afraid to sleep. I am afraid to close my eyes and then the next day my eyes would not open." Patient 1, Female, 55, Breast cancer

Comments related to different concerns participants had were raised about used anticancer treatment, from overdosing and becoming addicted, to the management of side effects.

"The feeling of chemotherapy is too bad. This just made me go crazy. I told the doctor after these six (circles), please let me stop. I was going crazy. It is suffering…When I got back home, I couldn't stand still or sit still, so I walked back and forth. I can't even stand still for a little while, for one or two minutes, I had to walk fast like I was crazy…Anxious, anxious as hell." Patient 15, Female, 59, Rectal cancer

5.4.2 Theme 2: Financial difficulties

Patients and families reported that patients could experience a range of direct medical costs including hospital bills, consultant fees and non-medical cost including increased household bills and travelling cost to hospital appointments particularly those living in rural areas.

Debt

Patient stated that rural households in China usually have severe medical debt due to high out-of-pocket payments, which contributes to bankruptcy.

"I am in financial trouble…Living in the rural area, and I am now about 60 years old, it is not possible for me to lend money at all. Who would lend me money? People know I will die soon someday." Patient 11, Male, 61, Prostate cancer

Health insurance

Health insurance can affect cancer patients' quality of life. Some participants expressed frustration with their insurance not paying for all aspects of their care and their frustration with the absence of clear and easily accessible information on the costs of cancer care when shopping for health insurance plans. In addition, there was no consensus among participants about the best place to learn about insurance information.

"Now I am bankrupt because of this cancer. The cost of treatment is too high. If you are from the city, you should be covered more if you have the medical insurance. In rural areas, the reimbursement of cooperative medical system is less. You have to go through a referral procedure locally, and you will be reimbursed more at that time. If you don't go through the referral procedure, you will be reimbursed less." Patient 10, Female, 55, Rectal cancer

Compromised treatment for cost reduction

Cancer patients carried rising burdens of health care-related out-of-pocket expenses, and a growing number of patients were considered "underinsured." Participants struggling to pay for their cancer treatment altered their lifestyles considerably to defray out-of-pocket expenses. Participants reported taking less medication than prescribed, replacing prescription medications with over-the-counter drugs, and taking medications prescribed for others in order to defray costs.

"Because my mother has just changed this new drug, and this new drug is not included in the medical insurance. If it can be included in the medical insurance ahead of time, our family may choose it earlier, instead of thinking about it when the illness is a little urgent.

Originally, it might be the plan. My mother used the medicine in the medical insurance first. Wait until the new drug, the special drug, is included in the medical insurance. But it is urgent, you have to use it first... Maybe this medicine is very expensive, foreign medicine, ordinary people can't afford it. You may choose some other ways, choose some imitation drugs that have similar effect but are cheaper, or choose some drugs that are already in medical insurance, conservative or not so effective." Patient 1, Female, 55, Breast cancer

5.4.3 Theme 3: Impacts on family

Change of roles

Participants reported whole family was affected by cancer, and no one went through this experience unchanged. Cancer and the treatments can introduce a complex array of lifestyle and family role changes and emotional responses, which can be difficult for family members to handle.

"I can't take care of my grandson… He is one year old, cannot even speak, and he wants to hug me." Patient 14, Female, 55, Breast cancer

"(My father) is no longer like the head of a family. After all, we are older, and he may listen to our opinions. He may have a stiff tongue about what we say to do at present. Psychologically, he is more comfortable, or obedient, listen... it turns out that I'm not willing to make a decision for him. It's his business to let them make their own decisions. However, after he got ill, I was pushed to the front. I need to make decisions." Family 3, Son of lung cancer patient, 28

Burden on the family

Family participants reported they experienced huge pressure and anxiety to care for the patients while they had to take care of other family members.

"Huge pressure to take care of him. (Besides my mother) My father-in-law is sick *too and lying in bed. My kids are young." Family 10, Daughter of hypopharyngeal cancer patient, 38*

"I barely sleep, especially at night. Once I wake up, I cannot sleep again. I cannot sleep on the rest of the night… I am worried about my body. I am super thin. I used to weigh 55kg. Now I weigh 45kg." Family 7, Daughter of lung cancer patient, 43

5.4.4 Theme 4: Practical impacts and coping

Healthcare resource inaccessibility

Patients complained they were unable to access health services and regular physical examination due to living in rural areas given the great health services disparity between urban and rural areas in China.

"Most of the young people in rural area in China go out to work... It's up to the parents themselves to care for their parents. There is no so-called physical examination. Sometimes they don't take medicine for minor diseases. Maybe it is fine if they just have a cold." Family 5, Son of endometrial cancer patient, 43

Participants reported they had to rely on village clinics, or travel hundreds of miles to find the closest facility. Instead of going to a doctor's office or a community clinic, they tended to rush to the top hospitals to see specialists for best care in major cities, most people are relegated to overcrowded hospitals, while patients had to wait long time for a bed or examination.

"It's just to check when some people arrive and slow down a little... It's just that the waiting time is too long. It's OK when catching up quickly. Sometimes it's a bit slow. There are too many people in the hospital. Sometimes it's too slow to make an appointment for an examination. There are too many patients in this big hospital, so they have to queue up."
Family 12, Son of rectal cancer patient, 36

Aspects of care

Patients and families valued about the healthcare providers and organisations. Participants reported that healthcare providers' behaviour, attitudes and good interpersonal skills could promote patients' satisfaction and they overall satisfied with the trustful relationship created by healthcare providers. A personal relationship to healthcare providers was identified as a particularly important factor of service delivery.

"(Medical staff) give me the greatest help, give me the feeling like family. As soon as I went to this department, the nurses and doctors were as enthusiastic as my family when they talked to me. Not only for me, I found that they were very patient with other patients, such

as older patients, just like coaxing children. It helped me a lot. It's like going home. I'm also worried. In the first few years, we all knew that the doctor-patient relationship was not very good... But when I came here, I really looked like my family. It was to ease my fear, so I didn't feel afraid." Patient 17, Female, 48, Breast cancer

Reduced work or socialising

The consequences of suffering from advanced cancer included reduced work and social limitations, resulting in loss of former social contacts and reluctance to create new ones. Social activities previously regularly performed were now cancelled. In addition, the physical appearance was often affected both by cancer and its treatment such as hair loss, loss of one or both breasts, loss of sexually attractiveness. Patients often perceived these changes in appearance to be disfiguring and feeling alienated.

"Before I got sick, I was very sociable and had many friends, classmates and families… After getting sick, I basically block myself with people who don't know what happened to me. Especially since I lost my hair ... I just kind of shut myself off ... I don't want people to know I am sick." Patient 17, Female, 48, Breast cancer

"My father didn't work much after the surgery, and he has been recovering because he had surgery, chemotherapy, radiotherapy and a lot of treatment. No energy for work." Family 8, Son of lung cancer patient, 24

5.4.5 Theme 5: Plans to the future

Attitudes toward dying and palliative care

All patients and family members concerned about the terminal nature of advanced cancer. Data suggested that patients frequently chose to escape the magnitude of this information by choosing not to think about dying and death.

“No matter what, all people will be dead. Besides, why do you have to endure that time. I've suffered a lot. I've been a burden to my children and my wife... I just want to ensure the quality of my life, relieve the pain and solve the problem of insomnia.” Patient 8, Male, 52, Lung cancer

“My goal of treatment is to reduce suffering. This disease can't be cured... This is the biggest wish. Even if we live for half a year, the second half of the year or the next spring, people will die eventually. “We can't afford to suffer too much... I don't need you to extend the time, because what, if you have a long illness and the illness has reached a certain degree, what's the use of extending it for 10 days, 20 days, a month or two months? It's unnecessary and useless, right? In this period of time, you will end up suffering less. I suggest that this is a digression. If we have euthanasia, which is the best. When the disease can't be cured, what do you want him to suffer, what do you want him to live It's better to live than to die. What's the use? It's still cumbersome.” Patient 11, Male, 61, Prostate cancer

Plans and unfulfilled wishes

Even though patients were diagnosed with advanced cancer with limited life expectation, some still had clear plans to bright future.

"If the body gets better, I will start from scratch and pay the money I owe. Raise cattle, raise a few cattle... Make tens of thousands of yuan a year... The other is the child. She is not married, a girl at school. No adult. If you are an adult, don't you have to worry about it? Without a family, she's the only one who is in school and need money. You have to pay for her education." Patient 10, Female, 55, Rectal cancer

5.5 CONCLUSION AND NEXT STEP

This study advances the understanding of patients' and family members' experiences in the context of advanced cancer care in China, which offers unique insights into what matters to patients and families towards person centredness. It presents a novel multidimensional conceptual model of person-centred care, which reflects the priorities of patients and family members. The study highlights the significance of patients' financial stability and trustful physician-patients relationship. This insight is a critical first step in delivering more person-centred care for patients with advanced cancer and family members in China. The qualitative data informed the next step refining the Chinese IPOS by translating and cross-culturally adapting IPOS to the Chinese context in advanced cancer care.

CHAPTER 6. RESULT 3- TRANSLATION AND CROSS-CULTURAL ADAPTATION OF A CHINESE VERSION OF IPOS

6.1 INTRODUCTION TO CHAPTER

This chapter presents findings from translation and cross-cultural adaptation of the Chinese version of IPOS which aimed to address study objective six to seven:

Objective 6 To conceptually map the qualitative data on symptoms and concerns from patients and families onto the IPOS and refine the items

Objective 7 To conduct cognitive interviews among patients and families and refine the final Chinese IPOS for validation

6.2 PHASE I: CONCEPTUAL DEFINITION: IN-DEPTH INTERVIEWS WITH PATIENTS AND FAMILIES

The findings of these qualitative interviews have been described in Chapter 5. The results presented in this chapter were in relation to conceptual mapping of the IPOS items.

6.2.1 Participants

Forty key stakeholders were recruited for in-depth qualitative interviews to inform the development and refinement of the IPOS: n=20 advanced cancer patients, n=20 family members.

6.2.2 Data analysis and finding

Analysis of in-depth qualitative interviews with patients and family members confirmed that original IPOS items mapped onto the main themes of identified need: (a) physical and psychological symptoms, (b) financial difficulties, (c) impacts on family, (d) practical impacts and coping, and (e) plans to the future.

However, "impacts on family" was identified as a core outcome which matters to the participants that was missing in the original IPOS. We decided to add a new item: ***Have you felt a burden to your family? / How much does the disease impact on your family?*** In addition, qualitative data indicated that practical problems, including financial difficulties, had a great impact on overall life of participants, whereas original item 9 (***Have any practical problems resulting from your illness been addressed? (such as financial or personal***) was felt to be too generic and incomprehensible. Therefore, we decided to split item 9 into two questions: ***Have any financial problems resulting from your illness been addressed? (such as debt or lack of access to health care)*** and ***Have any practical problems resulting from your illness been addressed? (such as social disability or inability to work).***

Table 4. Mapping of priorities of participants identified from qualitative interviews and the original IPOS

Priorities of participants	**IPOS domains**	**IPOS items**
Physical and psychological symptoms	Physical symptoms	Q2. Below is a list of symptoms, which you may or may not have experienced. For each symptom,

		please tick one box that best describes how it has affected you over the past 3 days.
Physical and psychological symptoms	Emotional symptoms	Q3. Have you been feeling anxious or worried about your illness or treatment?
Physical and psychological symptoms	Emotional symptoms	Q4. Have any of your family or friends been anxious or worried about you?
Physical and psychological symptoms	Emotional symptoms	Q5. Have you been feeling depressed?
Physical and psychological symptoms	Emotional symptoms	Q6. Have you felt at peace?
Financial difficulties, practical impacts and coping, plans to the future	Communication /practical issues	Q7. Have you been able to share how you are feeling with your family or friends as much as you wanted?
Financial difficulties, practical impacts and coping, plans to the future	Communication /practical issues	Q8. Have you had as much information as you wanted?
Financial difficulties, practical impacts and coping, plans to the future	Communication /practical issues	Q9. Have any practical problems resulting from your illness been addressed? (such as financial or personal)
Impacts on family	--	--

6.3 PHASE II AND III – TRANSLATION

There were few obvious discrepancies in the forward translations. When the translators had chosen different terms, the options were discussed and negotiated. The main situations where this occurred were for the terms at peace (Q6); these have no equivalent terms in Chinese, and so the Chinese terms for calm/ quiet (平静) were chosen. The back-

translations were compared, and no faulty or incorrect translations were discovered; only minor grammar discrepancies, which were adjusted.

6.4 PHASE IV – EXPERT REVIEW

An expert group consists of six researchers experienced with PROMs, three oncologists, three nurses and two PPI members was organized. All members of the expert group agreed that the translations were generally clear and easy to understand. They agreed to add a new item regarding family burden and split the item 9 into two questions to improve clarification. Experts suggested item 1 was not clear that might mislead patients into thinking that this question is only about the patient's physical symptoms, rather than the main problems bothering them in their whole life (probably because the patient's inherent impression of PROMs, or the item 2 question which were physical problems on the same piece of paper interfering with the patient's understanding). We decided to add “in your whole life” in item 1, making it: ***What have been your main problems or concerns in your whole life over the past 3 days?***

Item 6 were considered confusing in Chinese context. Experts suggested participants would naturally assume this problem was about the overall psychological state, which should be about spiritual wellbeing. After careful consideration of experts’ suggestions, we decided to keep the current expression (calm/quiet, 平静) and gave several alternative expressions, such as "are you relaxed (放松)?" "Do you have a good mood (好心情)?" and leave this to be explored further in the cognitive interviews. Detailed comments from the expert review committee and how we addressed them were presented in Table 5. The expert group

agreed on proposed Chinese versions of IPOS Patient and IPOS Staff are ready for cognitive interview.

Table 5. Comments from the expert review committee and actions to address them

General comments	1.Any refinement/ adding/ remove of items should match the options of the original IPOS. 2.While being consistent to the original IPOS, we should pay attention to the Chinese culture and language habits based on faithfulness, expressiveness and elegance.	
Q1. What have been your main problems or concerns over the past 3 days?	Experts agreed that open questions are necessary. They thought expression of Q1 is not clear, which may mislead patients into thinking that this question is only about the patient's physical symptoms, rather than the main problems bothering them in their whole life (probably because the patient's inherent impression of PROMs, or the Q2 question on the same piece of paper interfering with the patient's understanding, etc.). Suggestions: Add an explanation in Q1 to help patients understand that this is about the main problem or concern in their whole life.	**Action 1 – add a phrase to Q1: "in your whole life"** **Revised Q1: What have been your main problems or concerns in your whole life over the past 3 days?**

Q2. Below is a list of symptoms, which you may or may not have experienced. For each symptom, please tick one box that best describes how it has affected you over the past 3 days.	Experts' discussion mainly focused on: (1) whether the order of symptoms listed should be ranked according to the degree of the impact of symptoms on the quality of life, or just keep the original order. (2) Nausea and vomiting are difficult to distinguish when asking patients clinically. Whether to consider the combination of nausea and vomiting into one item? Suggestions: Keep the original order unchanged. The adjustment order will not have much significance in clinical use, as long as the symptoms are listed, the patients can clearly check according to their own situation. Although nausea and vomiting are easily confused in clinical consultation by patients, patients can still understand in writing that these two words are different concepts. Experts believed that more importantly, there are essential differences between the clinical significance and treatment methods of nausea and vomiting. For example, vomiting can bring serious electrolyte disorder, while nausea cannot. Therefore, keep	**Action 2 – Keep Q2 as original IPOS unchanged**

	both two items: nausea and vomiting unchanged.	
Please list any other symptoms not mentioned above, and tick one box to show how they have affected you over the past 3 days.	Experts thought it's good to set up an open question here. The expression in the Chinese version is appropriate.	
Q3. Have you been feeling anxious or worried about your illness or treatment?	The expression in the Chinese version is appropriate.	
Q4. Have any of your family or friends been anxious or worried about you?	The expression in the Chinese version is appropriate.	
Q5. Have you been feeling depressed?	Experts discussed that in the context of Chinese, the meanings of Q5 and	**Action 3 – Keep Q5 as original IPOS unchanged**

Q6. Have you felt at peace?	Q6 are repetitive to some content. For Q5, the question should be about the emotional/ psychological/ spiritual level of the patient. Q6 should be about patients' mentality/ mood/ spirituality. In the Chinese context, it is good and clear to use Q5 to explore patients' mood. But for the patients' mentality / mood / spirituality, there is less attention in Chinese culture. Patients would naturally assume the problem is to ask the overall psychological state. Suggestions: (1) Keep Q5 as original IPOS unchanged (2) As for Q6, keep the current wording in Chinese version. List several alternative questions, such as "Are you relaxed?" "Do you have a good mood?" In the cognitive interview, ask participants how they understand these questions.	**Action 4 – Keep Q5 as original IPOS unchanged. As for Q6, keep the current expression in Chinese version. At the same time, list several alternative questions, such as "are you relaxed?" "Do you have a good mood?"** **In the cognitive interview, ask participants how they understand these expressions.**
Q7. Have you been able to share how you are feeling with your family or friends as much as you wanted?	Experts thought that although Q7 has gone through the standardised process of forward and backward translation, it is still not accurate and does not reflect the concept "SHARE" which the question intend to capture.	**Action 5 –** **Revised Q7: Can you fully share your feelings with your family or friends?**

Q8. Have you had as much information as you wanted?	Experts thought it is important to consistent to the original IPOS. We cannot express the question as "do you know your condition?" or “What kind of information do you want?” In the current Chinese version, the meaning of "as much as you want" is not shown, so it is suggested to add the word "sufficient".	**Action 6 – add a word to Q8: "sufficient"** **Revised Q8: Have you had sufficient information?**

Q9. Have any practical problems resulting from your illness been addressed? (such as financial or personal)	Experts thought that the "practical problem" has a great impact on the overall life of patients. Q9 is too wide-ranging, and it will make it difficult for patients to understand what practical problems are. Suggestions: Split Q9 into two parts, one is about financial problems, the other is about personal problems. Give patients some tips, such as financial problems, including debt problems, medical insurance problems, etc. In the cognitive interview, ask participants how to understand these questions, and know how to further optimise the items.	**Action 7–** **Split Q9 into two questions.** **" Have any financial problems resulting from your illness been addressed? (such as debt or lack of access to health care) "** **and** **"Have any practical problems resulting from your illness been addressed? (such as social disability or inability to work) "** **And in the subsequent cognitive interview, ask participants how to understand these questions.**
Q10. How did you complete this questionnaire?	The expression in the Chinese version is appropriate.	

Add a new item?	Experts agreed that family burden has a great impact on the overall needs of patients according to the qualitative data and the characteristics of Chinese culture. Adding a new item related to family burden is suggested. Considering the comparability of the Chinese version of IPOS with other languages, we could consider putting the newly added question before the last one.	**Action 8–** **Add items:** **Have you felt a burden to your family?** **/How much does the disease impact on your family?** **And in the subsequent cognitive interview, ask participants how to understand these questions.**

6.5 PHASE V: COGNITIVE INTERVIEWS

6.5.1 Demographics of cognitive interviews

Interviews with six patients and six healthcare professional interviews (12-25 min long) were completed between March and April 2021. The mean age was 33.5 years in healthcare professional group (range 28–40 years) and 57 years in patient group (range 47–68 years). In healthcare professional group, 6/6 and in the patient group, 1/6 participants were female. Two patients had stage III while four patients had stage IV cancer. All participants were in-patients with disease duration of several months to 13 years. Details of each group are shown in the Table 6 and Table 7.

Table 6. Demographic of healthcare professional participants of cognitive interviews

No.	Gender	Age	Marital Status	Education	Profession	Duration of working
S-C-1	Female	35	Married	UG	Nurse	10
S-C-2	Female	35	Married	UG	Nurse	14
S-C-3	Female	40	Married	PG	Physician	16
S-C-4	Female	33	Married	PG	Physician	4
S-C-5	Female	28	Married	UG	Nurse	5
S-C-6	Female	30	Married	UG	Nurse	6

Table 7. Demographic of patient participants of cognitive interviews

No.	Gender	Age	Marital Status	Employment Status	Education	Diagnosis	Stage	Age at onset	Disease duration (years)	Patient's KPS
P-C-1	Female	47	Married	Not employed	Junior High School	Lung cancer	IV	34	13	80
P-C-2	Male	61	Married	Not employed	Junior High School	Gastric cancer	IV	59	2	90
P-C-3	Male	51	Married	Not employed	Junior High School	Lung cancer	III	50	< 1	90
P-C-4	Male	68	Married	Retired	UG	Colon cancer	III	67	1	80
P-C-5	Male	54	Married	Not employed	Junior High School	Gastric cancer	IV	53	< 1	80
P-C-6	Male	61	Married	Retired	UG	Gastric cancer	IV	60	< 1	80

6.5.2 Findings from cognitive interviews

The interviews in both groups demonstrated that for the majority of participants, most questions and answer options worked well. The identified difficulties were mainly comprehension problems. No problems were identified with retrieval or response formulation. See Appendix 3 for selected quotations from the cognitive interviews.

Patients were certain about their main problems and concerns (Item 1), and many described these as the things that are always on your mind. Positive comments about the symptom list in question 2 included the following: *This (item 1) includes all aspects, not just having disease, but also other trivial things in my daily life… They are easy to understand. These are basically routine questions, which are directly related to patients.* (Male, aged 61 years, gastric cancer) *These questions have good generality. They are straightforward, easy to understand and answer.* (Male, aged 68 years, colon cancer)

Physical symptoms such as 'Pain', 'shortness of breath', 'nausea', 'poor appetite' and 'constipation' listed in item 2 were well understood by all participants. Comprehension of item 3 (anxiety/worries) was also good for all participants. Some comprehension problems were identified. For example, difficulties arose with the wording of specific questions. The term 'drowsiness' in question 2 was regarded as not plain language, and in contrast to the intent of the question, many patients misunderstand the word when answering it. We decided to use **sleepiness (昏昏欲睡)** to replace drowsiness. As for item 6, most participants preferred **calm/quiet (平静)** to express the meaning of "feel at peace".

Finally, format of questionnaire was asked. Most participants preferred to use paper format. *I like to put it on paper. As for people at my age, it's very convenient to use paper. I'm not familiar with tablets or mobile phones. However, along with the development and requirements of society, it is convenient and easy to store data in computers.* (Male, aged 68 years, colon cancer)

The final Chinese IPOS of patient version (see Appendix 13) and staff version (see Appendix 14) were really for further psychometric testing.

Table 8. Issues regarding IPOS completion identified in the cognitive interviews

Item	Quotations in English (translated)	Original quotations in Chinese
1	<PATIENT-1> I think it (item 1) is about the patient's personal life or financial problems, or what they worry about in the hospital. As for myself, I think that financial hardship is the biggest issue. <PATIENT-4> I'm not worried about the disease a lot. It seemed to be horrifying in the past few years, and the cure rate is not ideal. Many people get cancer. Now, I found the cure rate is relatively high. I'm a little worried that I won't be cured, but I still have confidence. This is how I felt when I got sick. I'm afraid that I won't be fixed. <PATIENT-5> I always thought about income, and money for medication. I was distraught and panicked. But I got a lot of healthcare reimbursement afterwards. <PATIENT-6> This includes all aspects, not just having disease, but also other trivial things in my daily life. For example, in a family, children and immediate family members' attitude and concern influence your life. Impacts are multifaceted, which also including environmental factors. Some environment is not good. Even people around may impact the disease. <STAFF-1> (Item 1) is about how are you doing in your daily life. It's also about psychological impacts, right? Some trivial things in life also count. There is a phrase "in every aspect of your life" in this	<PATIENT-1> 我觉得它是问患者的个人生活或者是经济问题或者是到医院来担心什么。要是在我自身来说，我感觉经济问题是我最大的问题。 <PATIENT-4> 没有什么多大的担忧，就是对于这种疾病来说，在前几年的时候偶尔听起来很害怕的，同时治愈率也比较不太理想。得这种病的也多了，但是我看治愈率也都挺高的。有一点担心怕治愈不了，但实际上信心还是有的，这是我得病的一个心情就是担忧怕治不了。 <PATIENT-5> 生活当中一直考虑到资金啥的，生活来源啥的，再说治病的钱都从哪来，我就挺愁的慌的，后来社保一办理报销的也不少。 <PATIENT-6> 就是属于全方位的方方面面的呗，就不包括这单指病情的，就是说生活上其他的一些琐碎的事可能都联系在一起了。比如就说家庭的就是亲戚间这些孩子或者直系的对自己的态度和对自己的关心方面，我估计就是多方面的，全方位的就是环境因素都得包括了。环境有些不好了，或者是周围闲杂人可能一些言谈举止对病情都有影响。 <STAFF-1> 这一天都干什么了？做什么了？还有心理的波动，对吧？生活中的一些琐事也都算。这个问题中有“一个整个生活中”，能不能具体

	question. Can you be more specific, such as work and so on? I find that every aspect of your life is too general and there are no details. Can you refine the item by listing some examples which could give more details? <STAFF-2> (Item 1) maybe about medication, diet, eating, drinking, sleeping, the effectiveness of the drug, finance, etc. <STAFF-3> After diagnosed, the patient's mind focuses on the disease. They would keep thinking about cancer, and all his behaviours would be related to the disease, such as diet. <STAFF-4> I think it's about daily life, such as some activities after getting up, including cleaning, cooking, going out for a walk or having everyday conversations.	化些，如工作等，整个生活我感觉太笼统的了，没有细节。比如说举两个例子，这样我感觉能好一点，能细化一下。 <STAFF-2> 他们可能的用药、饮食，咱所说的吃喝拉撒睡这些问题，用这个药我管不管用是吧。还会有一些经济的问题。 <STAFF-3> 患者他生病之后，他的主要思维可能主要是集中它在这个病上的，这就是他一直在考虑的一件事，包括他的所有的行为都跟这个病有关系。包括饮食各个方面。 <STAFF-4> 我觉得还是日常生活，比方说起床之后的一些活动，包括打扫卫生、做饭、出去遛弯儿或者这种日常交流。
2	<PATIENT-2> Interviewee: what is this? Interviewer: drowsiness. Interviewee: what does drowsiness mean? <PATIENT-4> Interviewee: Drowsiness is mild. Interviewer: How did you feel? Interviewee: It means almost no sleep. My sleep is very light. Usually 6-7 hours in a day. Interviewer: how do you understand the word drowsiness? Interviewee: I don't understand it well. <PATIENT-5> Interviewer: how do you understand the word drowsiness? Interviewee: my understanding is I am able to fall asleep. <STAFF-1> Interviewer: How would you change this drowsiness item?	<PATIENT-2> 受访者：这个是啥玩意? 访谈者：嗜睡。 受访者：嗜睡什么意思? <PATIENT-4> 受访者：嗜睡是轻度的。 访谈者：有啥表现呢? 受访者：几乎没有觉，我觉非常轻，24 小时正常情况下是 6~7 个小时算多的。 访谈者：嗜睡这个词您是怎么理解的? 受访者：理解不太好。 <PATIENT-5> 访谈者：嗜睡这个词儿您咋理解呢? 受访者：我的理解就是睡觉睡着就行呗。 <STAFF-1> 访谈者：您觉得嗜睡这个词还有什么其他的表达方法吗? 受访者：写睡眠情况。

	Interviewee: sleep condition. Interviewer: Do you find drowsiness or insomnia a common symptom (in cancer patients)? Interviewee: insomnia is common. I think it is better to change this into insomnia. Many patients in the oncology department do have insomnia. <STAFF-2> Interviewer: how do you understand the word drowsiness? Interviewee: always sleeping, but I can wake the patient up. Interviewer: I interviewed some patients a few days ago. Some thought that drowsiness and insomnia had the same meaning. They can't be distinguished. Interviewee: "Drowsiness" is not commonly used in daily life. I think it is academic language. Interviewer: what would you say in plain language? Interviewee: do you sleep more or less? From my point of view, I don't think we need to change it. If we ask patients to fill in the scale, we can explain it to them. Or we can add a bracket to clarify it means sleep longer than usual during the day. Interviewer: Which way do you prefer to ask this question? Interviewee: I think it's enough to explain it when I send out the scale. <STAFF-3> Interviewee: drowsiness, as we have learned to define it, means feeling abnormally sleepy during the day and can be weakened up and communicate normally. Interviewer: I interviewed six patients a few days ago. Some thought that drowsiness means not sleeping, which is the same as insomnia. Interviewee: So, from the patient's perspective, they might not be able to understand what drowsiness is.	访谈者：您觉得嗜睡的多，还是失眠的多。 受访者：失眠的多。我感觉这块改成失眠是不是能好一点？我们肿瘤科的患者确实很多有一个失眠的情况。 <STAFF-2> 访谈者： 您觉得嗜睡这个词怎么理解？ 受访者： 总在睡，但是我能叫醒他能醒。 访谈者： 我这是之前几天访问了好多患者，他们好多人觉得嗜睡跟失眠是一个意思。 受访者：他们区别不开，应该是这个词很生活中不太常用。我觉得学术。 访谈者： 要是换成日常用语怎么讲？ 受访者： 睡得多还是睡得少？从我们这个角度来看，我觉得不用换（用词）。我们给他发量表的时候让他评的话，我们可以给他解释一下。或者是加一个括号，解释一下每天睡的时间，比常规的要时间长。 访谈者： 您更倾向于怎么写这个问题？ 受访者： 我觉得发量表的时候解释一下就可以了。 <STAFF-3> 受访者：嗜睡，咱们学的定义睡眠特别多，但是还能正常起来沟通和交流。 访谈者：前几天我访谈了 6 个患者，他们中有人认为嗜睡的意思是睡不着，跟失眠是一个意思。 受访者：所以说从患者的角度，他不能很好的理解是嗜睡是啥。 访谈者：您觉得这个词应该叫啥？ 受访者：那就是睡眠是否受到干扰。有的人是睡的多了，但是其实有一部分人睡得更不好了。治疗之后，因为疾病的压力，或者是用上换药之后的这种反应，睡得更不好了。

	Interviewer: what would you ask in your own words? Interviewee: I would ask if your sleep were disturbed. Some people sleep more, but in fact, some people less. They sleep even worse because of the disease's pressure and side effects due to chemotherapy. <STAFF-4> Interviewee: shortness of breath, to what degree? I think "shortness of breath" gives me a sense that the symptom is severe. When you feel shortness of breath, it feels like you cannot breathe at all. Most people may just feel a little panting, not in such a very urgent situation. Interviewer: what do you think of the word sleepiness? Is it easy to understand? Interviewee: drowsiness is easy to understand because we are healthcare workers. We can understand the meaning of drowsiness. However, some patients may not understand it. When we make rounds, we may ask them how they sleep. Some patients may say that they can't sleep at night. Interviewer: do you think it's better to change the words? Interviewee: more sleep? Some people may not understand "drowsiness" as a medical term. I think "more sleep" is understandable. <STAFF-5> Interviewer: what do patients say if they sleep more than usual? Interviewee: patients would say that they are sleepy all day. Patients who take anti-allergy medications before chemotherapy would say that they can't wake up all days. <STAFF-6> increased sleep? we can say mild increase, moderate increase, severe increase.	<STAFF-4> 受访者：呼吸急促，说到什么程度，我觉得有点呼吸急促，有点标的特别重的那种感觉。急促的时候，会是那种喘不上气来的那种感觉。而实际上大部分有些人可能就是觉着呼吸稍微有点喘而已，不是达到这种很急的那种状态。 访谈者：您觉得嗜睡这个词怎么样？容易理解吗？ 受访者：嗜睡很容易理解。因为我们本身就是学医的，然后这一方面肯定是就是说通过学这些知识肯定能理解嗜睡这个意思，但是可能有些患者就不太理解，我们查房的时候可能会问你睡眠咋样，可能有的人患者说我晚上睡不着。 访谈者：您觉得用什么词换一下它比较好吗？ 受访者：睡眠增多不可以吗？可能说有一些人不理解嗜睡，在医学上的表达是什么意思？我觉得睡眠增多还是比较通俗易懂的。 <STAFF-5> 访谈者：要是患者睡得多，患者自己一般会咋说？ 受访者：患者就会说这一天可困了，比如说我们上化疗药，前期用点防过敏的，患者就会说这一天睡不醒，就会这样。 <STAFF-6> 就是说睡眠增加行吗？可以说有没有轻度增加，中度增加重度增加。

3	<PATIENT-1> I'm worried that I won't be cured. I'm afraid that I'll run out of my money and I won't be cured. I have to go that step (die) in the end—cancer patients like me (would definitely choose) most of the time or always. <PATIENT-3> No, because I felt that the effect was very significant after the second chemotherapy. <STAFF-5> When you talk with him, you will find that he is not satisfied with his care workers. I felt that he was in an anxious and irritable mood.	<PATIENT-1> 担心治不好、担心人财两空，把所有的钱都花没了，完了也没治好最后还得走那一步。我感觉尤其是像我们这种病，肯定大多数时间或者总是这种感觉。 <PATIENT-3> 这个没有，因为我第二次化疗以后就感觉效果挺显著的。 <STAFF-5> 跟他交谈的时候，你就会发现他对他的护工不满意，感觉他是一个处于挺焦虑挺烦躁那种心情之类的。
4	<PATIENT-1> Yes, especially with my mother, husband, children, immediate family, and friends. They definitely feel worried for me. They always chat with me to help me to have a good attitude to face the disease. <PATIENT-3> Occasionally worry. My families are very anxious, to be honest. They are distraught as I have cancer. <PATIENT-4> My choice is "always". I feel that my relatives and friends are worried about me all the time. <PATIENT-6> They all have (been anxious or worried about me), but I don't think they worry a lot. Now I have a good recovery. I was a little concerned at the beginning (of the treatment), but now I have to face it. <STAFF-5> His family rarely visited after hiring a care worker. If the patient lacks company, I think he will feel that his families don't care about him.	<PATIENT-1> 会，尤其是我妈妈、我老公、孩子、直系亲属，还有我的朋友肯定都会为我感到着急担心，总也跟我聊天，让我有个好心态正常去面对。。 <PATIENT-3> 偶尔担心，你看家里人都挺着急的，咱们说实在的，得癌症都挺担心的。 <PATIENT-4> 我这个是选择“总是”，我感觉我的亲属和我的朋友总是每时每刻都在担忧我的事。 <PATIENT-6> 他们都有，但是我觉得也不算太大，现在我这恢复效果还算是比较好。刚开始有点担心，现在也都面对了。 <STAFF-5> 有了护工后，他的家人几乎就很少来了。患者如果缺少陪伴的话，我觉得患者会觉得他的家人不重视他。
5	<PATIENT-2> It's impossible not to be depressed. My mood before and after getting sick is definitely different.	<PATIENT-2>

	Anyway, I have to relax. It is not good to worry about it all the time. <PATIENT-3> Yes, sometimes. When I have nothing to do, I would think about why I got cancer at a young age. I'm only 51 years old, right? I definitely feel depressed. <PATIENT-6> Occasionally depressed, but not severe. Anyway, I have to face it seriously.	低落，要说不低落是不可能的，得病和不得病之前的心情肯定是不一样，但是你也得放松心态，老担心那点事也不行。 <PATIENT-3> 有，有时候没事的时候一想这年轻轻的得这病了，也不是岁数太大，才 51 岁是吧，这低落肯定是有。 <PATIENT-6> 偶尔低落，但是不算太低落，反正认真面对呗。
6	<PATIENT-2> I would say, "are you relaxed? "It's plain language. <PATIENT-3> If I would say, "are you in a good mood? "I am not educated, but the most common way is to ask your mentality, right? <PATIENT-4> My understanding of this problem is that you will feel at peace if you are not feeling burdensome or worried. I choose "occasionally", which means to worry occasionally, but I feel at peace most of the time. If you have a good attitude, you will be happy. If you have a bad attitude, you will be unhappy. <PATIENT-5> This means always be happy and not think of the disease. Be happy and stay calm. Relax your mind and don't think about bad things. <PATIENT-6> (Peace means) not take it (cancer) too seriously, and don't take it as a mental pressure. If you worry and think about it every day, you still have to face it. So, I practice calligraphy now. When I'm tired, I will sleep for a while without thinking about my disease. <STAFF-3>	<PATIENT-2> 我会说“你的心态放松吗？”放松吧听着就是很普遍的这么个话。 <PATIENT-3> 要是我会说“你心态好吧？”老百姓咱们本身就没文化，就是最普通的看你心态啥样，是吧? <PATIENT-4> 对这个问题的理解就是，如果也没有负担不担忧，所以心情就会平静下来。我选偶尔的意思就是偶尔有时候担忧，但是大多数状态都还是平静的。心态要好就比较高兴，心态不好想高兴也高兴不起来。 <PATIENT-5> 就是这一天天乐呵呵的，不乱想这些东西不想这些病情的话，心平平静静的就行乐呵呵的心里平静下来。心态放松以后，不想这些烂事一点没有压力了，所以就放松了。 <PATIENT-6> 就别把它太当回事，也别把它当做一个心病。天天愁眉苦脸，天天寻思这事能咋的，不也还得面对嘛。所以我现在写书法，累了就睡会儿觉，不寻思这个事。 <STAFF-3> 心情平静，我理解就是最起码没有太大的起伏。心情平静和心态放松不是很一样，只是

	My understanding of "peace" is not to have mental ups and downs. Peace is not the same as relaxation. It just means that you can accept things for the moment, but it can't be pleasant. <STAFF-4> Peace of mind means to accept the reality, and not to be in a very low mood. I think “have you felt at peace” is a good statement.	说有一些事情我暂时还能接受，但是没有能达到那么愉悦的程度。 <STAFF-4> 心情平静应该就是接受现实，也不是特别的心情低落。我觉得“你的心情平静吗？”这种表述很好。
7	<PATIENT-1> Yes, I love to talk. My voice is not pleasant because my lungs and lymph nodes oppress the vocal cords. I chatted and shared with cancer patients like me at home and in the hospital regardless I know them before. <PATIENT-3> Occasionally. I talk with my family about the disease. <STAFF-3> Some patients have good communication with doctors. Doctors in my department may have done a great job. Anyway, patients always want to communicate with us about their discomfort and concerns. <STAFF-5> His family and friends didn't often visit because of the pandemic. He has been hospitalised and unable to communicate. I seldom hear patients have video calls. Care workers are taking care of him. Their families ask their subordinates to visit. It's hard for him to share.	<PATIENT-1> 能，我爱说，我现在嗓子是因为我肺和淋巴压迫了声带了，说话的声音就不好听，我可爱说了。然后在家里也是碰到和我一样的病友认识不认识，或者到医院来住院的时候碰到的病友就互相唠嗑，都是互相分享。 <PATIENT-3> 这个偶尔有，偶尔的跟家里人说说这个病怎么回事。 <STAFF-3> 我们有一些患者可能跟医生交流还挺好的，也有可能是我们科的医生做的比较好，反正总是想愿意交流，有什么不舒服，有什么哪方面的担心这些。 <STAFF-5> 因为他的家人朋友不怎么来，加上疫情的原因，可能是他一直住院，没法沟通。我很少听过患者打电话视频什么的，都是护工（照顾），还有他的家属派他的下属过来看一下，所以说他很难分享。
8	<PATIENT-1> Occasionally, for example, when the examination results come out, I never see them. My responsibility is to cooperate with the doctor. My husband and doctors will see the results, while I don't want to see them. <PATIENT-3>	<PATIENT-1> 这个偶尔，比如说检查结果出来，我从来不看。我的责任就是配合医生治疗。我对象看、大夫看，我不管。 <PATIENT-3> 这个能，偶尔的也能听着，一般的大夫这个都跟家属说，家属反正一般的也不说。一般

	Occasionally. I overhear something. Doctors always discuss things with my families. And they don't tell me basically. Most of them keep it from me, and I don't ask them. Cancer is not like headaches or colds. Families do not tell me, and I do not want to ask either. Anyway, I feel that the effect of these two chemotherapies is quite remarkable. <STAFF-3> It's intuitive to think whether the doctor told me everything. But if we think about it carefully, more information such as information on the Internet would come to my mind. <STAFF-6> It's mainly about asking the patients about the things related to disease and treatment. For example, understanding what chemotherapy drugs are used and side effects are is comprehensive information that patients want.	的这个病家属都瞒着我，我也不问她。你说这个病不像别的头疼感冒的，这个病一般的家属也不说，我也不愿意问。反正总归感觉这两次化疗以后效果挺显著的。 <STAFF-3> 很直观的就是，大夫是不是跟我说了所有的事。但是咱们要再细想的话，可能就想什么其他的信息网络的信息可能就多了。 <STAFF-6> 主要是问患者获得了与这个疾病相关的东西，主要是说治疗的这些东西。比如说我用这个化疗药都有哪些，副反应是什么就比较全面的。
New Family item	<PATIENT-1> I personally find it's very clear to use the word "burden" because it's a real problem. I've borrowed a lot of money, which will definitely cause a burden. Sometimes my partner says, "everyone else has a car, and we can't afford it.". Then I would think that I spent all the money and couldn't afford anything. This made me feel like a burden to my family. Sometimes I feel bad, but my husband is in a bad mood too. Interviewer: do you think this question is important? Interviewee: it's important. I think it's crucial. My child just started to work. I don't have enough money to spend so I can't support him. When he gets married, I can't buy him an apartment. I feel that the burden is really heavy. <PATIENT-3> I think "burden" is reasonable. I feel that there is still a significant burden. I can't get much	<PATIENT-1> 对我来说我感觉用负担这个词挺明确的，因为这个是太现实的问题了，就我个人来说，我就已经借了很多钱了，肯定造成负担的。有的时候我对象说：“你看人家都有车，咱家这车也买不上”，我就自己开始想，这钱都让我花了，啥也买不上，我就感觉给家里造成负担。有的时候我可难受了，我老公心情也不好。 访谈者：您觉得这个问题重要吗？ 受访者：重要，我感觉挺重要的，你看孩子刚参加工作，我自己钱还不够花呢，我也帮不上他，也到了该娶媳妇的时候，房子也给他买不上，也帮不上他，我感觉这个负担是确实挺重的。 <PATIENT-3> 我感觉第一个“负担”这个问法好。我感觉还是负担大，花钱咱们又报销不了那么多，另

	reimbursement (from medical insurance). Besides, children have to take care of me. Isn't it burdensome? The "burden" is a more unambiguous statement. <PATIENT-4> The term "impact on the family" is appropriate. Because an "impact" is enough to cover all my family's circumstances, including impact on finance and work. Everything in my family will be affected in the future. <PATIENT-5> I think "burden" is more appropriate. It must be a burden to pay for treatment when you are sick. Once you have no income, the family must have a heavy burden. <PATIENT-6> This does not affect me for the moment. My wife has a salary. My daughter and her husband earn a lot, and I earn a lot. This is not a problem for me. But it depends on specific situations. Those who come from rural area must have a heavy burden. I have no burden, no matter how much money I spend. <STAFF-1> "Burden" is more appropriate. It is general and intuitive. <STAFF-4> "Burden" is more appropriate and easier to understand. Because ("burden" is the word we would use when) we chat, most people know the meaning of burden, which is easy to understand. <STAFF-5> "A burden on the family" is more appropriate. It's intuitive and easy to understand. <STAFF-6> "Burden" is easier to understand. Because I think it is simple and straight. Patients have a more intuitive feeling after reading it.	外孩子还得伺候我，这不都是负担吗。负担这个说法更明确。 <PATIENT-4> “对家庭造成影响”这个说法合适。因为一个“影响”就足以包括我的家庭所有情况了，包括经济影响、工作影响，我的家将来一切都会受到影响。 <PATIENT-5> 我觉得“负担”比较合适。生病的时候治疗用钱，那肯定是有负担的。一得病经济来源没有了，肯定家庭负担很重。 <PATIENT-6> 这个目前对我来说没啥影响，老伴有工资，姑娘、姑爷都不少挣，我这也不少挣，这个负担都不算事儿，这也分人了，那农村来的肯定负担就大了，我就是自己没啥负担，就是全力以赴花多少钱都不算事儿，没有啥负担。 <STAFF-1> 我感觉“负担”比较合适。“负担”有概括性，比较直观明了。 <STAFF-4> 我觉得是“负担”更合适。“负担”应该是比较好理解的。因为咱平常聊天，大部分人也都知道明白负担这个意思，很容易能理解。 <STAFF-5> “对家庭构成负担”更合适。比较直观，能好理解一点。 <STAFF-6> 我觉得“负担”更容易理解一点。因为我觉得它比较简单直接。患者看完之后有比较直观的感觉。

9	<PATIENT-1> It's better to split it into two questions. It will be easier to answer and understand. I chose "not addressed". My financial issues are not addressed. In terms of work, I can't do anything considering my physical condition now. When I go downstairs for a walk, It's fine when I walk, but it's too hard to go up to the sixth floor. I was better last year. Now my physical strength is too weak. <PATIENT-3> It's more comprehensive to ask one question. Both financial and social issues are included. <PATIENT-4> It's right to split it into financial and personal problems. Personal problems include whether you can work and what you can do. It is different from your financial situation. Split to make it understandable and easy to answer. <PATIENT-5> It's better to split it into two questions. I can't solve my working problem. I lost my job after I was sick, so my financial situation will definitely be affected. But in terms of medical insurance, the country has solved it well. Now the medical insurance in this country is standardised. <PATIENT-6> This needs to be split into two questions. These are two aspects, really. <STAFF-1> It is good to ask one single question. I don't feel good talking about debt directly, which might cause psychological pressure on patients and make them feel depressed. Because patients in the oncology department are always in debt, they are more pessimistic when admitted. <STAFF-3> It's more appropriate to split it into two questions. If you ask in one single question, the question is too	<PATIENT-1> 还是拆开问吧，比较好解答好理解。我选择的是“没有解决”，没有解决的还是资金上的事。工作上就我现在的体力也不可能干啥，下楼去溜达两圈，溜达时候没事，我家 6 楼上去太费劲了，去年还不这样呢，现在体力太不好了。 <PATIENT-3> 合起来问更全面。一个财务、社交这些都包括了。 <PATIENT-4> 拆开是对的，就是把财务和个人问题给拆开。你个人问题就包括你能不能工作能不能干什么，至于你的财务状况这是两码事。拆开就可以理解的非常清楚，回答也非常好回答。 <PATIENT-5> 还是拆开问的好，我这个工作就解决不了了，一病之后工作没了，肯定财务就影响了。医保给你解决了，国家现在都是全国统一。 <PATIENT-6> 还得拆两个问题，实际来说本身就是两个问题。 <STAFF-1> 合着问好一点。直接说债务，我感觉不太好，一下就给患者造成心理压力，心情变得低落了。因为咱们科患者也有债务的，一上来就问就比较消极。 <STAFF-3> 拆开文更合适。合在一起问的话，问题太大了。对太大的问题就不好回答。不好回答的时候，患者就不愿意想，他有可能就随便选一个，那对答案是不准确的。问题越直接越具体越好。 <STAFF-4>

	big. It's hard to answer big questions. When it's not easy to respond, the patient will not think through. They may choose an option randomly. The answer will be not accurate. The more direct the problem, the better. <STAFF-4> I think these two aspects are different. <STAFF-5> It's better to split it into two questions. I think it's more detailed. <STAFF-6> I think these are two independent issues. One is social problems, and the other is debt. I think it's two aspects. So, I think it should be taken apart. When I read it (the original problem), I had doubts about how to choose.	我觉得这两方面问的不一样的。 <STAFF-5> 拆开问更好。我觉得这样更细化。 <STAFF-6> 我觉得这是两个问题，一个是说社交上还有一个和债务，我觉得它本身它就是两个方面的事情。所以说我觉得他应该拆开，我当时看（原始的问题）的时候看，还存在疑问了，这样怎么选。
10	<PATIENT-1> This item is very clear. <PATIENT-5> It was completed by myself. This question is easy to understand and answer.	<PATIENT-1> 这个问题挺清晰的。 <PATIENT-5> 那是自己完成的。这个问题好理解，也容易回答。
General comments		
Comprehension	<PATIENT-4> These questions have good generality. They are straightforward, easy to understand and answer. <PATIENT-6> They are easy to understand. These are basically routine questions, which are directly related to patients.	<PATIENT-4> 这些问题概括性很强，同时容易理解也很容易回答，这些问题很简单。 <PATIENT-6> 容易理解，这些基本都是常规的，这都是和实际患者本身比较直接的。
Recall	<PATIENT-2> Three or seven days is appropriate. If you can't think back on the past seven days, your mental capacity is too bad. <PATIENT-3> I am clear about what happened over the past seven days as I am always in hospitalisation. I don't	<PATIENT-2> 三天或七天时间是合适的。七天之内要是再回想不过来，思维有点太差了。 <PATIENT-3> 总是住院这七天的情况基本上自己也都明白，七天或三天我觉得没什么太大的区别，基本不会记不起来。 <STAFF-4>

	think there is much difference between seven days and three days. I can't forget (how I felt). <STAFF-4> It's easy to recall the past seven or three days.	7 天之内或者 3 天之内还是比较容易的，是比较能够回忆起来的。
Paper /Tablet format	<PATIENT-1> I think the paper format is better. Let alone the elderly, sometimes I can't even understand tablets and mobile phones. It's not convenient for the elderly. They don't use mobile phones well and surf the Internet. It's inconvenient for them, so it's better to use paper format. <PATIENT-2> It depends on the level of education. I don't know how to use a tablet or a mobile phone. I use a phone designed for the elderly. I am an old people who come from the old era. It's more convenient to take the paper up and read it, which is more convenient. <PATIENT-3> Mobile phone format. Mobile phones are common now. It is good to fill in the blanks on mobile phones, tick the right ones and cross the wrong ones. I think it's convenient to use mobile phones. <PATIENT-4> I like to put it on paper. As for people at my age, it's very convenient to use paper. I'm not familiar with tablets or mobile phones. However, along with the development and requirements of society, it is convenient and easy to store data in computers. <PATIENT-5> I won't use mobile phones or computers. I have to use paper questionnaires. <PATIENT-6> Paper format. Some people are old and can't understand the computer. It's hard for them to use tablets or mobile phones. I met two people (in the hospital) who come from rural areas, and (scales of	<PATIENT-1> 我感觉还是纸质的比较好。平板还有手机别说是老年人了，有的时候我都弄不明白，这样的话就不方便老人。老人不会玩手机的不会上网的，不方便他们，所以说还是纸质的好。 <PATIENT-2> 这就得看文化程度了，我不会平板电脑也不会手机，就是老年机。我这个岁数就是这个时代过来的，还是纸质的拿起来比较方便翻着看，然后方便点。 <PATIENT-3> 还是手机，现在手机多普遍啊，手机上到时候一填多好，就是认为对的打勾，认为错的打叉，我感觉还是手机方便。 <PATIENT-4> 我喜欢落实在纸上。对于我这个岁数来说，一般都是用纸，所以用起来就很方便。我对于平板电脑或手机很生疏和不熟练。但是如果按照社会的发展和要求来说，还是把它纳入到电脑里，既方便又易储存。 <PATIENT-5> 我不会使手机、电脑的，我就得使纸质的。 <PATIENT-6> 我感觉还是这纸质版的，有些人岁数大了电脑他整不明白。让他用平板电脑或手机是难为他了，你看我接触的有两个农村来的，那都是孩子帮填的（其他科研项目的量表）。 <STAFF-1> 我感觉两者都有吧。因为患者他有年龄大的，你要对手机有的根本就不会用。我感觉

	another research project) were all filled in by their children. <STAFF-1> I think we should keep both formats. Because the patients are old, some of them don't use mobile phones at all. But for young patients, it's entirely possible to use mobile phones. <STAFF-2> I think the paper format is suitable. It's convenient to read. Because some people use phones designed for elderly. If you put it on smartphones, I don't think they can read it. The font size on mobile phones is small. The font size on the papers can be bigger and easier to read. <STAFF-3> I like paper. Usually, I enjoy reading on papers while I don't want to read on electronic screens. When I read the paper version of the questionnaire, I feel that I will be more serious. Because I am using my mobile phone every day, I feel a little numb when I fill in scales through my mobile phone and not take it seriously. <STAFF-4> I think the paper format is more suitable. Because there are some old patients, they don't use mobile phones. They don't have smartphones. For example, suppose you want patients to be added to a WeChat group to contact us at any time, in this case, they will possibly say they cannot because they do not have a smartphone. I think the paper version is better. Most people are literate. <STAFF-5> Both tablet and paper. Now, most people like to use mobile phones. It's very convenient to read on mobile phones and tablets. Even if there are only a few items in the IPOS and it is clear, some people still may not have the patience to choose. People may be willing to read on mobile phones while	但是对于年轻的患者来说，完全可以用手机。 <STAFF-2> 我觉得纸质版的就可以。看着方便。因为还有一些人用老年机，你整到手机里，我觉得他们有时候看不好。手机字小一点，我觉得纸质版字能大一点，看着能容易方便一点。 <STAFF-3> 我喜欢纸质。平时看书也喜欢纸质的，不喜欢电子的东西。我觉得面对纸质版问卷的时候，感觉给人的感觉会比较认真。因为我每天都在看手机，这个量表还是通过手机填写的话，感觉有点麻木了，大概随便填一填。 <STAFF-4> 我觉得纸质版更合适。因为有一些稍微年龄偏大一点的，他是不会玩手机的。没有这种智能手机。就跟现在一样，比方说告诉患者需要加个微信群，有啥事随时问我们，患者就会说他们不会加微信群，没有智能手机。我觉得纸质版更好一些，大部分人还都是识字的。 <STAFF-5> 平板跟纸质都要有。现在人大多数都喜欢玩手机，你要是从手机上、平板上一看，挺方便的。即便这个 IPOS 量表问题很少，也挺清晰的，但是有人可能就没有耐心，就随便选一选了，他不像是看手机那种感觉。同样的东西，可能在手机上就愿意看，这个纸质版就不愿意看。纸质版不像手机方便上下划来划去，填问卷时可能会错过问题。 <STAFF-6> 还是纸质版的比较好，因为咱们好多患者还是说老年机或者是他不会不太会用手机。然后使用纸质版时可能某些问题患者不懂，我

	unwilling to read on papers although they have the same content. The paper version is not as convenient as the mobile phone, which may lead to miss items when filling in the questionnaire. <STAFF-6> The paper version is better because many of our patients still use phones designed for the elderly, or they cannot use mobile phones at all. When using the paper version, the patient may not understand some items. We (medical staff) will read and explain for the patient, and they will be able to answer them.	们（医护人员）给患者读一遍，他就能够回答。

6.6 CONCLUSION AND NEXT STEP

Informed by the priorities of key stakeholders captured with in-depth qualitative interviews, the Chinese IPOS has supporting evidence for face and content validity and high levels of acceptability following initial cognitive testing which reflects the range of multidimensional outcomes matters to people living with advanced cancer to drive and evaluate their care. Next steps for the validation of the IPOS include completion of psychometric test to establish reliability, validity and responsiveness. Considerations are given at the time to the scoring system and any modifications to further consolidate IPOS that may be required. In addition, further work to promote the implementation of Chinese IPOS in research and clinical practical practice within and beyond advanced cancer patients is required to broaden its use across the country. The remaining steps of validation have been undertaken at two sites in China (manuscripts in Appendix 17 and 18).

CHAPTER 7. RESULT 4- VALIDATION OF CHINESE VERSION OF IPOS

7.1 INTRODUCTION TO CHAPTER

Chapter seven described the development process of the IPOS Chinese version and the steps taken to test and ensure the questionnaire's content and face validity. This chapter highlighted the steps taken to further establish the remaining psychometric properties of the IPOS Chinese version by determining aspects of reliability and validity. To do so the questionnaire was administered to a sample of individuals previously diagnosed with advanced cancer.

This chapter began by providing an overview of the different aspects of reliability and validity that warrant consideration when aiming to address study objective eight:

> **Objective 8** To assess the validity, reliability and responsiveness of the Chinese IPOS (patient and staff versions) among patients with advanced cancer, family members and health professionals in China.

7.2 SUBJECT CHARACTERISTICS

Study recruitment took place from January to September 2021 at Chaoyang Central Hospital in Liaoning and Peking University Shenzhen Hospital in Guangdong, China. 753 individuals that accessing cancer treatment at inpatient settings were screened at admission and of those 609 were eligible for this study. A total of 308 patient participants were recruited. The

demographic and clinical characteristics were presented in the Table 9. The number of screened, eligible, approached and consented participants, plus those who completed the first (n=308) and second (n=186) assessments, with reasons for non-completion, are shown in Figure 6.

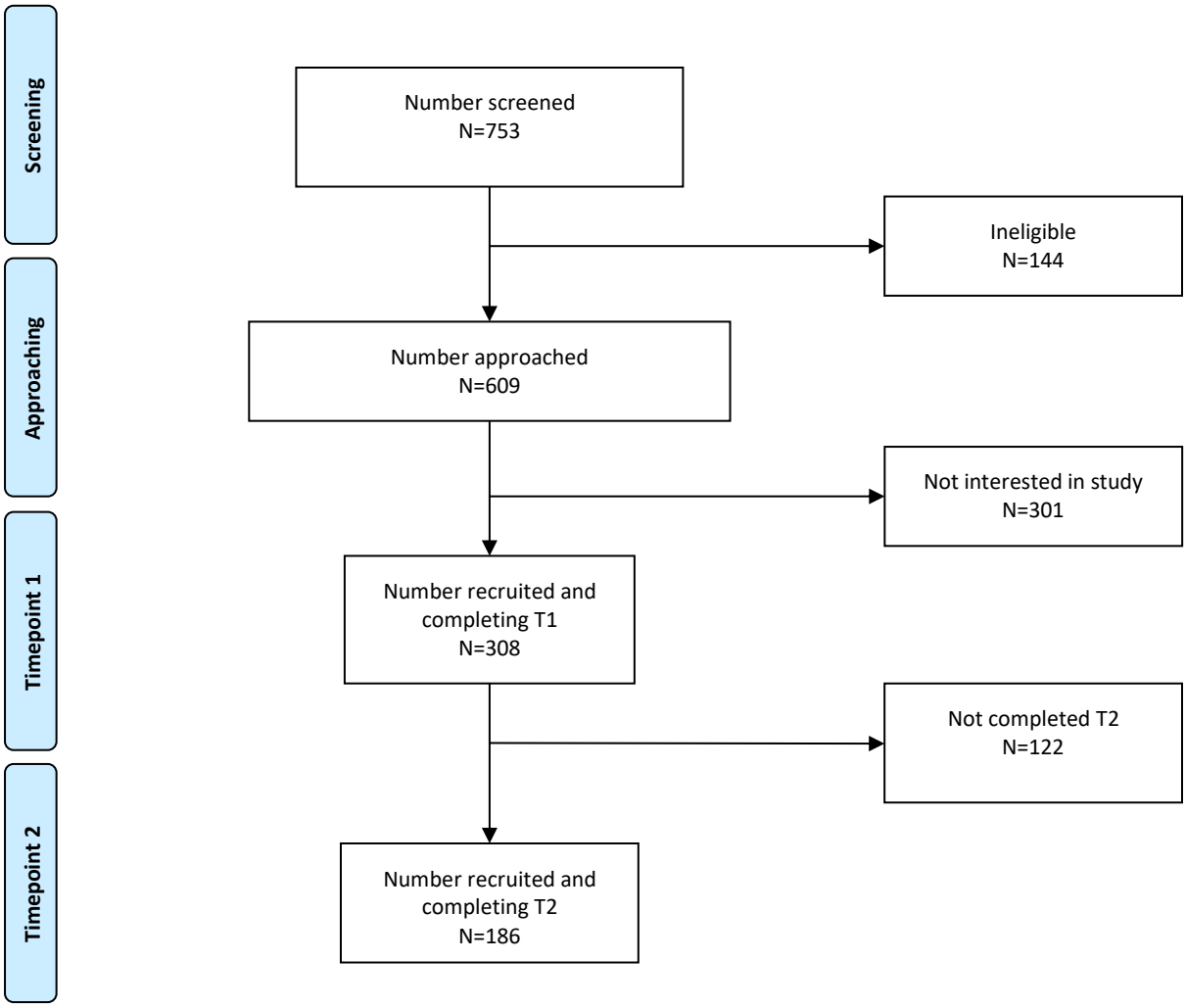

Figure 6. Sample size at each stage of screening, recruitment and analysis

Table 9. Demographic and clinical characteristics for all patient participants (n = 308)

Variable	Patient	
	n	%
Age	Mean 55.6	SD 11.0

< 60 years	196	63.6
≥60 years	112	36.4
Gender		
F	159	51.6
M	149	48.4
Marital Status		
Divorced	3	1.0
Married	282	91.6
Single	16	5.2
Widowed	7	2.3
Employment Status		
Employed Full-Time	46	14.9
Employed Part-Time	3	0.1
Not Employed	127	41.2
Self Employed	23	7.5
Retired	104	33.8
Missing	5	1.6
Primary diagnosis		
CRC	97	31.4
Lung	75	24.4
Breast	47	15.2
Gastric	25	8.1
Oesophageal	11	3.5
H&N	10	3.2
Ovarian	8	2.6
Liver	7	2.3
Cervical	5	1.6
Pancreatic	5	1.6
Bladder	4	1.3
Endometrial	4	1.3
Sarcoma	4	1.3
Neuroendocrine	3	1.0
Prostate	2	0.6
Gallbladder	1	0.3
Stage		
III	123	39.9
IV	185	60.1
Karnofsky performance status	Mean 87.66	SD 8.7
50	1	0.3
60	2	0.6

70	8	2.6
80	115	37.3
90	113	36.7
100	69	22.4
IPOS completion		
Completed IPOS alone	160	51.9
Completed IPOS with family help	39	12.7
Completed IPOS with staff help	109	35.4
Time between timepoint 1 & 2 (in days)	Mean 7.1	SD 2.6

7.3 DESCRIPTIVE STATISTICS AND DISTRIBUTION

Table 10 shows the distribution of IPOS scores at T1. The full range of response options on the 5-point Likert scale of the IPOS was used by all participants. The most burdensome physical symptom is poor appetite (12.9%), followed by pain (10.6%), weakness or lack of energy (10.3%) and poor mobility (7.5%). With regard to emotional and communication issues, family anxiety (50%) was reported as slightly or above, followed by sharing feelings (48.7%). Family burden (66.9%) was the most burdensome practical issues of advanced cancer patients, followed by financial issues (36%) and personal issues (33.4%). There was no missing data as research nurses double checked as soon as the scales were completed and would have notified the patients if any items missed.

Table 10. Descriptive statistics and distribution for IPOS items at T1 (n= 308)

	Not at all (0)	%	Slight (1)	%	Moderate (2)	%	Severe (3)	%	Overwhelming/ all the time (4)	%
Physical symptoms										
1-Pain	197	64	78	25.3	25	8.1	6	1.9	2	0.6
2- Shortness of breath	217	70.5	78	25.3	11	3.6	2	0.6	0	0
3- Weakness or lack of energy	149	48.4	127	41.2	24	7.8	6	1.9	2	0.6

4- Nausea	242	78.6	45	14.6	17	5.5	2	0.6	2	0.6
5- Vomiting	263	85.4	30	9.7	11	3.6	4	1.3	0	0
6- Poor appetite	185	60.1	83	26.9	28	9.1	10	3.2	2	0.6
7- Constipation	223	72.4	65	21.1	13	4.2	3	1	4	1.3
8- Sore or dry mouth	209	67.9	79	25.6	16	5.2	2	0.6	2	0.6
9- Drowsiness	242	78.6	45	14.6	16	5.2	3	1	2	0.6
10- Poor mobility	249	80.8	36	11.7	15	4.9	8	2.6	0	0
Emotional and communication issues										
11- Patient anxiety	123	39.9	92	29.9	58	18.8	23	7.5	12	3.9
12- Family anxiety*	87	28.2	67	21.8	77	25	44	14.3	33	10.7
13- Depression	144	46.8	89	28.9	56	18.2	17	5.5	2	0.6
14- Feeling at peace	108	35.1	113	36.7	44	14.3	33	10.7	10	3.2
15- Sharing feelings*	100	32.5	58	18.8	72	23.4	49	15.9	29	9.4
16- Information*	124	40.3	75	24.4	54	17.5	39	12.7	16	5.2
Practical issues										
17- Family burden*	48	15.6	54	17.5	62	20.1	64	20.8	80	26
18- Financial issues	115	37.3	82	26.6	76	24.7	22	7.1	13	4.2
19- Personal issues*	150	48.7	55	17.9	44	14.3	26	8.4	33	10.7

7.4 STRUCTURAL VALIDITY, IDENTIFICATION OF SUBSCALES

As expected for IPOS (a multidimensional measure), the goodness-of-fit indices of the initial EFA suggest no adequate fit to the single factor model, with fit indices CFI (0.58) and RMSEA (0.15). The three-factor solution showed a better fit than the two-factor and one-factor solutions. The EFA indicated a three-factor structure, with factor one loaded with ten items physical subscale, factor two with 6 items (emotional and communication subscale) and factor three with three items (practical issues subscale). (See Table 11 for result of EFA and Table 12 for standardised factor loadings)

Table 11. Result of EFA

Index of fit	One-factor	Two-factor	Three-factor

Chi-Square	1196.92	740.91	652.25
df	152.00	151.00	148.00
p-value	<0.001	<0.001	<0.001
Chi-Square/df	**7.87**	**4.91**	**4.41**
CFI	0.58	0.76	0.80
TLI	0.52	0.73	0.76
RMSEA	**0.15**	**0.11**	**0.11**

Table 12. Result of factor loadings for all Chinese IPOS items from structure matrix

Items	Factor 1	Factor 2	Factor 3
Pain	**.64**		
Shortness of breath	**.63**		.34
Weakness or lack of energy	**.81**		
Nausea	**.75**		
Vomiting	**.71**		
Poor appetite	**.81**		
Constipation	**.54**		
Sore or dry mouth	**.66**		
Drowsiness	**.69**	.31	
Poor mobility	**.78**		
Patient anxiety	.31	**.73**	.38
Family anxiety		**.69**	.41
Depression	.39	**.54**	.52
Feeling at peace		**.70**	
Sharing feelings		**.67**	
Information		**.70**	
Burden to family			**.37**
Financial issues			**.71**
Personal issues		.468	**.61**

The first factor, Physical Symptoms, comprises 10 items and explains 31.46% of the variance. The second factor, Emotional Symptoms and communication issues, consists of 6 items and explains 13.55% of the variance. The third factor, Practical Issues, contains 3 items and explains 7.15% of the variance. (These three factors were used throughout the analysis as subscales: the Physical, Emotional/Communication and Practical subscales, see Table 12).

In this three-factor model, CFA fit indices were CFI = 0.80, TLI=0.76 and RMSEA=0.11 indicated poor fit of the model to the data ($\chi 2 = 652.25$, df = 148.00, $\chi 2/df = 4.41$, $p < 0.0001$). Even though the CFI and SMRM parameters approached the minimums, they were not within the required defined parameters recommended for small samples. For this reason, the CFA was inconclusive and cross-cultural validity could not be confirmed or negated. The standardised parameter estimates of the modified model are shown in Figure 7.

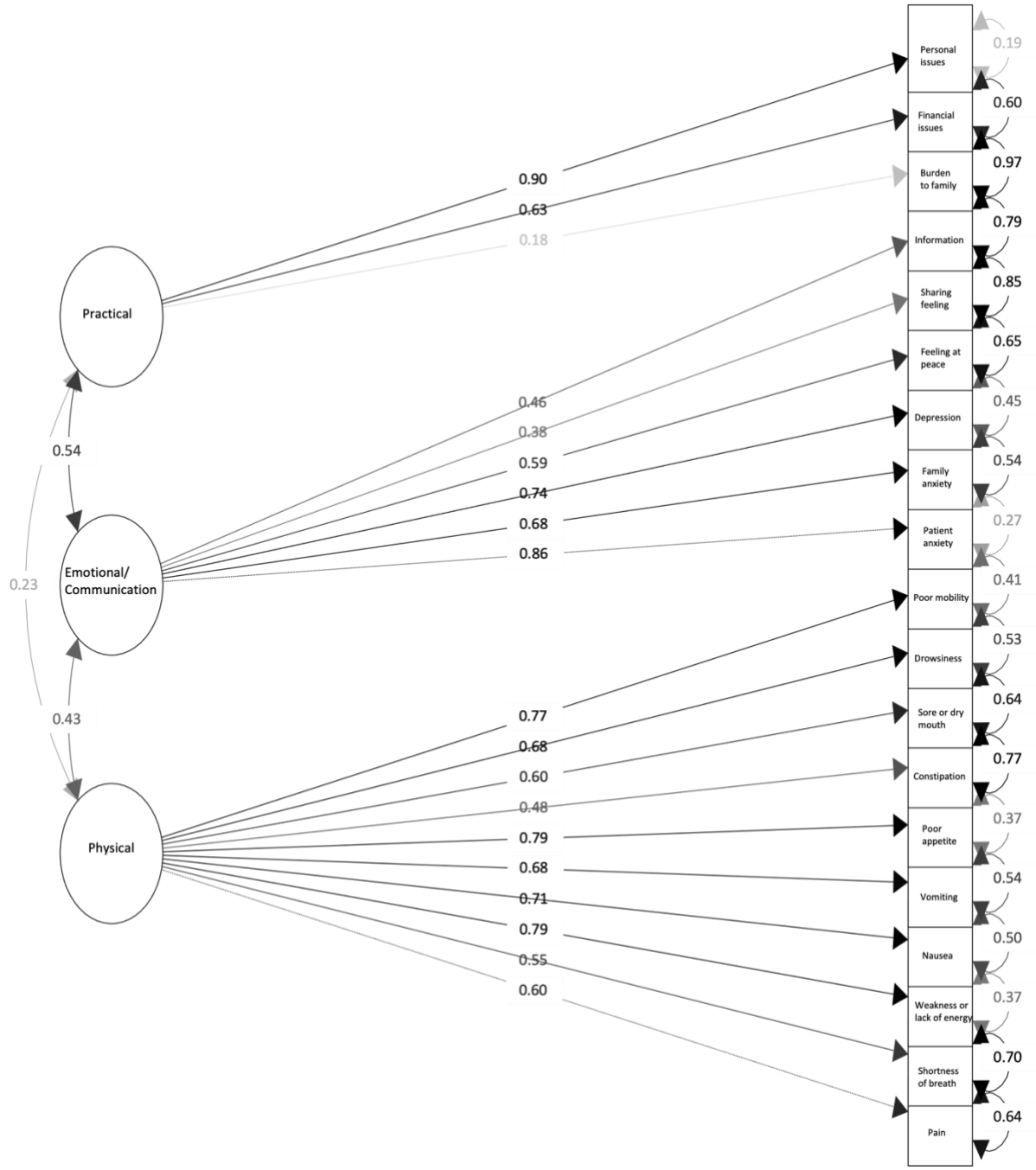

Figure 7. Standardised measurement model for Confirmatory Factor Analysis (n = 308)

7.5 CONVERGENT VALIDITY

Convergent validity assessment also comprised testing hypotheses for how IPOS subscales and single items correlate with single items, subscales and total scores of the ESAS (which assesses physical and emotional symptoms). Correlations between IPOS and ESAS were confirmed. Pain (r=0.77), drowsiness(r=0.61), nausea(r=0.766) and poor appetite(r=0.61)

were highly correlated between IPOS single symptom items and the corresponding Edmonton Symptom Assessment Tool items. Weakness or lack of energy/tiredness (r=0.57), depression (r=0.49) and anxiety or worry about illness or treatment/anxiety were moderate correlated. Only one pair of items (shortness of breath) had low correlation. The Chinese IPOS was highly correlated with total ESAS (r=0.76, 95% CI 0.681-0.819), with physical (r=0.76) and emotional/ communication subscales (r=0.57) highly to moderately correlated. IPOS practical issues subscale had low correlation with total ESAS (r=0.20). R values were in the hypothesised range of direction and magnitudes. (See Table 13 and 14)

Table 13. Correlations between IPOS single symptom items and the corresponding Edmonton Symptom Assessment Tool items (n=308)

IPOS	ESAS	r	95% CI
Pain	Pain	0.77	0.69-0.84
Weakness or lack of energy	Tiredness	0.57	0.47-0.667
Drowsiness	Drowsiness	0.61	0.46-0.73
Nausea	Nausea	0.76	0.64-0.85
Poor appetite	Lack of appetite	0.61	0.49-0.71
Shortness of breath	Shortness of breath	0.35	0.20-0.50
Depression	Depression	0.49	0.36-0.60
Anxiety or worry about illness or treatment	Anxiety	0.52	0.40-0.63

Table 14. Correlations between IPOS (Total and subscales) and ESAS (Total) (n=308)

	Total IPOS		IPOS Physical		IPOS Emotional/ Communication		IPOS Practical issues	
	r	95% CI	r	95% CI	r	95% CI	r	95% CI
Total ESAS	0.76	0.681-0.819	0.73	0.635-0.801	0.57	0.48-0.65	0.20	0.08-0.30

Table 15. Descriptive statistics and distribution for IPOS total and subscale scores at T1 (n= 308)

	#items	Range	Mean	SD	Skew	Cronbach's α	Eigenvalue	% variance
IPOS Total Score	19	0-58	15.76	9.39	1.11	0.83		
IPOS Physical symptoms	10	0-27	3.96	4.92	2.16	0.89	5.98	31.46
IPOS Emotional/ Information Issues	6	0-20	7.27	4.94	0.32	0.79	2.57	13.55
IPOS Practical Issues	3	0-12	4.53	2.86	0.40	0.55	1.36	7.15

7.6 RELIABILITY

7.6.1 Internal consistency

IPOS total score had a very good internal consistency (Cronbach's α was 0.83). For the subscales, both physical and emotional/ information issues had very good internal consistency (Cronbach's α was 0.89 and 0.79, respectively), whereas practical issues subscale had poor internal consistency (Cronbach's α was 0.55).

7.6.2 Test-retest reliability

According to the participant-reported change question used in the time point 2 survey, 85 patients reported no change on the global change rating at time point 2. For these 85 stable patients, test-retest reliability weighted kappa values showed fair to good agreement (range 0.40 to 0.75) except for the items 'Nausea' (κw = 0.39), 'Constipation' (κw = 0.30), 'Sore or dry mouth' (κw =0.36), 'Feeling at peace' (κw = 0.36) and 'Burden to family' (κw = 0.39). The proportion agreement within one score between assessments was generally fair to good

with only ‘Pain’ achieved substantial to excellent agreement (κw =0.80). (See Table 16). The agreement of total IPOS score between two timepoints was fair to good with κw=0.59.

7.6.3 Inter-rater reliability: patient and staff

The level of agreement between independent patient and staff ratings measured by weighted Kappa scores was good (≥ κw = 0.40) for 14 of 19 IPOS items with the highest levels of agreement being achieved for the items ‘Pain’ (κw = 0.73), ‘Shortness of breath’ (κw = 0.66) and ‘Poor mobility’ (κw = 0.64). Lower levels of agreement were observed for items ‘Patient anxiety’, ‘Family anxiety’, ‘Feeling at peace’, ‘Sharing feelings’ and ‘Burden to family’. The agreement of total IPOS score between patient and staff reported was fair to good with κw=0.48.

Table 16. Test-retest reliability (n=85): weighted kappa (κw) between T1 and T2 and Inter-rater reliability (n=251): weighted kappa (κw) between patient and staff ratings at T1

	Test-retest (n=85)	Inter-rater (n=251)
	Cohen's weighted kappa	
1-Pain	0.80	0.73
2- Shortness of breath	0.73	0.66
3- Weakness or lack of energy	0.55	0.51
4- Nausea	0.39	0.60
5- Vomiting	0.43	0.47
6- Poor appetite	0.48	0.56
7- Constipation	0.30	0.60
8- Sore or dry mouth	0.36	0.55
9- Drowsiness	0.51	0.42
10- Poor mobility	0.51	0.64
11- Patient anxiety	0.60	0.34
12- Family anxiety	0.43	0.39
13- Depression	0.48	0.42
14- Feeling at peace	0.36	0.36

15- Sharing feelings	0.58	0.35
16- Information	0.49	0.41
17- Burden to family	0.39	0.26
18- Financial issues	0.59	0.43
19- Personal issues	0.68	0.49
IPOS Physical symptoms	0.46	0.60
IPOS Emotional and communication issues	0.28	0.39
IPOS Practical issues	0.55	0.31
Total IPOS	0.59	0.48

7.7 RESPONSIVENESS TO CHANGE

The global change question 'Over the last three days, has your condition changed/ would you say that things have got better /worse / there has been no change?' was answered by 180 (96.8%) patients. Mean change scores for the total score were as large as -3.00 in the "much better" group and even larger ($Mean_{change}$ = 4.36) for the group that described themselves as 'a little worse'. Total IPOS score discriminated between patients who indicated that their health improved, got worse, or remained unchanged between the two assessment timepoints.

Table 17. Mean total IPOS score changes (between T1-T2) by global change scale (a positive change score indicates deterioration)

Has your condition changed?	n=180	IPOS $Mean_{change}$±SD_{change}
Things have got		
Much better	22	-3.00±8.36
A little better	62	-1.02±7.07
No significant change	85	0.76±6.62
A little worse	11	4.36±8.31
Much worse	0	0

Do not know	0	0

7.8 INTERPRETABILITY

The ceiling effect was evident in only one item (*Q9: Have you felt a burden to your family?*) with 15.6% patients soring 4. The floor effect was present for all items, with 26.0 – 85.4% of the patients reported the lowest possible score (0).

7.9 TIME TO COMPLETE

The mean time to complete at timepoint 1 and timepoint 2 is 6.23 min (1-25, SD=3.97) and 5.54 min (1-26, SD=4.14).

7.10 CONCLUSION

The Chinese IPOS is a valid and reliable outcome measure for use with people with advanced illness, ready to be used both in its patient self-report and staff proxy-report versions. It is suitable for assessing and monitoring symptoms and concerns in advanced cancer, monitoring change over time, determining the impact of healthcare interventions, and demonstrating the quality of care in China.

CHAPTER 8. DISCUSSION

8.1 INTRODUCTION OF THE CHAPTER

This study provides strong evidence that Chinese IPOS is a valid and reliable palliative care outcome measure for use with people with advanced cancer in China. The psychometric evaluation shows Chinese IPOS has good content validity, internal consistency, structural validity, with three underlying factors – physical symptoms, emotional/ communication symptoms, and practical issues – and appropriate convergent and discriminant validity when compared with ESAS (validated in China). Most individual IPOS items show good agreement when re-tested in stable patients. There is also acceptable or good agreement between the majority of patient self-reported and staff proxy-reported items. Most importantly, the total IPOS score showed a change in keeping with patient-report of the overall change in their symptoms and other concerns, both in direction and magnitude of change.

8.2 REFLECTIONS ON EACH PHASE OF THE STUDY

8.2.1 Systematic review

The objective of this section is to provide an understanding of the context in which better measurement tools are needed. A total of 46 studies, including 39 PROMs, were included in this review. None of the PROMs addressed all four domains of concern to patients with advanced cancer (i.e. physical, psychological, social and spiritual), and none were valid

across all psychometric properties. No articles were rated "+" in more than four stages of the cross-cultural adaptation process, demonstrating weak equivalence between the original language version and Chinese. The quality of measurement properties varied greatly. Content validity was tested and reported satisfaction in 21 (45.7%) studies. Internal consistency was tested in 44 (95.7%) studies, including 38 (97.4%). Responsiveness was only analysed in one study. Based on COSMIN, none of the identified PROMs were valid across all properties nor appropriate to use. Despite the incomplete information in the identified studies, results of this review suggest researchers and physicians working with advanced cancer patients in China have to choose the available measures without adequate psychometric properties, which risk unethical research and wasted resources.[1]

None of the studies on measurement properties in this review achieved a rating of good quality in all characteristics. Internal consistency and construct validity were widely assessed in the included studies. In contrast, a high proportion the information on properties per measure in each included study is missing and evidence is particularly limited in test-retest reliability, responsiveness, floor and ceiling effects and interpretability and greatly variations were observed in the methodological quality. Since accurate and reproducible measurements are pre-requisites for an adequate instrument, acceptable validity and reliability is essential. There is a clear need for re-evaluation of some particular properties of measures with poor psychometric testing quality in future research. There is currently no ideal outcome measure for use in advanced cancer patients in China as the COSMIN recommends PROMs with evidence for sufficient content validity and at least low-quality evidence for sufficient internal consistency can be trusted.[2-4]

Given that multidimensional unmet needs are associated with increased healthcare costs and increased distress, which can reduce survival, measures should ensure that all relevant dimensions are assessed efficiently.[5, 6] For the quality-of-life scale, the only scale that met this standard was QLASTCM-Ga, which is specifically for gastric cancer patients in mainland China. There was no other quality of life scale that met standards for other cancer types in Hong Kong and Taiwan. Similarly, the only emotional and cognitive symptom scale that met standards was MAX-PC, which measures anxiety in prostate cancer patients in mainland China. MSAS met standards for use in the mainland and Hong Kong for evaluating physical symptoms, while MPI-sC met standards for use in Taiwan to measure pain in patients with advanced cancer. For scales measuring spirituality domain, C-MiLS met standards for use in mainland China and C-SpIRIT in Taiwan. Further research is needed to promote the use of multidimensional measures in China for clinical trials to measure treatment effects and in clinical practice to identify and prioritise problems, facilitate communications, monitor changes and treatment responses, staff training, and in clinical audit and governance.

When measuring non-tangible concepts, such as palliative care needs for advanced cancer patients, the methodological challenge in content validation is longstanding regarding what matters and what should be measured. Most of the included studies used CVI to establish face and content validity, which is the widely used method of quantifying content validity for multiitem scales.[7] An alternative method to establish face and content validity is qualitative methods, which were used in none of the included studies. Rigorous and transparent qualitative methodology is one of the most suitable methods for assessing content validity.[8] Qualitative analyses of the content validity of a measure assess not only the opinions on the measure under consideration but also the target population's

conceptualisation intended to be assessed in order to have a better understanding of what matters to the participants and a firmer conclusion as to the content validity. Qualitative content validation can be established with the stakeholders who have first-hand and personal experience, which allow researchers to observe individuals with different background and how the construct of interest manifests itself in different individuals.[9] As there was no study reporting content validity qualitatively in advanced cancer patients in China, qualitative work amongst this population is needed to allow data from different perspectives and different methodologies.

This systematic review summarised and critically appraised the psychometric measurement properties of existing PROMs used among advanced cancer patients in China, which provided the first robust and transparent evaluation of patient-reported measures for advanced cancer patients in China. The strengths of this systematic review are the comprehensive search strategy which found more than 10000 articles for potential inclusion and 46 papers were systematically appraised and compared, and the use of the COSMIN methodology.

This review also has several limitations. First, the search was restricted to databases in English or in Mainland China as the authors had no access to databases in Hong Kong and Taiwan. In addition, it was sometimes unclear if specific criteria on the COSMIN checklist were not performed or not reported on. Therefore, we had to use other evaluation criteria that were not suggested by COSMIN to assess the quality of measurement properties.

8.2.2 Qualitative study

The findings from this qualitative study highlighted the multidimensional ramifications of advanced cancer for patients and their main family caregivers in China. Five themes of symptoms, concerns and the priority outcomes for advanced cancer patients and family members were identified and devised a model for person-centred advanced cancer care in China. Being an advanced cancer patient was seen as difficult, especially due to high physical and psychological symptoms throughout the disease trajectory. Professional behaviours, good attitudes and interpersonal skill of healthcare providers have been identified as beneficial to promote satisfaction and trustful relationship and these aspects of care are appreciated by the participants. Financial difficulties and sense of burdensome to families have become a major concern of patients. Advanced cancer patients developed coping strategies and made future despite encountering several practical challenges from cancer.

Sharing thoughts in terms of the topics as a therapeutic process. Some participants may find it helpful and cathartic to express their feelings, opinions, and experiences regarding their illness and care. This may enhance their emotional well-being, coping skills, and sense of meaning and purpose.[10, 11] Contributing to this study with the purpose of improving research design as an empowering process. Some participants may feel valued and respected for their input and feedback on the research process and outcomes. This may increase their self-esteem, confidence, and autonomy.[12, 13] Reflecting on the care patients received which could be the reference to improve clinical practice. Some participants may gain new insights and perspectives on patients' care needs, preferences,

and expectations. This may improve their communication and collaboration with health care providers, as well as patients' satisfaction and quality of life.[14]

The patients and families we interviewed referred to the physical and emotional impact of advanced cancer and the disease process, which led many of them to experience pain, fatigue, anxiety, or depression. Pain and fatigue are distinctive characteristics of advanced cancer.[15] The physical change, resulting from surgery or loss of fat or hair is clinically considered the most recognisable sign of cancer. Participants were very aware of their appearance and described how cancer and its treatment continually reinforced its serious connotations in all domains of the patient's life. The results echo Body Image Dimensions which outlines how altered physical appearance can change a person's perception of 'self', which in turn can impact socialisation patterns. [16, 17] Such findings reinforce the modern societal focus on appearance. Even when patients were physically able to engage in socialisation, they declined to do so because they were concerned about peoples' reaction to their cachectic appearance.[18]

Participants also alluded to how high health expenses impact patients' treatment and how they had to compromise their treatment due to the high cost. The cost of treatment is reported as a barrier in seeking treatment among cancer patients.[19] Although by achieving near-universal population coverage of health insurance, China has improved access to and use of health services and reduced the proportion of out-of-pocket spending, catastrophic health expenses for poor people are still high, disproportionately affecting deprived populations.[20] Systematic reviews showed that financial burdens are disproportionately impacting socioeconomically disadvantaged cancer patients and are

associated with worse therapeutic adherence and quality of life.[19, 21] More effort should be made to identify vulnerable patients needing oncology provider engagement and response.[22]

There are long-lasting misunderstandings about palliative care in China among the public and healthcare professionals.[23] Some people believe receiving palliative care services is interpreted as giving up the treatment and wait to death, which is against cultural values.[24] Therefore healthcare professionals are pressured to provide curative treatment to advanced patients by the patient's families, which makes patients and families exposed to untenable anguish, and may lead to and exacerbate the financial burden for the patients and families and even accelerate the patients' death.

A growing body of evidence is now available to inform the key domains in the practice of cancer palliative care, including symptom management, psychosocial care, communication, decision-making, and end-of-life care.[25] Yet limited access to palliative care forced cancer patients and families to endure a tremendous burden of avoidable suffering in China. Staff training and capacity building would be essential to improve cancer care and palliative care for this vulnerable and neglected patients and families.

Patients have described the practical challenges induced by disease and treatment, including the lack of financial support, healthcare resources, medical insurance and working opportunities as cancer patients. Therefore, policymakers and organisational leaders should consider all these factors affected the multidimensional wellbeing of patients and families which would subsequently influence their quality of life.

Our finding adds important new evidence of priority outcomes for advanced cancer patients and family members and devised a model for person-centred advanced cancer care in China. To our knowledge, few studies have explored the role and experiences of cancer patients qualitatively in China.[26, 27] In contrast to the greater attention paid to the experiences of patients living in western countries, who commonly report uncertainty about their future,[28, 29] our findings are consistent with those of several studies that have examined the experiences of cancer patients,[30-32] or of patients with chronic disease.[33-35]

There were several limitations to consider. One of the limitations of this study is that it was carried out in a single specialist unit for cancer. Hence, our participants' experiences may not be generalisable to other centres. That said, our findings echo the international literature on the experiences of advanced cancer patients and caregivers of individuals with other similar diseases. Another limitation is the lack of a wider variety of participants: most participants interviewed were diagnosed with breast or lung cancer. Further research with more devised cancer type from multi-sites is needed to build upon our understanding of the experiences and needs of more representative patients.

Dyads are important for understanding the complex and dynamic interactions that occur in palliative care settings, and how they affect the outcomes and quality of life of both patients and their families. In this study, a subsample of participants (two pairs) happened to be dyads, which offered us opportunity to explore the perspectives of both patients and their families in palliative care, and to examine the similarities and differences between them.[36,

37] This raises interesting possibilities in terms of future research since there are some intriguing potential effects of collecting data from dyads. Further investigation could potentially deepen our understanding of the dyadic relationships in palliative care and provide valuable insights into tailored interventions and support mechanisms for both patients and their caregivers

8.2.3 Translation and cross-cultural adaptation of the IPOS Chinese version

In this study, we translated and culturally adapted IPOS Patient and IPOS Staff into Chinese and demonstrated face and content validity and acceptability of the scale through expert review and cognitive interviews with patients and staff. The clear articulation of these crucial steps is often under-reported. There were several concepts where a direct translation from English to Chinese became misleading and in need of cultural adaptation. One new item was developed, and changes were made, agreed by the expert review meeting. The comprehension and judgement difficulties identified in the pre-final patient and staff versions were successfully solved during the cognitive interviewing process. The Chinese translation of IPOS has thus been shown to be acceptable for both patients and staff. None of the items were considered inappropriate, and all questions were judged relevant and important.

We assessed the IPOS against the COSMIN criteria for evaluating the content validity of PROMs, providing supporting evidence for the relevance, comprehensiveness and comprehensibility (content validity) of the Chinese IPOS.[38] (See Table 18) Importantly, the translation and cultural adaptation of the Chinese IPOS was achieved through the expert

contribution of researchers, patients, families and healthcare professionals. It means the measure reflects the priorities of key stakeholders which established a sound face and content validity of the Chinese IPOS and improving this utility in routine clinical practice and research.[39]

Table 18. COSMIN criteria and rating system for evaluating the content validity of PROMs

Criteria	Assessment
Relevance	
Are the included items relevant for the construct of interest?	✓
Are the included items relevant for the target population of interest?	✓
Are the included items relevant for the context of use of interest?	✓
Are the response options appropriate?	✓
Is the recall period appropriate?	✓
Comprehensiveness	
Are all key concepts included?	✓
Comprehensibility	
Are the PROM instructions understood by the population of interest as intended?	✓
Are the PROM items and response options understood by the population of interest as intended?	✓
Are the PROM items appropriately worded?	✓
Do the response options match the questions?	✓

The main problems with comprehension in the process of cross-cultural adaptation of IPOS involved finding an appropriate Chinese term for “at peace”, which has been reported previously from other regions.[40-42] The replacement terms (relaxed or in good mood) tested were understood as meaning satisfying/ comforting emotionally, and hence neither appropriate nor equivalent. The intention of the question is to measure spiritual wellbeing. The similar challenges of translation of “at peace” were identified in other languages/cultures. For example, Italian “feeling at peace” was confused with “not at war” or “only the dead are at peace”.[43] Beck et al. reported there was no equivalent terms so “satisfied” was chosen in Swedish.[44] In the Chinese version, we eventually found that both patients and staff considered the term for calm and quiet within themselves to be a suitable expression for feeling at peace in terms of spiritual wellbeing, without excluding either those that practice religion and those who do not.

Another problem with comprehension was identified for drowsiness since this term was not seen as “feel asleep at daytime”. Some patients confused this with “cannot sleep” as drowsiness is an academic word which causes misunderstand. Similarly, Laissaar et al. described disagreement in the translation of “drowsiness” in Estonian.[41] We changed it to plain language in the pre-final version. There were also inconsistencies related to the Chinese term for addressed in the question about practical problems (Q9). Both patients and staff considered this question to be an important one, which should allow participants having more opportunity to discuss it. The pre-final version included two items regarding participants’ financial issues and personal issues.

The need for person-centredness, focusing on what core outcome matters to people living with advanced cancer, has long been recognised.[45] However, to date there was no validated PROM that reflected the breadth of concerns for people living with advanced cancer in China.[46] Integrating the IPOS into routine cancer care and palliative care will support patients and family members to set their priorities, actively involve them in decision making, facilitate communication with healthcare professionals and improve quality of care.[47, 48]

IPOS measures core outcomes for patients in need of holistic palliative care.[49] Highlighting these questions is because non-physical aspects are easily neglected while physical symptoms are prioritized in advanced cancer patients, and so these areas are considered to be essential for both patients and staff.[50] It is crucial for a holistic palliative care to use measures that include multiple dimensions beyond physical symptoms, to ensure that other concerns are acknowledged and addressed.[51, 52] The next step, to further contribute to increased knowledge about outcomes within palliative care, is to psychometrically validate Chinese IPOS of patient and staff versions.

The translation and cultural adaptation of the Chinese IPOS, a brief, comprehensive tool for use within palliative care, represents a significant step towards a person-centred approach in China. A major strength of this study is the methodological rigour with which it was undertaken, with transparent reporting of the PROM development process following both COSMIN and Rothrock guidance. Many reports of PROM development fail to describe the processes of item generation or cross-cultural adaptation in detail. Another strength is the

meaningful engagement of patients and families (including PPI members in expert review meeting phase) throughout this study.

Although we worked to ensure that the participants in the in-depth qualitative interviews and cognitive interviews represented the diversity of participants, there was underrepresentation of patients with low level of activity with high medical care requirements (low KPS), which could possibly lead to doubtful content validity of the Chinese IPOS when using it with seriously ill patients. Further exploration of priorities of critical conditions should be performed in the future.

8.2.4 Assessment of Psychometric properties

Among the tested solutions, the 3-factor solution performed best. This solution is very similar to the one obtained on the original IPOS and APCA African POS, with the difference of the emotional items now clustering with the communication items.[53, 54] The item 'burden to family', loading on the symptom factor, was the only item with a factor loading below 0.30. This suggests that 'burden to family' may not be collapsed into the construct of 'practical issues'. As this item was newly developed for Chinese IPOS informed by qualitative research, these results warrant further exploration, particularly given the diversity of settings and patients included. It may be explained by underlying heterogeneity in the sample which could be explored by latent mixture modelling. It should also be investigated whether burden to family forms an overarching factor, affecting and explaining the other factors and subscales in the IPOS.

In terms of test-retest reliability, we found mostly fair to excellent agreement demonstrated by weighted kappa values ranging from 0.40 to 0.80. These values are similar or higher than similar studies of test-retest reliability of IPOS in other cultures. However, some items demonstrated low weighted kappa values, namely 'Constipation' (κw=0.30), 'Sore or dry mouth' (κw=0.36) and 'Feeling at peace' (κw=0.36). These are also the items showing very low agreement in comparing patient and staff ratings. The low agreement for the information item had also been observed. The Czech IPOS validation study found a weighted kappa value as low as 0.33 for this item.[40, 55] Several explanations can account for this result. A qualitative study accompanying low agreement scores of the Palliative care Problem Severity Index, identified reasons and features of the raters (e.g., new staff member with new patient), patient characteristics (e.g., communication problems, dementia, drowsiness or immigrant), family characteristics (e.g., lacking interaction with family, appropriate distress in face of advanced illness), or features of the item itself (e.g., time frame of question not matching the assessment time frame) as impeding high agreement scores.[56] It is likely that these features may also have been present in the Chinese IPOS validation study. Specifically, lack of familiarity with patients and their families and IPOS assessment occurring prior to taking the first, comprehensive history at admission of the patient. These features may also well explain the low agreement scores observed with items asking about family issues.

The Chinese IPOS is innovative as burden to family (n=1 item) and practical issues (n=2 items) were newly developed or refined. It enables healthcare professionals to assess the multidimensional outcomes of palliative care contextually. Importantly, patients were an integral part of the entire development process, with more than 300 patients involved

throughout to shape the scope of the Chinese IPOS. It is flexible because it has developed a staff-reported version for patients unable to self-report their symptoms and concerns.

There are some limitations in this study. Firstly, the findings from this oncology sample should be reproduced in non-cancer palliative populations that also bring serious health-related suffering at the end of life.[57] In addition, 96.4% of the sample reported good functional status (KPS≥80). Lastly, only two study sites were included across China, and there are regional differences in the Chinese language and a large and diverse geography.

8.3 OVERALL LIMITATIONS

This study has several limitations. In the systematic review, the search was restricted to databases in English or in Mainland China as the authors had no access to databases in Hong Kong and Taiwan. In addition, it was sometimes unclear if specific criteria on the COSMIN checklist were not performed or not reported on. Therefore, we had to use other evaluation criteria that were not suggested by COSMIN to assess the quality of measurement properties.

Considering the regional differences in the Chinese language and a large and diverse geography, this study was carried out only in cancer departments from two hospitals across China. Hence, our participants' experiences may not be generalisable to other centres, leading to a lack of a wider variety of participants. The findings from this oncology sample should be reproduced in non-cancer palliative populations that also bring serious health-related suffering at the end of life.[58] Further research with more devised cancer type from

multi-sites is needed to build upon our understanding of the experiences and needs of more representative patients.

Recruiting advanced patients for palliative care research is important to capture the needs and experiences of the vulnerable population, who often face complex physical, psychological, social, and spiritual problems at their end of life. Some of the factors that may deter lower KPS patients from participating in research include poor health status, fatigue, cognitive impairment, lack of interest, fear of burdening others, and preference for spending time with family and friends.[59]

The sample included a smaller proportion of patients with low level of activity with high medical care requirements (low KPS). High KPS patients may have different perspectives, preferences, outcomes, responses to palliative care interventions and expectations regarding palliative care than low KPS patients.

Future research on palliative care priorities of advanced patients in China is needed to fill the gap in the literature and to inform clinical practice and policy. Some of the recommendations and suggestions for future research include: identifying and recruiting patients at advanced stage by increasing participation rates at palliative settings; developing and evaluating tailored interventions that address the specific needs and preferences of advanced patients; and conducting longitudinal studies that follow advanced patients over time to monitor their changes in needs and outcomes. However, given the low coverage of palliative care services in China, I also recognise that this additional sampling may be complex.

8.4 IMPLICATIONS AND FUTURE RESEARCH

This study has produced a new language version of IPOS and demonstrated that the Chinese IPOS is valid, reliable and responsive. Because it is brief and underpinned by the symptoms and concerns of people with advanced illness, it will be invaluable for clinical practice (both clinical care delivery and audit) and research.

The evidence base for advanced cancer palliative care in China is currently limited, and Chinese IPOS will enable health outcomes to be appropriately measured and plays an increasingly crucial role.[46] There is strong evidence for the utility of the validated outcome measures within palliative care settings in: (a) improving communication between patients and clinicians; (b) identifying unrecognised needs and monitoring symptoms; (c) increasing the amount of clinical action taken; (d) improving outcomes through person-centred care; and (e) demonstrating the value of palliative care.[60] Therefore, IPOS should be used as a fundamental component in advanced cancer palliative care in China to provide the necessary information clinicians require to make decisions in patient management.

Despite the importance of successful implementation of PROMs, their routine use in palliative care practice has been slow, which hinders their optimal role in assisting decision-making and improving quality of care.[61-63] To facilitate the implement of Chinese IPOS in routine clinical practice, there is the need to make careful preparation and planning before use and acknowledge interpersonal relationships between the clinical team members and the ongoing emotional and cognitive processes that occur in each individual.[64, 65] Table

19 lists the EAPC recommendations for outcome measurement in palliative care, which need to be carefully considered while implementing IPOS in China.

Table 19. Outcome measurement in palliative care: Improving practice, attaining outcomes and delivering quality services – Recommendations from the European Association for Palliative Care (EAPC)

Key parameters of measures
Recommendation 1: Use patient-reported outcome measures (PROMs) that have been validated with relevant populations requiring palliative care and make sure these are sufficiently brief and straightforward and that they allow for proxy reports to be collected for when the patient is unable to self-report.
Recommendation 2: Use multidimensional measures that capture the holistic nature of palliative care.
Recommendation 3: Use outcome measures to assess the needs of unpaid caregivers (family and others) alongside the needs of patients.
Recommendation 4: Use measures that have sound psychometric properties.
Adequate measure for the task
Recommendation 5: Use measures that are suited to the clinical task being delivered and also suited to the aims of your clinical work and the population you work with.
Recommendation 6: Use valid and reliable measures in research that are relevant to the research question and consider patient burden when using measures.
Introduction of outcome measurement into practice
Recommendation 7: Use change management principles, facilitation and communication to embed outcome measurement into routine clinical practice and evaluate the

implementation process to ensure sustained use that penetrates practice within the organisation.
National and international: outcome comparisons and benchmarking
Recommendation 8: Relate outcome measurement to quality indicators.
Recommendation 9: Establish and use quality improvement systems to sustain routine practice of outcome measurement and institute interoperable electronic systems to ensure integration of measures and across settings.
Recommendation 10: Use measures that allow for comparisons across care settings and throughout Europe. Therefore, use measures that are culturally sensitive and have validated translations in relevant languages/countries.
Recommendation 11: Advance the field of palliative and end-of-life care through establishing national and international outcome collaborations that work towards benchmarking to establish and improve care standards.
Recommendation 12: To improve and monitor palliative care practice, policy makers should recommend routine collection of outcome data, and then these data should be used to establish a minimum dataset of palliative care outcome measures in order to improve and advance clinical care and research.

The health system should plan locally acceptable ways of implementing the measure into routine clinical practice.[66-68] The Chinese IPOS must be used and evaluated in normal palliative care settings in China. There needs to be an ongoing process of refinement and evaluation according to Rothrock's guidance[69]– essentially closing the loop on ongoing instrument improvement with implementation and evaluation/further refinement and development studies. The new items developed in this study will need further evaluation

and validation once the tool is available for use. It is essential to revisit some of these in the light of experience in using the Chinese IPOS.

8.5 FINAL CONCLUSIONS

In this study, we translated, cross-culturally adapted, and validated the Chinese IPOS among adults with cancer. We established the sound psychometric properties by synthesising evidence using systematic review, qualitative interviews, translation, culturally adaptation and validation of IPOS Patient and Staff versions into Chinese. Chinese IPOS is a brief outcome measure that reflects the breadth of symptoms and needs, concerns and practical issues experienced by people living with advanced cancer, translated and culturally adapted in accordance with recognised international methodological guidance. Informed by the priorities of key stakeholders captured with in-depth qualitative interviews, the Chinese IPOS has supporting evidence for face and content validity and high levels of acceptability following initial cognitive testing which reflects the range of multidimensional outcomes matters to people living with advanced cancer to drive and evaluate their care.

The Chinese IPOS is a valid and reliable outcome measure for use with people with advanced illness, ready to be used both in its patient self-report and staff proxy-report versions. It is suitable for assessing and monitoring symptoms and concerns in advanced cancer, monitoring change over time, determining the impact of healthcare interventions, and demonstrating the quality of care in China.

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Appendix 1. Ethics approval for qualitative studies

Research Ethics
Office

Franklin Wilkins Building
5.9 Waterloo Bridge Wing
Waterloo Road
London SE1 9NH
Telephone 020 7848 4020/4070/4077
rec@kcl.ac.uk

KING'S College LONDON

Houshen Li

29 August 2019

Dear Houshen,

Study Title: Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Qualitative and Cognitive Interview

Study Reference:HR-18/19-12556

I am pleased to inform you that full approval for your project has been granted by the PNM Research Ethics Subcommittee .

For your information, ethical approval has been granted for 3 years from 29 August 2019. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results. For secondary data-analysis, ethical approval is applicable to the data that is sensitive or identifies participants.

Please ensure that you follow the guidelines for good research practice as laid out in UKRIO's Code of Practice for research: https://www.kcl.ac.uk/research/support/integrity-good-conduct/index.aspx

Please note you are required to adhere to all research data/records management and storage procedures agreed to as part of your application. This will be expected even after the completion of the study.

If you do not start the project within three months of this letter, please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study. This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process:

https://internal.kcl.ac.uk/innovation/research/ethics/applications/modifications.aspx

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact the Research Ethics Office:

(https://internal.kcl.ac.uk/innovation/research/ethics/contact.aspx)

We wish you every success with this work.

Yours sincerely,

Mr James Patterson
Senior Research Ethics Officer

For and on behalf of the PNM Research Ethics Subcommittee

Appendix 2. Ethics approval for the psychometric testing

Research Ethics
Office

Franklin Wilkins Building
5.9 Waterloo Bridge Wing
Waterloo Road
London SE1 9NH
Telephone 020 7848 4020/4070/4077
rec@kcl.ac.uk

KING'S College LONDON

Houshen Li

13 January 2021

Dear Houshen,

Project Title: Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Psychometric testing
Project Reference:HR-20/21-18713

I am pleased to inform you that full approval for your project has been granted by the PNM Research Ethics Subcommittee .

Important coronavirus update: In light of the COVID-19 pandemic, the College Research Ethics Committee has temporarily suspended all primary data collection involving face to face participant interactions until further notice. **Ethical clearance for this project is granted. However, the clearance outlined in the attached letter is contingent on your adherence to the latest College measures when conducting your research.** Please do not commence data collection until you have carefully reviewed the update and made any necessary project changes:

https://internal.kcl.ac.uk/innovation/research/ethics/applications/COVID-19-Update-for-Researchers

For your information, ethical approval has been granted for 3 years from 13 January 2021. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results.

Please ensure that you follow the guidelines for good research practice as laid out in UKRIO's Code of Practice for research: http://ukrio.org/publications/code-of-practice-for-research/.

If you do not start the project within three months of this letter, please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study.This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process:

https://internal.kcl.ac.uk/innovation/research/ethics/applications/modifications.aspx

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact the Research Ethics Office:

(https://internal.kcl.ac.uk/innovation/research/ethics/contact.aspx)

We wish you every success with this work.

Yours sincerely,

Mr James Patterson
Senior Research Ethics Officer

For and on behalf of the PNM Research Ethics Subcommittee

Appendix 3. Example of information sheet and consent form – qualitative interviews (patient version)

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: 12556

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study

Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Qualitative Interview

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.

Palliative care needs among people living with advanced cancer and their families are crucial yet sometimes unmet in China. Regularly collecting patient reported outcome measures (PROMs) data is an effective way to standardize practice and improve patient management. By conducting this interview, we will determine optimal implementation of a patient reported outcome measure- IPOS among stakeholders i.e. patients, families and staff members and conceptually map the qualitative data on symptoms and concerns from patients and families onto the IPOS and refine the items. We will ask you questions regarding needs and experience regarding disease and treatment received and your opinions on the IPOS.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The objectives of the study are:

Objective 9. To identify palliative care needs among people living with advanced cancer in China and their families

Objective 10. To determine optimal implementation of the IPOS among stakeholders

Objective 11. To conceptually map the qualitative data on symptoms and concerns from patients and families onto the IPOS and refine the items

Why have I been invited to take part?

You are being invited to participate in this study because we are asking people living with advanced cancer who are aged 18 years or over in China. We expect to recruit 20 people in this study.

What will happen if I take part?

If you decided to take part you will be given this information sheet to keep and will be asked to sign a consent form. I will then discuss the interview procedure with you and arrange to interview you in a private place (for confidentiality reasons) within the hospital or place you prefer. After this one interview, there will be nothing more for you to do.

The interview will take up to 60 minutes and it will be based on a semi-structured interview topic guide, which is designed to be flexible. The interview will be recorded, subject to your permission. All recordings of data on audio-equipment will be deleted after transcription. Even if you have decided to take part, you are still free to stop your participation at any time during the interview and to have research data/ information relating to you with drawn without giving any reason before 30th November 2020. All data is de-identified by removing all names of people and places and replacing with an identification code.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information

sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

Patients will also be informed that the decision they make to be involved or refuse participation in the study will not in any way influence the care and treatment they receive currently, nor in the future. Participants will be free to withdraw from the study at any time, without providing a reason.

What are the possible risks of taking part?

The potential risks you maybe expose to is that you will be reminded the disease diagnoses and prognoses, which could be distressing for you. If you feel uncomfortable about anything, please inform the research or clinical team immediately.

If you find any of the questions upset during the research interview, you may ask for the interview to stop and speak to the researcher or members of the clinical team at Chaoyang Central Hospital about how you feel.

What are the possible benefits of taking part?

When we finish the study, we will get copies of the final report to Chaoyang Central Hospital and arrange that you have a copy if you want.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

- Your interview will be the anonymised and any identifiable references will be removed in accordance with the General Data Protection Regulation 2016 (GDPR) and research governance, and requirements in China. You and your data will not be identifiable in any report or publication.
- Any information about you will be kept confidential and secure at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, King's College London, UK and

Chaoyang Central Hospital, China; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets.

- Research data (e.g. audio recordings), transcripts and personal demographic/clinical information will be stored or accessed by the research team for 7 years after the study has ended. After this period, all data will be permanently deleted or destroyed. If withdraw during the study, we will remove your data from the research records according to your wishes.

- Only the study team including principal investigator, supervisors and clinical leaders who assist the delivery of study can have accesses to the study materials. Anonymised data may also be used in future research studies and teaching by appropriately qualified researchers, trained and supervised by the research team.
- The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the interview. We will **NOT** let anyone have any information that could identify you.
- There are some instances, i.e. participants disclose any ideation of self-harm or other risks of others, where the researcher is obliged to break confidentiality due to the nature of the disclosure being made or concern of risk of harm to themselves or others. The researcher will inform and discussed with the clinical leaders in the study site and supervisors at Kings College London.

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest' You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up until 30th November 2020, after which withdrawal of your data will no longer be possible due to the data will have been anonymised or committed to the final report. If you choose to withdraw from the study we will not retain the information you have given thus far.

How is the project being funded?

This study is being funded by the researcher and Chaoyang Central Hospital, Liaoning Province, China.

What will happen to the results of the study?

The results of the study will be summarised in PhD thesis, scientific journals and reports will be made available for you to access if you wish. We will also plan to disseminate the research findings through publication and conferences.

After the data collection and once the report is ready, we shall invite all of you to a meeting where we will share the results of the findings.

The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the interview. We will NOT let anyone have any information that could identify you.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact the principal investigator *Houshen Li* for further explanation or help.

The contact detail is:

Tel/ Mobile: +86-150 4285 7477

Email: houshen.li@kcl.ac.uk

If you still have any doubts about the study, you can also contact the Medical Ethics Committee of Chaoyang Central Hospital for further information. (Tel: +86 421 281 1701)

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Professor Richard Harding

Email: richard.harding@kcl.ac.uk

Address: Cicely Saunders Institute, Bessemer Road, London SE5 9PJ

Thank you for reading this information sheet and for considering taking part in this research.

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Qualitative Interview

King's College Research Ethics Committee Ref: 12556

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.	☐

	Please tick or initial
1. ***I confirm that I have read and understood the information sheet dated [09/08/2019 version 2] for the above study. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.**	☐
2. **I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason, up until 30th November 2020.**	☐

3. ***I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation.** ☐

4. ***I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.** ☐

5. **I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs.** ☐

6. I agree to be contacted in the future by King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature. ☐

7. I agree that the research team may access my medical records for the purposes of cross-checking the diagnoses and demographic data. No other information will be exacted from medical records. ☐

8. I agree that the research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would/would not be identifiable in any report). ☐

9. I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. ☐

10. I consent to my interview being audio/video recorded. ☐

11. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**

Appendix 4. Example of information sheet and consent form – qualitative interviews (family version)

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study

Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Psychometric testing

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.

Palliative care needs among people living with advanced cancer and their families are crucial yet sometimes unmet in China. Regularly collecting patient reported outcome measures (PROMs) data is an effective way to standardize practice and improve patient management. By conducting this interview, we will determine optimal implementation of a patient reported outcome measure- IPOS among stakeholders i.e. patients, families and staff members and conceptually map the qualitative data on symptoms and concerns from patients and families onto the IPOS and refine the items. We will ask you questions regarding needs and experience regarding disease and treatment received and your opinions on the IPOS.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The objectives of the study are:

Objective 12. To identify palliative care needs among people living with advanced cancer in China and their families

Objective 13. To determine optimal implementation of the IPOS among stakeholders

Objective 14. To conceptually map the qualitative data on symptoms and concerns from patients and families onto the IPOS and refine the items

Why have I been invited to take part?

You are being invited to participate in this study because we are asking family members who are aged 18 years or over, and your relatives are now living with advanced cancer in China. We expect to recruit 20 people in this study.

What will happen if I take part?

If you decided to take part you will be given this information sheet to keep and will be asked to sign a consent form. I will then discuss the interview procedure with you and arrange to interview you in a private place (for confidentiality reasons) within the hospital or place you prefer. After this one interview, there will be nothing more for you to do.

The interview will take up to 60 minutes and it will be based on a semi-structured interview topic guide, which is designed to be flexible. The interview will be recorded, subject to your permission. All recordings of data on audio-equipment will be deleted after transcription. Even if you have decided to take part, you are still free to stop your participation at any time during the interview and to have research data/ information relating to you with drawn without giving any reason before 30th November 2020. All data is de-identified by removing all names of people and places and replacing with an identification code.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information

sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

Family members will also be informed that the decision they make to be involved or refuse participation in the study will not in any way influence the care and treatment they receive currently, nor in the future. Participants will be free to withdraw from the study at any time, without providing a reason.

What are the possible risks of taking part?

The potential risks you maybe expose to is that you will be reminded the experience of taking care of your relatives, which could be distressing for you. If you feel uncomfortable about anything, please inform the research or clinical team immediately.

If you find any of the questions upset during the research interview, you may ask for the interview to stop and speak to the researcher or members of the clinical team at Chaoyang Central Hospital about how you feel.

What are the possible benefits of taking part?

When we finish the study, we will get copies of the final report to Chaoyang Central Hospital and arrange that you have a copy if you want.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

- Your interview will be the anonymised and any identifiable references will be removed in accordance with the General Data Protection Regulation 2016 (GDPR) and research governance, and requirements in China. You and your data will not be identifiable in any report or publication.
- Any information about you will be kept confidential and secure at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, King's College London, UK and

Chaoyang Central Hospital, China; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets.

- Personal data (e.g. audio recordings) will be stored and accessed by the research team for 12 months - 3 years and the transcripts will be securely archived for 7 years after the study has ended. After this period, all data will be permanently deleted or destroyed. If withdraw during the study, we will remove your data from the research records according to your wishes.
- Only the study team including principal investigator, supervisors and clinical leaders who assist the delivery of study can have accesses to the study materials. Anonymised data may also be used in future research studies and teaching by appropriately qualified researchers, trained and supervised by the research team.
- The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the interview. We will **NOT** let anyone have any information that could identify you.
- There are some instances, i.e. participants disclose any ideation of self-harm or other risks of others, where the researcher is obliged to break confidentiality due to the nature of the disclosure being made or concern of risk of harm to themselves or others. The researcher will inform and discussed with the clinical leaders in the study site and supervisors at Kings College London.

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest' You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up until 30th November 2020, after which withdrawal of your data will no longer be possible due to the data will have been anonymised or committed to the final report. If you choose to withdraw from the study we will not retain the information you have given thus far.

How is the project being funded?

This study is being funded by the researcher and Chaoyang Central Hospital, Liaoning Province, China.

What will happen to the results of the study?

The results of the study will be summarised in PhD thesis, scientific journals and reports will be made available for you to access if you wish. We will also plan to disseminate the research findings through publication and conferences.

After the data collection and once the report is ready, we shall invite all of you to a meeting where we will share the results of the findings.

The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the interview. We will NOT let anyone have any information that could identify you.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact the principal investigator *Houshen Li* for further explanation or help.

The contact detail is:

Tel/ Mobile: +86-150 4285 7477

Email: houshen.li@kcl.ac.uk

If you still have any doubts about the study, you can also contact the Medical Ethics Committee of Chaoyang Central Hospital for further information. (Tel: +86 421 281 1701)

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Professor Richard Harding

Email: richard.harding@kcl.ac.uk

Address: Cicely Saunders Institute, Bessemer Road, London SE5 9PJ

Thank you for reading this information sheet and for considering taking part in this research.

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Qualitative Interview

King's College Research Ethics Committee Ref: 12556

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.	☐

	Please tick or initial
1. ***I confirm that I have read and understood the information sheet dated [09/08/2019 version 2] the above study. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.**	☐
2. **I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason, up until 30th November 2020.**	

3. ***I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation.** ☐

4. ***I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.** ☐

5. **I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any research outputs** ☐

6. I agree to be contacted in the future by King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature. ☐

7. I agree that the research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would/would not be identifiable in any report). ☐

8. I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. ☐

9. I consent to my interview being audio/video recorded. ☐

10. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**

Appendix 5. Example of information sheet and consent form – cognitive interviews (patient version)

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: 12556

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study

Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Cognitive Interview

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.

Palliative care needs among people living with advanced cancer and their families are crucial yet sometimes unmet in China. Regularly collecting patient reported outcome measures (PROMs) data is an effective way to standardize practice and improve patient management. By conducting this interview, we will determine optimal implementation of a patient reported outcome measure- IPOS among stakeholders i.e. patients, families and staff members and conceptually map the qualitative data on symptoms and concerns from patients and families onto the IPOS and refine the items. We will ask you questions regarding your opinions on the IPOS.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of the study is to conduct cognitive interviews among patient and families and refine the final Chinese IPOS for validation.

Why have I been invited to take part?

You are being invited to participate in this study because we are asking people living with advanced cancer who are aged 18 years or over in China. We expect to recruit 6 people in this study.

What will happen if I take part?

If you decided to take part you will be given this information sheet to keep and will be asked to sign a consent form. I will then discuss the interview procedure with you and arrange to interview you in a private place (for confidentiality reasons) within the hospital or place you prefer. After this one interview, there will be nothing more for you to do.

The interview will take up to 60 minutes and it will be based on a semi-structured interview topic guide, which is designed to be flexible. The interview will be recorded, subject to your permission. All recordings of data on audio-equipment will be deleted after transcription. Even if you have decided to take part, you are still free to stop your participation at any time during the interview and to have research data/ information relating to you with drawn without giving any reason before 30th November 2020. All data is de-identified by removing all names of people and places and replacing with an identification code.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

Patients will also be informed that the decision they make to be involved or refuse participation in the study will not in any way influence the care and treatment they receive currently, nor in the future. Participants will be free to withdraw from the study at any time, without providing a reason.

What are the possible risks of taking part?

The potential risks you maybe expose to is that you will be reminded the disease diagnoses and prognoses, which could be distressing for you. If you feel uncomfortable about anything, please inform the research or clinical team immediately.

If you find any of the questions upset during the research interview, you may ask for the interview to stop and speak to the researcher or members of the clinical team at Chaoyang Central Hospital about how you feel.

What are the possible benefits of taking part?

When we finish the study, we will get copies of the final report to Chaoyang Central Hospital and arrange that you have a copy if you want.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

- Your interview will be the anonymised and any identifiable references will be removed in accordance with the General Data Protection Regulation 2016 (GDPR) and research governance, and requirements in China. You and your data will not be identifiable in any report or publication.
- Any information about you will be kept confidential and secure at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, King's College London, UK and Chaoyang Central Hospital, China; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets.

- Personal data (e.g. audio recordings) will be stored and accessed by the research team for 12 months - 3 years and the transcripts will be securely archived for 7 years after the study has ended. After this period, all data will be permanently deleted or destroyed. If withdraw during the study, we will remove your data from the research records according to your wishes.

- Only the study team including principal investigator, supervisors and clinical leaders who assist the delivery of study can have accesses to the study materials. Anonymised data may also be used in future research studies and teaching by appropriately qualified researchers, trained and supervised by the research team.
- The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the interview. We will **NOT** let anyone have any information that could identify you.
- There are some instances, i.e. participants disclose any ideation of self-harm or other risks of others, where the researcher is obliged to break confidentiality due to the nature of the disclosure being made or concern of risk of harm to themselves or others. The researcher will inform and discussed with the clinical leaders in the study site and supervisors at Kings College London.

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest' You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up until 30th November 2020, after which withdrawal of your data will no longer be possible due to the data will have been anonymised or committed to the final report. If you choose to withdraw from the study we will not retain the information you have given thus far.

How is the project being funded?

This study is being funded by the researcher and Chaoyang Central Hospital, Liaoning Province, China.

What will happen to the results of the study?

The results of the study will be summarised in PhD thesis, scientific journals and reports will be made available for you to access if you wish. We will also plan to disseminate the research findings through publication and conferences.

After the data collection and once the report is ready, we shall invite all of you to a meeting where we will share the results of the findings.

The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the interview. We will NOT let anyone have any information that could identify you.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact the principal investigator *Houshen Li* for further explanation or help.

The contact detail is:

Tel/ Mobile: +86-150 4285 7477

Email: houshen.li@kcl.ac.uk

If you still have any doubts about the study, you can also contact the Medical Ethics Committee of Chaoyang Central Hospital for further information. (Tel: +86 421 281 1701)

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Professor Richard Harding

Email: richard.harding@kcl.ac.uk

Address: Cicely Saunders Institute, Bessemer Road, London SE5 9PJ

Thank you for reading this information sheet and for considering taking part in this research.

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Cognitive Interview

King's College Research Ethics Committee Ref: 12556

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.	☐

	Please tick or initial
1. ***I confirm that I have read and understood the information sheet dated [09/08/2019 version 2] the above study. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.**	☐
2. **I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason, up until 30th November 2020.**	☐

3. ***I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation.** ☐

4. ***I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.** ☐

5. **I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any research outputs** ☐

6. I agree to be contacted in the future by King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature. ☐

7. I agree that the research team may access my medical records for the purposes of cross-checking the diagnoses and demographic data. No other information will be exacted from medical records. ☐

8. I agree that the research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would/would not be identifiable in any report). ☐

9. I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. ☐

10. I consent to my interview being audio/video recorded. ☐

11. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**

Appendix 6. Example of information sheet and consent form – cognitive interviews (staff version)

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: 12556

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study

Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Cognitive Interview

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.

Palliative care needs among people living with advanced cancer and their families are crucial yet sometimes unmet in China. Regularly collecting patient reported outcome measures (PROMs) data is an effective way to standardize practice and improve patient management. By conducting this interview, we will determine optimal implementation of a patient reported outcome measure- IPOS among stakeholders i.e. patients, families and staff members and conceptually map the qualitative data on symptoms and concerns from patients and families onto the IPOS and refine the items. We will ask you questions regarding your opinions on the IPOS.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of the study is to conduct cognitive interviews among patient and families and refine the final Chinese IPOS for validation.

Why have I been invited to take part?

You are being invited to participate in this study because we are asking healthcare professionals who work with patients living with advanced cancer who are aged 18 years or over in China. We expect to recruit 6 people in this study.

What will happen if I take part?

If you decided to take part you will be given this information sheet to keep and will be asked to sign a consent form. I will then discuss the interview procedure with you and arrange to interview you in a private place (for confidentiality reasons) within the hospital or place you prefer. After this one interview, there will be nothing more for you to do.

The interview will take up to 60 minutes and it will be based on a semi-structured interview topic guide, which is designed to be flexible. The interview will be recorded, subject to your permission. All recordings of data on audio-equipment will be deleted after transcription. Even if you have decided to take part, you are still free to stop your participation at any time during the interview and to have research data/ information relating to you with drawn without giving any reason before 30th November 2020. All data is de-identified by removing all names of people and places and replacing with an identification code.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

Staff will also be informed that the decision they make to be involved or refuse participation in the study will not in any way influence the care and treatment they receive currently, nor in the future. Participants will be free to withdraw from the study at any time, without providing a reason.

What are the possible risks of taking part?

The potential risks you maybe expose to is that you will be reminded the experience of treating advanced cancer patients, which could be distressing for you. If you feel uncomfortable about anything, please inform the research or clinical team immediately.

If you find any of the questions upset during the research interview, you may ask for the interview to stop and speak to the researcher or members of the clinical team at Chaoyang Central Hospital about how you feel.

What are the possible benefits of taking part?

When we finish the study, we will get copies of the final report to Chaoyang Central Hospital and arrange that you have a copy if you want.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

- Your interview will be the anonymised and any identifiable references will be removed in accordance with the General Data Protection Regulation 2016 (GDPR) and research governance, and requirements in China. You and your data will not be identifiable in any report or publication.
- Any information about you will be kept confidential and secure at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, King's College London, UK and Chaoyang Central Hospital, China; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets.

- Personal data (e.g. audio recordings) will be stored and accessed by the research team for 12 months - 3 years and the transcripts will be securely archived for 7 years after the study has ended. After this period, all data will be permanently deleted or destroyed. If withdraw during the study, we will remove your data from the research records according to your wishes.

- Only the study team including principal investigator, supervisors and clinical leaders who assist the delivery of study can have accesses to the study materials. Anonymised data may also be used in future research studies and teaching by appropriately qualified researchers, trained and supervised by the research team.
- The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the interview. We will **NOT** let anyone have any information that could identify you.
- There are some instances, i.e. participants disclose any ideation of self-harm or other risks of others, where the researcher is obliged to break confidentiality due to the nature of the disclosure being made or concern of risk of harm to themselves or others. The researcher will inform and discussed with the clinical leaders in the study site and supervisors at Kings College London.

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest' You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up until 30th November 2020, after which withdrawal of your data will no longer be possible due to the data will have been anonymised or committed to the final report. If you choose to withdraw from the study, we will not retain the information you have given thus far.

How is the project being funded?

This study is being funded by the researcher and Chaoyang Central Hospital, Liaoning Province, China.

What will happen to the results of the study?

The results of the study will be summarised in PhD thesis, scientific journals and reports will be made available for you to access if you wish. We will also plan to disseminate the research findings through publication and conferences.

After the data collection and once the report is ready, we shall invite all of you to a meeting where we will share the results of the findings.

The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the interview. We will NOT let anyone have any information that could identify you.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact the principal investigator *Houshen Li* for further explanation or help.

The contact detail is:

Tel/ Mobile: +86-150 4285 7477

Email: houshen.li@kcl.ac.uk

If you still have any doubts about the study, you can also contact the Medical Ethics Committee of Chaoyang Central Hospital for further information. (Tel: +86 421 281 1701)

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Professor Richard Harding

Email: richard.harding@kcl.ac.uk

Address: Cicely Saunders Institute, Bessemer Road, London SE5 9PJ

Thank you for reading this information sheet and for considering taking part in this research.

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: **Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Cognitive Interview**

King's College Research Ethics Committee Ref:12556

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.	☐

	Please tick or initial
1. ***I confirm that I have read and understood the information sheet dated [09/08/2019 version 2] for the above study. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.**	☐
2. **I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason, up until 30th November 2020.**	☐

3. ***I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation.** ☐

4. ***I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.** ☐

5. **I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any research outputs** ☐

6. I agree to be contacted in the future by King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature. ☐

7. I agree that the research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would/would not be identifiable in any report). ☐

8. I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. ☐

9. I consent to my interview being audio/video recorded. ☐

10. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**

Appendix 7. Example of information sheet and consent form – psychometric testing (patient version)

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study

Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Psychometric testing (tests of reliability and validity)

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.

Palliative care needs among people living with advanced cancer and their families are crucial yet sometimes unmet in China. Regularly collecting patient reported outcome measures (PROMs) data is an effective way to standardize practice and improve patient management. By completing the questionnaires, we will assess the validity and reliability of the Simplified Chinese IPOS among patients with advanced cancer, family members and health professionals in China. We will ask you to complete questionnaires at three time points.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of the study is to assess the validity and reliability of the Simplified Chinese IPOS (patient and staff versions) among patients with advanced cancer, family members and health professionals in China.

Why have I been invited to take part?

You are being invited to participate in this study because we are asking people living with advanced cancer who are aged 18 years or over in China. We expect to recruit 300 people in this study.

What will happen if I take part?

If you decided to take part, you will be given this information sheet to keep and will be asked to sign a consent form. I will then discuss the study procedure with you in a private place (for confidentiality reasons) within the hospital or place you prefer. After completing the questionnaires at three timepoints, there will be nothing more for you to do. The survey will ask you questions about your palliative care needs and quality of life. The survey will take you approximately 15 minutes to complete each time. At timepoint 1, you will be asked to self-complete the patient version questionnaires (with assistance as required). After five to seven days, you will be asked to complete the IPOS for the second time (timepoint 2), and at a further five to seven days, a third IPOS will be completed (timepoint 3).

Before the first survey, you will be assigned an ID number (eg, P1234). You can be contacted by researchers at different stages of the data collection, using only random ID numbers and your phone number. Any information linking your identifiable data such as name, phone number or address with the ID number (which will be used in all future communication with the participant) will be destroyed after you finish the third IPOS. No data will be able to be linked to back to you taking part in the study. We will **NOT** let anyone have any information that could identify you.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information

sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

Participants will also be informed that the decision they make to be involved or refuse participation in the study will not in any way influence the care and treatment their patients receive currently, nor in the future. Participants will be free to withdraw from the study at any time, without providing a reason.

What are the possible risks of taking part?

The potential risks you maybe expose to is that you will be reminded the disease diagnoses and prognoses, which could be distressing for you. If you feel uncomfortable about anything, please inform the research or clinical team immediately.

If you find any of the questions upset during the completing the questionnaires, you may ask for the study to stop and speak to the researcher or members of the clinical team at Chaoyang Central Hospital about how you feel.

What are the possible benefits of taking part?

When we finish the study, we will get copies of the final report to Chaoyang Central Hospital and arrange that you have a copy if you want.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

- Your questionnaires will be the anonymised and any identifiable references will be removed in accordance with the General Data Protection Regulation 2016 (GDPR) and research governance, and requirements in China. You and your data will not be identifiable in any report or publication.

- The research team may access your medical records for the purposes of cross-checking the diagnoses and demographic data. No other information will be exacted from medical records.
- Any information about you will be kept confidential and secure at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, King's College London, UK and Chaoyang Central Hospital, China; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets.

- Personal data will be stored and accessed by the research team for 12 months - 3 years and the transcripts will be securely archived for 7 years after the study has ended. After this period, all data will be permanently deleted or destroyed. If withdraw during the study, we will remove your data from the research records according to your wishes.

- Only the study team including principal investigator, supervisors and clinical leaders who assist the delivery of study can have accesses to the study materials. Anonymised data may also be used in future research studies and teaching by appropriately qualified researchers, trained and supervised by the research team.
- The research founding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the study. We will **NOT** let anyone have any information that could identify you.
- There are some instances, i.e. participants disclose any ideation of self-harm or other risks of others, where the researcher is obliged to break confidentiality due to the nature of the disclosure being made or concern of risk of harm to themselves or others. The researcher will inform and discussed with the clinical leaders in the study site and supervisors at Kings College London.

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest' You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College

London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up until 1st February 2022, after which withdrawal of your data will no longer be possible due to the data will have been anonymised or committed to the final report. If you choose to withdraw from the study we will not retain the information you have given thus far.

How is the project being funded?

This study is being funded by the researcher and Chaoyang Central Hospital, Liaoning Province, China.

What will happen to the results of the study?

The results of the study will be summarised in PhD thesis, scientific journals and reports will be made available for you to access if you wish. We will also plan to disseminate the research findings through publication and conferences.

After the data collection and once the report is ready, we shall invite all of you to a meeting where we will share the results of the findings.

The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the study. We will NOT let anyone have any information that could identify you.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact the principal investigator *Houshen Li* for further explanation or help.

The contact detail is:

Tel/ Mobile: +86-150 4285 7477

Email: houshen.li@kcl.ac.uk

If you still have any doubts about the study, you can also contact the Medical Ethics Committee of Chaoyang Central Hospital for further information. (Tel: +86 421 281 1701)

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Professor Richard Harding

Email: richard.harding@kcl.ac.uk

Address: Cicely Saunders Institute, Bessemer Road, London SE5 9PJ

Thank you for reading this information sheet and for considering taking part in this research.

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Psychometric testing

King's College Research Ethics Committee Ref: HR-20/21-18713

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.	☐

	Please tick or initial
1. *I confirm that I have read and understood the information sheet dated [XX/XX/XXXX version X] the above study. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.	☐
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason, up until 1st February 2022.	☐

3. ***I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation.** ☐

4. ***I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.** ☐

5. **I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any research outputs.** ☐

6. I agree to be contacted in the future by King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature. ☐

7. I agree that the research team may access my medical records for the purposes of cross-checking the diagnoses and demographic data. No other information will be exacted from medical records. ☐

8. I agree that the research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would/would not be identifiable in any report). ☐

9. I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. ☐

10. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**

Appendix 8. Example of information sheet and consent form – psychometric testing (staff version)

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study

Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Psychometric testing (tests of reliability and validity)

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.

Palliative care needs among people living with advanced cancer and their families are crucial yet sometimes unmet in China. Regularly collecting patient reported outcome measures (PROMs) data is an effective way to standardize practice and improve patient management. By completing the questionnaires, we will assess the validity and reliability of the Simplified Chinese IPOS among patients with advanced cancer, family members and health professionals in China. We will ask you to complete questionnaires at three time points.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of the study is to assess the validity and reliability of the Simplified Chinese IPOS (patient and staff versions) among patients with advanced cancer, family members and health professionals in China.

Why have I been invited to take part?

You are being invited to participate in this study because we are asking healthcare professionals who work with patients living with advanced cancer who are aged 18 years or over in China.

What will happen if I take part?

If you decided to take part, you will be given this information sheet to keep and will be asked to sign a consent form. I will then discuss the study procedure with you in a private place (for confidentiality reasons) within the hospital or place you prefer. After completing the questionnaires at three timepoints, there will be nothing more for you to do. The survey will ask you questions about your patients' palliative care needs and quality of life. The survey will take you approximately 15 minutes to complete each time. At timepoint 1, you will be asked to report for your patients by completing the staff version questionnaires (with assistance as required). After five to seven days, you will be asked to complete the IPOS for the second time (timepoint 2), and at a further five to seven days, a third IPOS will be completed (timepoint 3).
Before the first survey, you will be assigned an ID number (eg, S1234). You can be contacted by researchers at different stages of the data collection, using only random ID numbers and your phone number. Any information linking your identifiable data such as name, phone number or address with the ID number (which will be used in all future communication with the participant) will be destroyed after you finish the third IPOS. No data will be able to be linked to back to you taking part in the study. We will **NOT** let anyone have any information that could identify you.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

Patients will also be informed that the decision they make to be involved or refuse participation in the study will not in any way influence the care and treatment they receive currently, nor in the future. Participants will be free to withdraw from the study at any time without providing a reason and clearly assured that their employment will not be affected by their choice as to whether or not they take part.

What are the possible risks of taking part?

The potential risks you maybe expose to is that you will be reminded the experience of treating advanced cancer patients, which could be distressing for you. If you feel uncomfortable about anything, please inform the research or clinical team immediately.

If you find any of the questions upset during the completing the questionnaires, you may ask for the study to stop and speak to the researcher or members of the clinical team at Chaoyang Central Hospital about how you feel.

What are the possible benefits of taking part?

When we finish the study, we will get copies of the final report to Chaoyang Central Hospital and arrange that you have a copy if you want.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

- Your questionnaires will be the anonymised and any identifiable references will be removed in accordance with the General Data Protection Regulation 2016 (GDPR) and research governance, and requirements in China. You and your data will not be identifiable in any report or publication.
- Any information about you will be kept confidential and secure at Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, King's College London, UK and Chaoyang Central Hospital, China; electronic data on encrypted data sticks, encrypted hard drives or password protected computers and paper records in locked cabinets.

- Personal data will be stored and accessed by the research team for 12 months - 3 years and the transcripts will be securely archived for 7 years after the study has ended. After this period, all data will be permanently deleted or destroyed. If withdraw during the study, we will remove your data from the research records according to your wishes.

- Only the study team including principal investigator, supervisors and clinical leaders who assist the delivery of study can have accesses to the study materials. Anonymised data may also be used in future research studies and teaching by appropriately qualified researchers, trained and supervised by the research team.
- The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the study. We will **NOT** let anyone have any information that could identify you.
- There are some instances, i.e. participants disclose any ideation of self-harm or other risks of others, where the researcher is obliged to break confidentiality due to the nature of the disclosure being made or concern of risk of harm to themselves or others. The researcher will inform and discussed with the clinical leaders in the study site and supervisors at Kings College London.

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest' You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up until 1st February 2022, after which withdrawal of your data will no longer be possible due to the data will have been anonymised or committed to the final report. If you choose to withdraw from the study we will not retain the information you have given thus far.

How is the project being funded?

This study is being funded by the researcher and Chaoyang Central Hospital, Liaoning Province, China.

What will happen to the results of the study?

The results of the study will be summarised in PhD thesis, scientific journals and reports will be made available for you to access if you wish. We will also plan to disseminate the research findings through publication and conferences.

After the data collection and once the report is ready, we shall invite all of you to a meeting where we will share the results of the findings.

The research funding will be presented in an anonymous way (for example, removing names and using identification code). No data will be able to be linked to back to an individual taking part in the study. We will NOT let anyone have any information that could identify you.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact the principal investigator *Houshen Li* for further explanation or help.

The contact detail is:

Tel/ Mobile: +86-150 4285 7477

Email: houshen.li@kcl.ac.uk

If you still have any doubts about the study, you can also contact the Medical Ethics Committee of Chaoyang Central Hospital for further information. (Tel: +86 421 281 1701)

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Professor Richard Harding

Email: richard.harding@kcl.ac.uk

Address: Cicely Saunders Institute, Bessemer Road, London SE5 9PJ

Thank you for reading this information sheet and for considering taking part in this research.

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Translation, cross-cultural adaptation and validation of the Chinese Integrated Palliative care Outcome Scale (IPOS)- Psychometric testing

King's College Research Ethics Committee Ref: HR-20/21-18713

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.	☐

	Please tick or initial
1. ***I confirm that I have read and understood the information sheet dated [XX/XX/XXXX version X] for the above study. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.**	☐
2. **I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason, up until 1st February 2022.**	☐

3. ***I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation.** ☐

4. ***I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.** ☐

5. **I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any research outputs** ☐

6. I agree to be contacted in the future by King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature. ☐

7. I agree that the research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would/would not be identifiable in any report). ☐

8. I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. ☐

9. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**

Appendix 9. Topic guide – qualitative interviews (patient version)

Topic Guide for Patient Interview Participants

Understanding your needs and experiences of care (n=20)

Objective:

To identify palliative care needs among people living with cancer in China and their families and determine optimal implementation of the IPOS among stakeholders

Introduction:

- Thank you so much for agreeing to be interviewed today. My name is _____ and I'm a member of the team working on this study. When effected by disease, you may have multidimensional needs including physical, psychosocial, spiritual, and information needs. The purpose of today's interview is to understand your needs, symptoms, and concerns, experiences of care you have received or are receiving, and how care could be improved to meet these needs for patients with far advanced disease and their families. This will help us understand what your needs and concerns are, and how we can improve your experiences and/or identify gaps in our care.

- The interview should take up to 60 minutes. The information you share in this interview will be anonymised, so please feel free to share as much as you would like to. We may cover some difficult/challenging topics during the interview. You can stop the interview at any point or skip any questions should you wish to. Also, we can pause for breaks if you need to, and can restart recording when you are ready. Apologies of the questions get repetitive.

- Could I please just confirm that you have signed consent form and read the information sheet? And are you happy for the interview to be audio recorded today? And is it ok for me to make a few notes during the interview?

- You can tell me any thoughts or views you might have about the questions. Do you have any questions before we start?

---------- START RECORDING ----------

General probes: How did that make you feel? How did you deal with that? How do you think you will manage that? What do you think will happen?

1. Experience of illness – first I'd like to ask you about your health	
Topic area	Potential areas to be explored
Can you tell me a bit about how your health has been over the last 3 months?	Different illnesses, understanding of illness & of care received. Is health improving, staying the same or worsening?

Are you limited by health problems? How do health problems limit you day to day?	Effects on day to day life, isolation, maintaining independence, social support, external help.
What are your main health concerns at the moment?	Explore concerns, type, and number, is anything else concerning you? What is the worst thing? Explore symptoms and how they affect quality of life. Explore psychological symptoms.
What helps you cope with your illness? Is anything especially hard to cope with? How did you cope with these difficulties and challenges?	Support mechanisms, gaps in support, family support.
How did the medical team managing your care meet your support needs and family needs?	Physical/ psychological/ social/ spiritual/ religious needs.
Is there anything positive that we could take forward from your experience?	

2. Experience of healthcare – now I'd like to ask you about your experiences of healthcare services.	
Topic area	Potential areas to be explored
Could you tell me about the care you have received for your health in the last 3 months?	Types of care received, volume of service use, care burden. Explore kinds of care e.g. inpatient/ outpatient/ community services. Explore how patient came to receive these kinds of care – how/why did it happen? Explore what patient has found helpful/unhelpful
Tell me about your experience in the hospital.	Reason for admission, experiences during admission, especially focus on the run up to hospital admission
What changes would you like to make to the healthcare you've received? What would make it better.	Explore models of care and types of services that patients would prefer. What makes a service more acceptable? What change would make the biggest difference? Explore aspects relevant to palliative care.
How well did staff communicate with you and your family?	Feel that the people managing your care listened to you and your concerns. Have provided with enough information about your disease and care.

3. Preferences – the next section is about what's important to you in your life, and also, what is important with regard to your health	
Topic area	Potential areas to be explored
What would you say are the most important things/things you value most in your life at the moment?	Priorities – not necessarily health related. Social, psychological, physical, spiritual, needs. Explore how easy it is for patient sustain/ achieve important things? Anything they want to achieve – life goals. How are these affected by health?
And in terms of your health: what is important to you with regards to your health and the care you received?	Preferences for type of care, aggressiveness of care. Level of input from professionals. Level of engagement with illness. How do you decide what is important? Healthcare goals
How do you decide what's important for your health?	Explore how preferences and priorities develop. What things are taken into account. Who is involved How do people prioritise
Do you think what is important changes over time?	Explore ideas of how preferences may change over time. Do different things become important at different times? What changes what priorities.
How do you make choices about your health? When you have to make choices? How much information do you prefer to have?	Decision making preferences. Involvement in decision making process.

4. Ideas about the future – I'd like to ask about the future	
Topic area	Potential areas to be explored
How do you see your health changing in the near future/further ahead?	Explore concerns and thoughts about the future, ideas about what might happen
Are you someone who tends to think about what the future may hold for your health?	Temporal focus – does patient consider their future; do they plan ahead? If yes, what do they think about the future? If not, why not?
If your health were to worsen, are there treatments that you would or wouldn't	Explore preferences for future care

want to receive? Or things that you would/wouldn't want to happen to you?	If appropriate, explore perceptions of palliative care.

5. Comments on the Integrated Palliative care Outcome Scale (IPOS)	
Topic area	Potential areas to be explored
(The participants will be asked to look at a hard copy of translated IPOS and provide their comments) Before we finish this interview today, can you review this questionnaire–IPOS, we developed in the UK to capture people's symptoms, needs and concerns.	If all the needs are reflected by IPOS.
How would you like IPOS to be used in practice?	
Who do you think is appropriate to ask the questions on the scale?	Staff, families or patients themselves.
Would you like the information on the scale to be shared with your families?	When is a good opportunity to share? How/ good way to share? What information? Part or all on IPOS?

6. Anything else	
Topic area	Potential areas to be explored
Anything else to change or add?	Is there anything you would like to add about your experiences of care or anything we have missed out/not spoken about? You can always contact us after if there is anything you would like to add.

I'd like to thank you for taking the time to be interviewed today, we really appreciate it and your views will be a great help to us. Your answers have been really helpful. We have now come to the end of the interview.

---------- THANKS + STOP RECORDING ----------

---------- COMPLETION OF DEMOGRAPHICS FORM ----------

Appendix 10. Topic guide – qualitative interviews (family version)

Topic Guide for Family Members Interview Participants

Understanding patients' needs and experiences of care (n=20)

Objective:

To identify palliative care needs among people living with cancer in China and their families and determine optimal implementation of the IPOS among stakeholders

Introduction:

- Thank you so much for agreeing to be interviewed today. My name is _____ and I'm a member of the team working on this study. When effected by disease, patients may have multidimensional needs including physical, psychosocial, spiritual, and information needs. Family members may also be distressed due to taking care of patients. The purpose of today's interview is to understand patients' needs, symptoms, and concerns, experiences of care patients have received or are receiving, and how care could be improved to meet these needs for patients with far advanced disease and their families. This will help us understand what patients' needs and concerns are, and how we can improve patients' experiences and/or identify gaps in our care.

- The interview should take up to 60 minutes. The information you share in this interview will be anonymised, so please feel free to share as much as you would like to. We may cover some difficult/challenging topics during the interview. You can stop the interview at any point or skip any questions should you wish to. Also, we can pause for breaks if you need to, and can restart recording when you are ready. Apologies of the questions get repetitive.

- Could I please just confirm that you have signed consent form and read the information sheet? And are you happy for the interview to be audio recorded today? And is it ok for me to make a few notes during the interview?

- You can tell me any thoughts or views you might have about the questions. Do you have any questions before we start?

---------- START RECORDING ----------

General probes: How did that make you feel? How did you deal with that? How do you think you will manage that? What do you think will happen?

1. Experience of illness – first I'd like to ask a bit about yourself and about the patient	
Topic area	Potential areas to be explored
How are you related to the patient? How is your health?	
Can you tell me a bit about how patient's health has been over the last 3 months?	Carers view on patient illness

How has patent's illness affected you?	Carer burden, physical & mental difficulties. Isolation, positive aspects of care.
Is there anyone who provides you with support?	Who provides support? What kind of support, how has this helped? If not, who might provide support?
What helps you cope with patient's illness? Is anything especially hard to cope with? How did you cope with these difficulties and challenges?	Help seeking, access to support, unmet need.
How did the medical team managing your care meet your support needs and family needs?	Physical/ psychological/ social/ spiritual/ religious needs.
Who can you ask for help if needed urgently?	Point of contact, how was this made known?
What is important to you and patients to help you live with good quality of life? Is there anything positive that we could take forward from your experience?	Preferences for care & priorities for quality of life

2. Experience of healthcare– now I'd like to ask you about care	
Topic area	Potential areas to be explored
Could you tell me about patient care in the last 3 months?	Care experience of healthcare. Good/bad aspects.
Tell me about your experience and patients' experience in the hospital.	Reason for admission, experiences during admission, especially focus on the run up to hospital admission
What changes would you like to make to the healthcare you've received? What would make it better.	Explore models of care and types of services that patients would prefer. What makes a service more acceptable? What change would make the biggest difference? Explore aspects relevant to palliative care.
How well did staff communicate with you and your family?	Feel that the people managing your care listened to you and your concerns. Have provided with enough information about your disease and care.

3. Preferences – the next section is about what's important to patient in his/her life, and also, what is important with regard to patient's health	
Topic area	Potential areas to be explored
What would you say are the most important things/things that patient	Priorities – not necessarily health related.

value most in his/her life at the moment?	Social, psychological, physical, spiritual needs. Explore how easy it is for patient sustain/ achieve important things? Anything they want to achieve – life goals. How are these affected by health?
And in terms of patient's health: what is important to the patient with regards to health and the care the patient received?	Preferences for type of care, aggressiveness of care. Level of input from professionals. Level of engagement with illness. How do you decide what is important? Healthcare goals.
How do you decide what's important for patient's health?	Explore how preferences and priorities develop. What things are taken into account. Who is involved How do people prioritise
Do you think what is important changes over time?	Explore ideas of how preferences may change over time. Do different things become important at different times? What changes what priorities.
How do you think patients make choices about his/her health? When does the patient have to make choices? How much information do think the patient prefer to have?	Decision making preferences. Involvement in decision making process.

4. Ideas about the future – I'd like to ask about the future	
Topic area	Potential areas to be explored
How do you see patient's health changing in the near future/further ahead?	Explore concerns and thoughts about the future, ideas about what might happen
If patient's health were to worsen, are there treatments that you would or wouldn't want to him/ her receive? Or things that you would/wouldn't want to happen to the patient?	Explore preferences for future care. If appropriate, explore perceptions of palliative care.

5. Comments on the Integrated Palliative care Outcome Scale (IPOS)	
Topic area	Potential areas to be explored

(The participants will be asked to look at a hard copy of translated IPOS and provide their comments) Before we finish this interview today, can you review this questionnaire–IPOS, we developed in the UK to capture people's symptoms, needs and concerns.	If all the needs are reflected by IPOS.
How would you like IPOS to be used in practice?	
Who do you think is appropriate to ask the questions on the scale?	Staff, families or patients themselves.
Would you like the information on the scale to be shared with your families?	When is a good opportunity to share? How/ good way to share? What information? Part or all on IPOS?

6. Anything else	
Topic area	Potential areas to be explored
Anything else to change or add?	Is there anything you would like to add about your experiences of care or anything we have missed out/not spoken about? You can always contact us after if there is anything you would like to add.

I'd like to thank you for taking the time to be interviewed today, we really appreciate it and your views will be a great help to us. Your answers have been really helpful. We have now come to the end of the interview.

---------- THANKS + STOP RECORDING ----------

---------- COMPLETION OF DEMOGRAPHICS FORM ----------

Appendix 11. Topic guide – cognitive interviews (patient version)

Objective:

To explore the cognitive processes used by respondents when reading, interpreting and responding to items on the IPOS questionnaire

Introduction:

- Study purpose, confidentiality, able to stop at any time, decline questions

- I'm going to show you a questionnaire and I want you to read & answer the questions one at a time
- We will stop and talk about each question before moving onto the next
- Please try to 'think out loud' as you read and answer the questions (DEMONSTRATE)
- I will also ask you some more specific things about each question

- Apologies of the questions get repetitive

- In this study we are less interested in your answers to the questions, but how you arrive at the answers – what you think the question means, and the things you were thinking about when you chose your answer.

- You can tell me any thoughts or views you might have about the questions

---------- START RECORDING ----------

General:

- What were you thinking about when you answered that question?

- I noticed you hesitated before giving your answer – what were you thinking about then?

Comprehension: **What does the respondent believe the question to be asking?**

- What does the question mean to you, in your own words?

- What does the word XXXXXX mean to you? (if certain words are thought to be problematic)

- How easy or difficult was it to understand this question?

- (If problem) How would you change this question?

Retrieval: **Could they recall the information required by the question? Was the time frame suitable?**

- How well could you remember your experience when answering this question?

- Was it easy or difficult to think about the past [week] when answering this question?

- Would there be a different time period that would be easier to understand?

Judgement: **Is the respondent able to make an evaluation based on the information recalled?**

- What were you thinking about when you answered this question?

- How did you arrive at your answer to that question?

- Was that easy or hard to arrive at your answer? Why do you say that?
- How sure are you of the answer to this question?

Response: Is the respondent able to map their internally generated answer to a response option?

- How did you choose your answer to this question?

- Was it hard or easy to select an answer from the options given?
- Did all options make sense for this question?

Other:

- Is there anything else you would like to say about this question? / The questionnaire as a whole?
- Did you find any of the questions upsetting? / embarrassing? / inappropriate?
- Are there any topics/questions that you would leave out of this questionnaire?

- Are there any topics/questions that you would add to this questionnaire?

- Do you have any thoughts about the way your answers were captured? (i.e. tablet/paper)

---------- THANKS + STOP RECORDING ----------

---------- COMPLETION OF DEMOGRAPHICS FORM ----------

Appendix 12. Topic guide – cognitive interviews (staff version)

Objective:

To explore the cognitive processes used by respondents when reading, interpreting and responding to items on the IPOS questionnaire

Introduction:

- Study purpose, confidentiality, able to stop at any time, decline questions

- I'm going to show you a questionnaire and I want you to read & answer the questions one at a time

- We will stop and talk about each question before moving onto the next

- Please try to 'think out loud' as you read and answer the questions (DEMONSTRATE)

- I will also ask you some more specific things about each question

- Apologies of the questions get repetitive

- In this study we are less interested in your answers to the questions, but how you arrive at the answers – what you think the question means, and the things you were thinking about when you chose your answer.

- Could I please just confirm that you have signed consent form and read the information sheet? And are you happy for the interview to be audio recorded today? And is it ok for me to make a few notes during the interview?

- You can tell me any thoughts or views you might have about the questions

---------- START RECORDING ----------

General:

- What were you thinking about when you answered that question?

- I noticed you hesitated before giving your answer – what were you thinking about then?

Comprehension: **What does the respondent believe the question to be asking?**

- What does the question mean to you, in your own words?

- What does the word XXXXXX mean to you? (if certain words are thought to be problematic)

- How easy or difficult was it to understand this question?

- (If problem) How would you change this question?

Retrieval: **Could they recall the information required by the question? Was the time frame suitable?**

- How well could you remember the patients' experience when answering this question?

- Was it easy or difficult to think about the past [week] when answering this question?

- Would there be a different time period that would be easier to understand?

Judgement: **Is the respondent able to make an evaluation based on the information recalled?**

- What were you thinking about when you answered this question?

- How did you arrive at your answer to that question?

- Was that easy or hard to arrive at your answer? Why do you say that?

- How sure are you of the answer to this question?

Response: Is the respondent able to map their internally generated answer to a response option?

- How did you choose your answer to this question?

- Was it hard or easy to select an answer from the options given?

- Did all options make sense for this question?

Other:

- Is there anything else you would like to say about this question? / The questionnaire as a whole?

- Did you find any of the questions upsetting? / embarrassing? / inappropriate?

- Are there any topics/questions that you would leave out of this questionnaire?

- Are there any topics/questions that you would add to this questionnaire?

- Do you have any thoughts about the way your answers were captured? (i.e. tablet/paper)

---------- THANKS + STOP RECORDING ----------

---------- COMPLETION OF DEMOGRAPHICS FORM ----------

Appendix 13. Chinese version of Integrated Palliative care Outcome Scale (IPOS) (patient version)

IPOS 患者版本

www.pos-pal.org

姓　　名：.....

日期 (年-月-日): .....

病 历 编 号: ..... *(医务人员填写)*

填 表 用 时: .....*分钟(医务人员填写)*

问题 1. 在过去 3 天内，在您的整个生活中曾存在的主要问题或担忧是什么？

1. .....

2. .....

3. .....

问题 2. 下表所列症状，有的可能您经历过，有的可能您没有。在对应症状后打钩，标记出过去 3 天您所受这种症状困扰的程度。

	根本没有	*轻度*	*中度*	*重度*	*超重度*
疼痛	0☐	1☐	2☐	3☐	4☐
气短	0☐	1☐	2☐	3☐	4☐
虚弱或乏力	0☐	1☐	2☐	3☐	4☐
恶心（ 感到想要呕吐）	0☐	1☐	2☐	3☐	4☐
呕吐	0☐	1☐	2☐	3☐	4☐
食欲差	0☐	1☐	2☐	3☐	4☐
便秘	0☐	1☐	2☐	3☐	4☐
口疮或口干	0☐	1☐	2☐	3☐	4☐
昏昏欲睡	0☐	1☐	2☐	3☐	4☐
行动不便	0☐	1☐	2☐	3☐	4☐
请列出以上没有提及的其他症状，然后在对应方框中打勾以显示它们在过去三天内对您的影响。					
1.	0☐	1☐	2☐	3☐	4☐
2.	0☐	1☐	2☐	3☐	4☐
3.	0☐	1☐	2☐	3☐	4☐

在过去的 3 天内：

	根本没有	*偶尔*	*有时*	*大多数时间*	*总是*
问题 3.您对您的病情或治疗感到焦虑或担心吗？	0☐	1☐	2☐	3☐	4☐
问题 4.您的家人或朋友感到焦虑或为您担心吗？	0☐	1☐	2☐	3☐	4☐
问题 5. 您感到情绪低落吗？	0☐	1☐	2☐	3☐	4☐
	总是	*大多数时间*	*有时*	*偶尔*	*根本没有*
问题 6.您感到平静安宁吗？	0☐	1☐	2☐	3☐	4☐
问题 7.您是否能充分地与家人或朋友分享您的感受？	0☐	1☐	2☐	3☐	4☐
问题 8.您能充分地获得您想知道的信息吗？	0☐	1☐	2☐	3☐	4☐
问题9.您感到对家庭构成负担吗？	0☐	1☐	2☐	3☐	4☐
	已解决/没有问题	*大部分解决*	*部分解决*	*几乎没有解决*	*没有解决*
问题 10-1. 由您的病情所导致的财务问题，已得到解决了吗？（比如债务或无法获得医保）	0☐	1☐	2☐	3☐	4☐
问题 10-2.由您的病情所导致的个人问题，已得到解决了吗？（比如社交障碍或无法工作）	0☐	1☐	2☐	3☐	4☐

	自己独立完成	*在朋友或家人的帮助下完成*	*在工作人员帮助下完成*
问题 11.您是如何完成本问卷的？	☐	☐	☐

如果您对本问卷中的任何问题感到担忧
请与您的医生或护士联系

Appendix 14. Chinese version of Integrated Palliative care Outcome Scale (IPOS) (staff version)

IPOS 医务人员版本

www.pos-pal.org

患 者 姓 名：.....

日期 (年-月-日)：.....

病 历 编 号：.....

问题 1. 在过去 3 天内，在患者的整个生活中曾存在的主要问题是什么？

1. .....

2. .....

3. .....

问题 2. 请在您认为最能准确描述下列症状在过去 3 天内对患者产生了怎样的影响的对应方框内打勾。

	根本没有	*轻度*	*中度*	*重度*	*超重度*	*无法评估（例如，患者意识不清）*
疼痛	0☐	1☐	2☐	3☐	4☐	☐
气短	0☐	1☐	2☐	3☐	4☐	☐
虚弱或乏力	0☐	1☐	2☐	3☐	4☐	☐
恶心（感到想要呕吐）	0☐	1☐	2☐	3☐	4☐	☐
呕吐	0☐	1☐	2☐	3☐	4☐	☐
食欲差	0☐	1☐	2☐	3☐	4☐	☐
便秘	0☐	1☐	2☐	3☐	4☐	☐
口疮或口干	0☐	1☐	2☐	3☐	4☐	☐
昏昏欲睡	0☐	1☐	2☐	3☐	4☐	☐
行动不便	0☐	1☐	2☐	3☐	4☐	☐
请列出以上没有提及的其他症状，然后在对应方框中打勾以显示您认为它们在过去三天内对患者构成怎样的影响。						
1.	0☐	1☐	2☐	3☐	4☐	☐
2.	0☐	1☐	2☐	3☐	4☐	☐
3.	0☐	1☐	2☐	3☐	4☐	☐

在过去的 3 天内：

	根本没有	*偶尔*	*有时*	*大多数时间*	*总是*	*无法评估（例如，患者意识不清）*
问题 3.患者对他/她的病情或治疗感到焦虑或担心吗？	0☐	1☐	2☐	3☐	4☐	☐
问题 4.患者的家人或朋友感到焦虑或为患者担心吗？	0☐	1☐	2☐	3☐	4☐	☐
问题 5. 您认为患者感到情绪低落吗？	0☐	1☐	2☐	3☐	4☐	☐
	总是	*大多数时间*	*有时*	*偶尔*	*根本没有*	*无法评估（例如，患者意识不清）*
问题 6. 您认为患者感到平静安宁吗？	0☐	1☐	2☐	3☐	4☐	☐
问题 7.患者是否能充分地与家人或朋友分享他/她的感受？	0☐	1☐	2☐	3☐	4☐	☐
问题 8.患者能充分地获得他/她想知道的信息吗？	0☐	1☐	2☐	3☐	4☐	☐
问题9.您认为患者感到对家庭构成负担吗？	0☐	1☐	2☐	3☐	4☐	☐
	已解决/没有问题	*大部分解决*	*部分解决*	*几乎没有解决*	*没有解决*	*无法评估（例如，患者意识不清）*
问题 10-1. 由患者的病情所导致的财务问题，已得到解决了吗？（比如债务或无法获得医保）	0☐	1☐	2☐	3☐	4☐	☐
问题 10-2.由患者的病情所导致的个人问题，已得到解决了吗？（比如社交障碍或无法工作）	0☐	1☐	2☐	3☐	4☐	☐

Appendix 15. Submitted manuscript of paper 2

PLOS ONE

Towards person-centred care for people with advanced cancer and their families in China: what core outcomes matter? A qualitative study

--Manuscript Draft--

Manuscript Number:	
Article Type:	Research Article
Full Title:	Towards person-centred care for people with advanced cancer and their families in China: what core outcomes matter? A qualitative study
Short Title:	What core outcomes matter for people with advanced cancer and their families in China?
Corresponding Author:	Houshen Li King's College London Florence Nightingale Faculty of Nursing Midwifery & Palliative Care London, London UNITED KINGDOM
Keywords:	Advanced cancer; experiences; needs; person-centred care; palliative care; conceptual model; qualitative study; China
Abstract:	Introduction With increasing incidence and mortality, cancer has become one of the leading causes of death in China and a significant public health problem. People living with advanced cancer have multidimensional needs and concerns requiring person-centred care. However, little evidence exists on patients' priorities of advanced cancer care in China, and there is no ideal outcome measure that captures the breadth of needs and concerns of patients with advanced cancer in China. Objective To identify the main symptoms, needs, concerns and priority outcomes for patients with advanced cancer and family members and devise a model for person-centred advanced cancer care in China. Methods Semi-structured in-depth qualitative interviews with advanced cancer patients and family members at an inpatient oncology ward in China were conducted between October 2019 to January 2020. Data collection continued until thematic saturation was achieved. Interviews were audio-recorded, transcribed verbatim and analysed utilising framework analysis. Results Patients (n=20, median age 55.0, 60% female) and family members (n=20, median age 41.0, 45% female) described distinctive but highly interrelated concerns related to living with advanced cancer across five domains: (a) physical and psychological symptoms (e.g. pain and anxiety), (b) financial difficulties (e.g. debt and health insurance problems), (c) impacts on family (e.g. change of roles and burden on families), (d) coping and adapting to the disease (e.g. decision making and healthcare resource accessibility), and (e) plans to the future (e.g. attitudes toward dying and palliative care and unfulfilled wishes). A conceptual model showing the perspectives of patients and family members has been developed. Findings confirmed that advanced cancer has far-reaching implications for patients and family members in China, extending beyond physical and psychological problems into social (e.g. family issues), practical (e.g. financial difficulties and coping with cancer) needs and future plans. Conclusion This study advances the understanding of patients' and family members' experiences in the context of advanced cancer care in China. It presents a novel multidimensional

	conceptual model of person-centred care, which reflects the priorities of patients and family members. This insight is a critical first step in delivering more person-centred care for patients with advanced cancer and family members in China.
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Financial Disclosure Enter a financial disclosure statement that describes the sources of funding for the work included in this submission. Review the submission guidelines for detailed requirements. View published research articles from *PLOS ONE* for specific examples. This statement is required for submission and **will appear in the published article** if the submission is accepted. Please make sure it is accurate.	The authors received no specific funding for this work.

Unfunded studies Enter: *The author(s) received no specific funding for this work.* **Funded studies** Enter a statement with the following details: • Initials of the authors who received each award • Grant numbers awarded to each author • The full name of each funder • URL of each funder website • Did the sponsors or funders play any role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript? • **NO** - Include this sentence at the end of your statement: *The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.* • **YES** - Specify the role(s) played. * typeset	
Competing Interests Use the instructions below to enter a competing interest statement for this submission. On behalf of all authors, disclose any competing interests that could be perceived to bias this work—acknowledging all financial support and any other relevant financial or non-financial competing interests. This statement is required for submission and **will appear in the published article** if the submission is accepted. Please make sure it is accurate and that any funding sources listed in your Funding Information later in the submission form are also declared in your Financial Disclosure statement. View published research articles from *PLOS ONE* for specific examples.	The authors have declared that no competing interests exist.

NO authors have competing interests Enter: *The authors have declared that no competing interests exist.* **Authors with competing interests** Enter competing interest details beginning with this statement: *I have read the journal's policy and the authors of this manuscript have the following competing interests: [insert competing interests here]* * typeset	
Ethics Statement Enter an ethics statement for this submission. This statement is required if the study involved: • Human participants • Human specimens or tissue • Vertebrate animals or cephalopods • Vertebrate embryos or tissues • Field research Write "N/A" if the submission does not require an ethics statement. General guidance is provided below. Consult the submission guidelines for detailed instructions. **Make sure that all information entered here is included in the Methods section of the manuscript.**	Ethical approval was attained from both Kings' College London (HR-20/21-18713) and the Chaoyang Central Hospital in China. Information sheets and consent forms were translated from English into Chinese. Participants gave written informed consent before the interview.

Format for specific study types **Human Subject Research (involving human participants and/or tissue)** • Give the name of the institutional review board or ethics committee that approved the study • Include the approval number and/or a statement indicating approval of this research • Indicate the form of consent obtained (written/oral) or the reason that consent was not obtained (e.g. the data were analyzed anonymously) **Animal Research (involving vertebrate animals, embryos or tissues)** • Provide the name of the Institutional Animal Care and Use Committee (IACUC) or other relevant ethics board that reviewed the study protocol, and indicate whether they approved this research or granted a formal waiver of ethical approval • Include an approval number if one was obtained • If the study involved *non-human primates*, add *additional details* about animal welfare and steps taken to ameliorate suffering • If anesthesia, euthanasia, or any kind of animal sacrifice is part of the study, include briefly which substances and/or methods were applied **Field Research** Include the following details if this study involves the collection of plant, animal, or other materials from a natural setting: • Field permit number • Name of the institution or relevant body that granted permission	
Data Availability Authors are required to make all data underlying the findings described fully available, without restriction, and from the time of publication. PLOS allows rare exceptions to address legal and ethical concerns. See the PLOS Data Policy and FAQ for detailed information.	No - some restrictions will apply

A Data Availability Statement describing where the data can be found is required at submission. Your answers to this question constitute the Data Availability Statement and **will be published in the article**, if accepted. **Important:** Stating 'data available on request from the author' is not sufficient. If your data are only available upon request, select 'No' for the first question and explain your exceptional situation in the text box. Do the authors confirm that all data underlying the findings described in their manuscript are fully available without restriction?	
Describe where the data may be found in full sentences. If you are copying our sample text, replace any instances of XXX with the appropriate details. • If the data are **held or will be held in a public repository**, include URLs, accession numbers or DOIs. If this information will only be available after acceptance, indicate this by ticking the box below. For example: *All XXX files are available from the XXX database (accession number(s) XXX, XXX.).* • If the data are all contained **within the manuscript and/or Supporting Information files**, enter the following: *All relevant data are within the manuscript and its Supporting Information files.* • If neither of these applies but you are able to provide **details of access elsewhere**, with or without limitations, please do so. For example: *Data cannot be shared publicly because of [XXX]. Data are available from the XXX Institutional Data Access / Ethics Committee (contact via XXX) for researchers who meet the criteria for access to confidential data.* *The data underlying the results presented in the study are available from (include the name of the third party*	Data cannot be shared publicly because of ethical considerations. Data are available from the King's College London Institutional Data Access / Ethics Committee (contact via houshen.li@kcl.ac.uk) for researchers who meet the criteria for access to confidential data.

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19/09/2022

Dear Editor,

We wish to submit an original qualitative study entitled "Towards person-centred care for people with advanced cancer and their families in China: what core outcomes matter? A qualitative study" for consideration by ***PLoS One***.

We confirm that this work is original and has not been published elsewhere, nor is it currently under consideration for publication elsewhere.

This qualitative study enrolled 40 participants (20 patients, 20 families) to explore their experience and needs. These qualitative interview data highlighted and accentuated the dynamic nature of their experiences, which were characterised by distinctive but highly interrelated qualities across the illness experience: (a) physical and psychological symptoms, (b) financial difficulties, (c)impacts on family (d) practical impacts and coping and (e) plans to the future.

We believe that this manuscript is appropriate for publication by ***PLoS One*** because this original qualitative study provides the robust evidence for understanding experience and needs of advanced cancer patients in China and presents a novel multidimensional conceptual model of person-centred care, which reflects the priorities of patients and family members.

We have no conflicts of interest to disclose.

Please address all correspondence concerning this manuscript to me at houshen.li@kcl.ac.uk

Thank you for your consideration of our manuscript.

Best wishes,

Houshen

Towards person-centred care for people with advanced cancer and their families in China: what core outcomes matter? A qualitative study

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Abstract

Introduction:

With increasing incidence and mortality, cancer has become one of the leading causes of death in China and a significant public health problem. People living with advanced cancer have multidimensional needs and concerns requiring person-centred care. However, little evidence exists on patients' priorities of advanced cancer care in China, and there is no ideal outcome measure that captures the breadth of needs and concerns of patients with advanced cancer in China.

Objective:

To identify the main symptoms, needs, concerns and priority outcomes for patients with advanced cancer and family members and devise a model for person-centred advanced cancer care in China.

Methods:

Semi-structured in-depth qualitative interviews with advanced cancer patients and family members at an inpatient oncology ward in China were conducted between October 2019 to January 2020. Data collection continued until thematic saturation was achieved. Interviews were audio-recorded, transcribed verbatim and analysed utilising framework analysis.

Results:

Patients (n=20, median age 55.0, 60% female) and family members (n=20, median age 41.0, 45% female) described distinctive but highly interrelated concerns related to living with advanced cancer across five domains: (a) physical and psychological symptoms (e.g. pain and anxiety), (b) financial difficulties (e.g. debt and health insurance problems), (c) impacts on family (e.g. change of roles and burden on families), (d) coping and adapting to the disease (e.g. decision making and healthcare resource accessibility), and (e) plans to the future (e.g. attitudes toward dying and palliative care and unfulfilled wishes). A conceptual model showing the perspectives of patients and family members has been developed. Findings confirmed that advanced cancer has far-reaching implications for patients and family members in China, extending beyond physical and psychological problems into social (e.g. family issues), practical (e.g. financial difficulties and coping with cancer) needs and future plans.

Conclusion:

This study advances the understanding of patients' and family members' experiences in the context of advanced cancer care in China. It presents a novel multidimensional conceptual model of person-centred care, which reflects the priorities of patients and family members. This insight is a critical first step in delivering more person-centred care for patients with advanced cancer and family members in China.

Introduction

Much of the burden of cancer incidence and mortality occurs in the developing world.(1) With increasing incidence and mortality, cancer is the leading cause of death and is a significant public health problem in China.(2) An estimated 4.3 million new cancer cases and 2.9 million new cancer deaths occurred in China in 2018. China has lower cancer incidence but 30% and 40% higher cancer mortality than the UK and USA, and has relatively poorer prognoses.(3)

Patients with advanced cancer suffer from multidimensional symptoms which lead to significant distress and functional impairment.(4) Suffering is one of the primary concerns for patients at the terminal stage.(5) Relief of suffering in terminally ill patients is a major component of palliative care—an approach aiming to improve the quality of life of patients and their families facing the prevention and relief of suffering and treatment.(6) Systematic reviews have found that patients suffering affects themselves and others, particularly close relatives, which causes a wide range of problems.(7)

Preferences, values, preferences and needs of advanced cancer patients and their loved ones are the core of patient-centredness.(8, 9) In patient-centred care, patients, families and healthcare professional make shared decisions considering not only from a clinical perspective but also from a physical, psychological, spiritual, social, practical and financial perspective.(10) Therefore, it is crucial to understand what core outcomes matter to the patients and families to encourage active collaboration and shared decision-making between patients, families, and healthcare professionals to design and manage a customised and comprehensive care plan.

However, some Chinese cultural beliefs may hamper the implementation of patient-centred care and palliative care by preventing healthcare professionals from talking openly toward advanced patients regarding their diagnosis and prognosis,(11) as discussing about death and dying is seen to be bad fortune and disturb inner peace.(12, 13) Despite evidence showing that healthcare professionals in China generally recognise the significance of palliative care for advanced patients, they often express difficulties in dealing with

conversations regarding death and fear of being blamed and enraging the patient and their families.(14) Pressure from families not to disclose to the patient complicates the challenge of obtaining the patient's consent before initiating treatment and providing appropriate patient-centred care and palliative care.(15)

In a recent qualitative systematic review of adult cancer patients with cancer who had experienced suffering, only one Chinese study with nine participants was identified.(16) Little qualitative evidence exists on patients' priorities of advanced cancer care in China, and there is no ideal outcome measure that reflects the breadth of concerns for advanced cancer patients in China. This study aims to identify the main symptoms and concerns and the priority outcomes for advanced cancer patients and family members and devise a model for person-centred advanced cancer care in China.

Methods

Design

We performed a qualitative study which used semi-structured interviews and framework analysis and is reported in accordance with the consolidated criteria for reporting qualitative research (COREQ) guidelines.

Study participants

Advanced cancer patient participants and family participants were enrolled from an inpatient medical oncology ward in Chaoyang Central Hospital, a university teaching hospital in Liaoning Province, China. Eligible patient participants were adults (at least 18 years old), diagnosed with stage III or IV cancer or being the main carer of a relative with stage III or IV cancer, able to give informed consent, and judged to be physically and mentally well enough to participate by their clinical staff, and able to speak Mandarin. Eligible family participants were the main carer of a relative with stage III or IV cancer. We defined a diagnosis of stage III-IV cancer In line with the Chinese Society of Clinical Oncology clinical guidelines for the diagnosis and treatment.(17)

The purposive maximum variation sampling frame took account of age, gender, marital status, patient's primary diagnosis, and duration of disease to reflect the diversity of possible experiences. Families were recruited independently of the patients and interviewed separately. Patients and family members did not have to match unless the family members expressed a strong willingness to participate.

Data collection

A trained oncology research nurse (HX) was based at the study site and was responsible for approaching eligible patients and families in the inpatient ward. 48 hours were given to the approached eligible patients and family members when they could take careful consideration on whether to participate or not. Face-to-face, semi-structured in-depth interviews were conducted in the participants' preferred setting (e.g., a private ward or office) between October 2019 and January 2020. The interviewer (HL) had extensive experience in cancer palliative care and qualitative research and had no pre-existed relationship at the time of consenting and interviewing. A topic guide was developed from a review of evidence on experiences of palliative care needs in cancer patients and refined by the research team (see Appendix).

Interviews commenced with demographic questions followed by open questions exploring patients' experience of illness, the experience of healthcare, preferences, and ideas about the future. Participants were asked to tell stories based on their personal experience, from the point they were diagnosed with cancer, or their families were diagnosed with cancer. The participants are encouraged to tell stories following the prompts and questions being asked in the way they prefer, with minimum interruption from the interviewer. At the end of the interviews, the interviewer used open questions to explore particular issues further and offer participants opportunities to add/ change anything. Interviews are transcribed professionally, checked by the researcher, and returned to the respondent for change or approval before analysis. Field notes were made during each interview.

Data collection continued until data saturation was reached (i.e. no new themes were identified in line with the study aim), which was informed by diarised emergent themes. All interviews were conducted in Mandarin and digitally audio recorded, anonymised, transcribed verbatim by researchers (HL, LL, YG, YH, FY), and translated from Mandarin into English (HL). The research team reviewed the transcripts to check the accuracy of translations. In addition, we used the Karnofsky Performance Scale (KPS) to measure patients' functional status.(18, 19)

Analysis

Framework analysis was performed. Interview transcripts were read repeatedly and coded each transcript line by line after importing data into NVivo (Version 10, QSR International Pty Ltd. 2019), creating a coding frame of themes generated directly from the interview data. Transcribing, translating, and analysing the data occurred simultaneously as the data collection proceeded to refine the topic guide. Interview data were categorised and compared, enabling the identification of common themes and sub-themes. We used constant comparison in our analysis to ensure that the thematic analysis represented all perspectives. A list of themes and sub-themes were created, then examined for overlapping themes merged under descriptive labels and themes containing few quotations. Throughout this process, the data were consistently analysed to gain insight into the relationship between themes. To ensure open discussion of qualitative data collection and analysis throughout the project, the research team had regular meetings throughout the study. Besides, demographic data were descriptively analysed using SPSS (Version 26.0. Armonk, NY: IBM Corp).

Ethical approval

Ethical approval was attained from both Kings' College London (HR-20/21-18713) and the Chaoyang Central Hospital in China. Information sheets and consent forms were translated from English into Chinese. Participants gave written informed consent before the interview.

Results

Sample characteristics

53 eligible patients and 77 family members were approached using purposive sampling and introduced about the study, referring the participants' information sheet. 22 patients contacted the researcher with the interest in participating. Of those two patients withdrew because one refused to be recorded and another did not want to sign the consent form without giving a specific reason. 21 family members contacted the researcher for the interest of participation. Of those, one family member patient withdrew because he worried participating in the study could affect her wife's treatment. As a result, a total of 40 interviews were carried out (20 patients and 20 family members) at the participants' preferred places and times. Interviews lasted 20-60 minutes.

Demographic/ clinical information for patients and family member participants is shown in Table 1.

Table 1 Sample characteristics. For patients (n=20) and family members

Variable	Patients		Family members	
	n	%	n	%
Age	Median 55.0	8.3, 36-75 (SD, range)	Median 41.0	SD, range 13.5, 24-72
Gender				
Male	8	40.0	11	55.0
Female	12	60.0	9	45.0
Marital status				
Single	0	0	4	20.0
Married	18	90.0	16	80.0
Divorced	1	5.0	0	0
Widowed	1	5.0	0	0
Education				

Primary school	4	20.0	1	5.0
Junior high school	11	55.0	8	40.0
High school	4	20.0	4	20.0
Undergraduate	1	5.0	6	30.0
Postgraduate	0	0	1	5.0
Employment Status				
Employed full-time	0	0	7	35.0
Employed part-time	0	0	2	10.0
Self-employed	1	5.0	7	35.0
Retired	7	35.0	1	5.0
Not employed	12	60.0	3	15.0
Participant's relationship with patients				
Spouse	-	-	6	30.0
Child	-	-	14	70.0
Patient's diagnosis				
Breast cancer	9	45.0	7	35.0
Lung cancer	4	20.0	6	30.0
Gastric cancer	1	5.0	2	10.0
Rectal cancer	2	10.0	1	5.0
Colon cancer	2	10.0	2	10.0
Prostate cancer	1	5.0	0	0
Sarcoma	1	5.0	0	0
Endometrial cancer	0	0	1	5.0
Hypopharyngeal cancer	0	0	1	5.0
Patient's stage				
III	6	30.0	6	30.0
IV	14	70.0	14	70.0
Patient's age at onset	Median	9.8, 30-75	Median	9.4, 42-74
	54.5	(SD, range)	59.0	(SD, range)
Time since diagnosis (years)				

< 1	12	60.0	12	60.0
≥1 & ≤5	3	15.0	4	20.0
> 5	5	25.0	4	20.0
Patient's KPS	Median	SD, range	Median	SD, range
	85.0	6.0, 70-90	80.0	7.6, 60-90
60	0		1	5.0
70	1	5.0	2	10.0
80	9	45.0	12	60.0
90	10	50.0	5	25.0

KPS: Karnofsky Performance Score

Qualitative findings

These qualitative interview data highlighted and accentuated the dynamic nature of their experiences, which were characterised by distinctive but highly interrelated qualities across the illness experience: (a) physical and psychological symptoms, (b) financial difficulties, (c)impacts on family (d) practical impacts and coping and (e) plans to the future. Figure 1 presents themes and subthemes that emerged from the qualitative data.

Figure 1. Themes and subthemes: living with advanced cancer in China [figure attached separately]

Theme 1: Symptoms

Physical symptoms

Participants reported a wide range of physical symptoms, most frequently mentioning fatigue or pain. One of the most notable physical symptoms was cancer pain, which is often the most tangible sign of disease they and their families perceive. Respondents reported that they experienced pain as a highly stressful condition that adversely affects all aspects of

their life. Pain was associated with difficulties, negative thoughts, a range of functional limitations and the coping behaviours they adopted.

*"I have suffered from pain for 7 or 8 days in the hospital after my third chemotherapy. I feel pain. It is like a burning inside of my body. I just thought maybe I wanted to suicide. I am sweating all over my face…It is unbearable as a man." (*Patient 8, Male, 52, Lung cancer)

Fatigue is the most frequently reported symptom from participants. Participants reported they were less mobile than previously, and their physical fitness deteriorated. The tiredness and loss of control of their bodies fell more often, and they stumbled. In many cases, the loss resulted in a feeling of the need for a seat or rest or simply remaining asleep.
"He was weak. Since he was given the medicine, he has suffered from weakness. His feet were quite dragging and a little hard to lift… He could not move at all when he was sick and always sleeping. I did not notice this. He has not left the bed for 40 days." Family 7, Daughter of lung cancer patient, 43

Psychological symptoms

Some respondents described emotional reactions to the initial cancer diagnosis, including feelings of anxiety and distress. Patients often feel on an emotional rollercoaster, experiencing peaks and troughs at critical times of stress and uncertainty in the cancer trajectory.

"I feel anxious… I dare not sleep. It is not that I am not going to sleep. It is because I am afraid to sleep. I am afraid to close my eyes, and then the next day, my eyes would not open." Patient 1, Female, 55, Breast cancer

Comments related to different concerns participants had raised about using anticancer treatment, from overdosing and becoming addicted to the management of side effects.

"The feeling of chemotherapy is too bad. This just made me go crazy. I told the doctor that after these six (circles), please let me stop. I was going crazy. It is suffering…When I got back home, I could not stand still or sit still, so I walked back and forth. I could not even stand still

for a little while. For one or two minutes, I had to walk fast like I was crazy…Anxious, anxious as hell." Patient 15, Female, 59, Rectal cancer

Theme 2: Financial difficulties

Patients and families reported that patients could experience a range of direct medical costs, including hospital bills, consultant fees and non-medical costs, including increased household bills and travelling costs to hospital appointments, particularly those living in rural areas.

Debt

The patient stated that rural households in China usually have severe medical debt due to high out-of-pocket payments, contributing to bankruptcy.
"I am in financial trouble…Living in a rural area, and I am now about 60 years old, it is not possible for me to lend money at all. Who would lend me money? People know I will die soon someday." Patient 11, Male, 61, Prostate cancer

Health insurance

Health insurance can affect cancer patients' quality of life. Some participants expressed frustration with their insurance not paying for all aspects of their care and their frustration with the absence of clear and easily accessible information on the costs of cancer care when shopping for health insurance plans. In addition, participants had no consensus about the best place to learn about insurance information.

"Now I am bankrupt because of this cancer. The cost of treatment is too high. If you are from the city, you should be covered more if you have medical insurance. In rural areas, the reimbursement for cooperative medical systems is less. You have to go through a referral procedure locally, and you will be reimbursed more at that time. You will be reimbursed less if you do not go through the referral procedure." Patient 10, Female, 55, Rectal cancer

Compromised treatment for cost reduction

Cancer patients carried rising burdens of healthcare-related out-of-pocket expenses, and a growing number of patients were considered "underinsured." Participants were struggling to pay for their cancer treatment and altered their lifestyles considerably to defray out-of-pocket expenses. Participants reported taking less medication than prescribed, replacing prescription medications with over-the-counter drugs, and taking medications prescribed for others in order to defray costs.

"Because my mother has just changed this new drug, and this new drug is not included in the medical insurance. If it can be included in the medical insurance ahead of time, our family may choose it earlier instead of thinking about it when the illness is a little urgent. Originally, it might be the plan. My mother used the medicine in the medical insurance first. Wait until the new drug, the particular drug, is included in the medical insurance. But it is urgent, and you have to use it first... Maybe this medicine is very expensive, it is foreign medicine, and ordinary people cannot afford it. You may choose some other ways, some imitation drugs that have similar effects but are cheaper, or some drugs that are already in medical insurance, conservative or not so effective." Patient 1, Female, 55, Breast cancer

Theme 3: Impacts on family

Change of roles

Participants reported that the whole family was affected by cancer, and no one went through this experience unchanged. Cancer and the treatments can introduce a complex array of lifestyle and family role changes and emotional responses that can be difficult for family members to handle.

"I cannot take care of my grandson… He is one year old, cannot even speak, and he wants to hug me." Patient 14, Female, 55, Breast cancer
"(My father) is no longer like the head of a family. After all, we are older, and he may listen to our opinions. He may have a stiff tongue about what we say to do at present. Psychologically, he is more comfortable or obedient, listen... it turns out that I am not willing to make a decision for him. It is his business to let them make their own decisions. However,

after he got ill, I was pushed to the front. I need to make decisions." Family 3, Son of lung cancer patient, 28

Burden on the family

Family participants reported they experienced tremendous pressure and anxiety to care for the patients while they had to take care of other family members.

"Huge pressure to take care of him. (Besides my mother) My father-in-law is sick *too and lying in the bed. My kids are young." Family 10, Daughter of hypopharyngeal cancer patient, 38*

"I barely sleep, especially at night. Once I wake up, I cannot sleep again. I cannot sleep on the rest of the night… I am worried about my body. I am super thin. I used to weigh 55kg. Now I weigh 45kg." Family 7, Daughter of lung cancer patient, 43

Theme 4: Practical impacts and coping

Healthcare resource inaccessibility

Patients complained that they could not access health services and regular physical examination due to living in rural areas, given the disparity in health services between urban and rural areas in China.

"Most of the young people in rural China go out to work... It is up to the parents themselves to care for their parents. There is no so-called physical examination. Sometimes they do not take medicine for minor diseases. Maybe it is fine if they just have a cold." Family 5, Son of endometrial cancer patient, 43

Participants reported they had to rely on village clinics, or travel hundreds of miles to find the closest facility. Instead of going to an outpatient clinic at hospital or a community clinic, they tended to rush to the top hospitals to see specialists for best care in major cities, most people are relegated to overcrowded hospitals, while patients had to wait long time for a bed or examination.

"It is just to check when some people arrive and slow down a little... It is just that the waiting time is too long. It is OK when catching up quickly. Sometimes it is a bit slow. There are too many people in the hospital. Sometimes it is too slow to make an appointment for an examination. There are too many patients in this big hospital, so they have to queue up." Family 12, Son of rectal cancer patient, 36

Aspects of care

Patients and families valued about the healthcare providers and organisations. Participants reported that healthcare providers' behaviour, attitudes and good interpersonal skills could promote patients' satisfaction and overall satisfaction with the trustful relationship created by healthcare providers. A personal relationship with healthcare providers was identified as a crucial factor in service delivery.

"(Medical staff) give me the greatest help, the feeling like family. As soon as I went to this department, the nurses and doctors were as enthusiastic as my family when they talked to me. Not only for me, but I also found that they were very patient with other patients, such as older patients, just like coaxing children. It helped me a lot. It is like going home. I am also worried. In the first few years, we all knew that the doctor-patient relationship was not very good... But when I came here, I really looked like my family. It was to ease my fear, so I did not feel afraid." Patient 17, Female, 48, Breast cancer

Reduced work or socialising

The consequences of suffering from advanced cancer included reduced work and social limitations, resulting in loss of former social contacts and reluctance to create new ones. Social activities previously regularly performed were now cancelled. In addition, physical appearance was often affected both by cancer and its treatment such as hair loss, loss of one or both breasts, and loss of sexual attractiveness. Patients often perceive these changes in appearance to be disfiguring and feel alienated.

"Before I got sick, I was very sociable and had many friends, classmates and families… After getting sick, I basically block myself from people who do not know what happened to me. Especially since I lost my hair … I just shut myself off … I do not want people to know I am sick." Patient 17, Female, 48, Breast cancer

"My father did not work much after the surgery, and he has been recovering because he had surgery, chemotherapy, radiotherapy and a lot of treatment. No energy for work." Family 8, Son of lung cancer patient, 24

Theme 5: Plans for the future

Attitudes toward dying and palliative care

All patients and family members were concerned about the terminal nature of advanced cancer: data suggested that patients frequently chose to escape the magnitude of this information by choosing not to think about dying and death.

"No matter what, all people will be dead. Besides, why do you have to endure that time? I have suffered a lot. I have been a burden to my children and my wife... I just want to ensure the quality of my life, relieve the pain and solve the problem of insomnia." Patient 8, Male, 52, Lung cancer

"My goal of treatment is to reduce suffering. This disease cannot be cured... This is the biggest wish. Even if we live for half a year, the second half of the year or the next spring, people will die eventually. We cannot afford to suffer too much... I do not need you to extend the time because what, if you have a long illness and the illness has reached a certain degree, what is the use of extending it for 10 days, 20 days, a month or two months? It is unnecessary and useless, right? In this period, you will end up suffering less. I suggest that this is a digression. Suppose we have euthanasia, which is the best. When the disease cannot be cured, what do you want him to suffer? What do you want him to live? It is better to live than to die. What is the use? It is still cumbersome." Patient 11, Male, 61, Prostate cancer

Plans and unfulfilled wishes

Even though patients were diagnosed with advanced cancer with limited life expectations, some still had clear plans for a bright future.

"If the body gets better, I will start from scratch and pay the money I owe. Raise cattle, raise a few cattle... Make tens of thousands of yuan a year... The other is the child. She is not married; she is a girl at school. No adult. If you are an adult, don't you have to worry about it? Without a family, she is the only one in school and needs money. You must pay for her education." Patient 10, Female, 55, Rectal cancer

Discussion

The findings from this study highlighted the multidimensional ramifications of advanced cancer for patients and their families in China, identified five themes of symptoms, concerns and the priority outcomes for advanced cancer patients and family members and devised a model for person-centred advanced cancer care in China. Being an advanced cancer patient was seen as difficult, especially due to high physical and psychological symptoms throughout the disease trajectory. Professional behaviours, good attitudes and interpersonal skill of healthcare providers have been identified as beneficial to promote satisfaction and trustful relationship and these aspects of care are appreciated by the participants. Financial difficulties and sense of burdensome to families have become a major concern of patients. Advanced cancer patients developed coping strategies and made future despite encountering several practical challenges from cancer.

The patients and families we interviewed referred to the physical and emotional impact of advanced cancer and the disease process, which led many of them to experience pain, fatigue, anxiety, or depression. Pain and fatigue are distinctive characteristics of advanced cancer.(20) The physical change, resulting from surgery or loss of fat or hair is clinically considered the most recognisable sign of cancer. Participants were very aware of their appearance and described how cancer and its treatment continually reinforced its serious connotations in all domains of the patient's life. The results echo Body Image Dimensions which outlines how altered physical appearance can change a person's perception of 'self',

which in turn can impact socialisation patterns. (21, 22) Such findings reinforce the modern societal focus on appearance. Even when patients were physically able to engage in socialisation, they declined to do so because they were concerned about peoples' reaction to their cachectic appearance.(23)

Participants also alluded to how high health expenses impact patients' treatment and how they had to compromise their treatment due to the high cost. The cost of treatment is reported as a barrier in seeking treatment among cancer patients.(24) Although by achieving near-universal population coverage of health insurance, China has improved access to and use of health services and reduced the proportion of out-of-pocket spending, catastrophic health expenses for poor people are still high, disproportionately affecting deprived populations.(25) Systematic reviews showed that financial burdens are disproportionately impacting socioeconomically disadvantaged cancer patients and are associated with worse therapeutic adherence and quality of life.(24, 26) More effort should be made to identify vulnerable patients needing oncology provider engagement and response.(27)

Spirituality is an essential component of person-centredness and a critical factor in how cancer patients cope with their disease from diagnosis, treatment, survival, recurrence to dying and death.(28) However, it is noteworthy that only one of the participants reported some understanding that such alterations in appetite were expected consequences of cachexia in advanced cancer. This lack of insight might be due to Chinese cultural factors, which cultural factors take a vital role in the practice of medical issues.(29) However, some dying patients may know their health condition very well, even though they are kept uninformed. Some physicians preferred break bad news to dying patients, as they thought such disclosure might allow dying patients to complete unfinished wishes and manage the last days of their lives.(30, 31) Chinese cancer patients' attitude toward disclosure was associated with patients' disease stage considering fewer patients wanted to know their diagnosis during terminal stages than early stages of cancer.(32) Consequently, physicians are in a dilemma about whether terminal cancer information should be disclosed to dying patients.

There are long-lasting misunderstandings about palliative care in China among the public and healthcare professionals.(33) Some people believe receiving palliative care services is interpreted as giving up the treatment and wait to death, which is against cultural values.(34) Therefore healthcare professionals are pressured to provide curative treatment to advanced patients by the patient's families, which makes patients and families exposed to untenable anguish, and may lead to and exacerbate the financial burden for the patients and families and even accelerate the patients' death.

Implications

A growing body of evidence is now available to inform the key domains in the practice of cancer palliative care, including symptom management, psychosocial care, communication, decision-making, and end-of-life care.(35) Yet limited access to palliative care forced cancer patients and families to endure a tremendous burden of avoidable suffering in China. Staff training and capacity building would be essential to improve cancer care and palliative care for this vulnerable and neglected patients and families.

Patients have described the practical challenges induced by disease and treatment, including the lack of financial support, healthcare resources, medical insurance and working opportunities as cancer patients. Therefore, policymakers and organisational leaders should consider all these factors affected the multidimensional wellbeing of patients and families which would subsequently influence their quality of life.

Strength and Limitations

Our finding adds important new evidence of priority outcomes for advanced cancer patients and family members and devised a model for person-centred advanced cancer care in China. To our knowledge, few studies have explored the role and experiences of cancer patients qualitatively in China.(36, 37) In contrast to the greater attention paid to the experiences of patients living in western countries, who commonly report uncertainty about their future,(38, 39) our findings are consistent with those of several studies that have

examined the experiences of cancer patients,(40-42) or of patients with chronic disease.(43-45)

There were several limitations to consider. One of the limitations of this study is that it was carried out in a single specialist unit for cancer. Hence, our participants' experiences may not be generalisable to other centres. That said, our findings echo the international literature on the experiences of advanced cancer patients and caregivers of individuals with other similar diseases. Another limitation is the lack of a wider variety of participants: most participants interviewed were diagnosed with breast or lung cancer. Further research with more devised cancer type from multi-sites is needed to build upon our understanding of the experiences and needs of more representative patients.

Conclusion

This study advances the understanding of patients' and family members' experiences in the context of advanced cancer care in China, which offers unique insights into what matters to patients and families towards person centredness. It presents a novel multidimensional conceptual model of person-centred care, which reflects the priorities of patients and family members. This insight is a critical first step in delivering more person-centred care for patients with advanced cancer and family members in China. The study highlights the significance of patients' financial stability and trustful physician-patients relationship.

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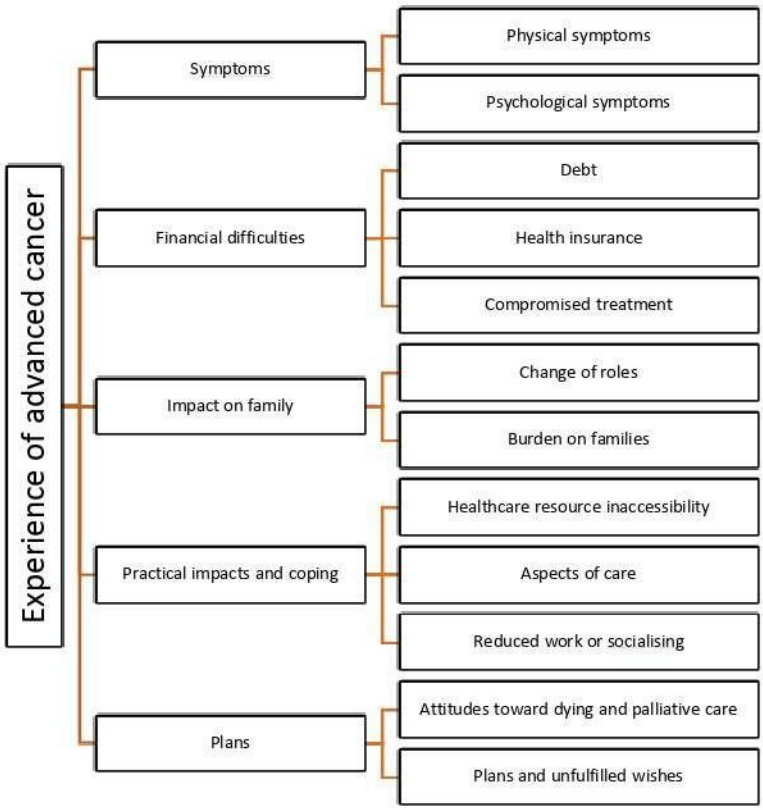

Figure 1. Themes and subthemes: living with advanced cancer in China

Appendix 16. Paper 2's comments from reviewer- major revision

Reviewers' comments:

Reviewer's Responses to Questions

Comments to the Author

1. Is the manuscript technically sound, and do the data support the conclusions?

The manuscript must describe a technically sound piece of scientific research with data that supports the conclusions. Experiments must have been conducted rigorously, with appropriate controls, replication, and sample sizes. The conclusions must be drawn appropriately based on the data presented.

Reviewer #1: Yes

Reviewer #2: Partly

2. Has the statistical analysis been performed appropriately and rigorously?

Reviewer #1: N/A

Reviewer #2: N/A

3. Have the authors made all data underlying the findings in their manuscript fully available?

The PLOS Data policy requires authors to make all data underlying the findings described in their manuscript fully available without restriction, with rare exception (please refer to the Data Availability Statement in the manuscript PDF file). The data should be provided as part of the manuscript or its supporting information, or deposited to a public repository. For example, in addition to summary statistics, the data points behind means, medians and variance measures should be available. If there are restrictions on publicly sharing data—e.g. participant privacy or use of data from a third party—those must be specified.

Reviewer #1: Yes

Reviewer #2: No

4. Is the manuscript presented in an intelligible fashion and written in standard English?

PLOS ONE does not copyedit accepted manuscripts, so the language in submitted articles must be clear, correct, and unambiguous. Any typographical or grammatical errors should be corrected at revision, so please note any specific errors here.

Reviewer #1: Yes

Reviewer #2: Yes

5. Review Comments to the Author

Please use the space provided to explain your answers to the questions above. You may also include additional comments for the author, including concerns about dual publication, research ethics, or publication ethics. (Please upload your review as an attachment if it exceeds 20,000 characters)

Reviewer #1: This paper identifies the concerns of patients with advanced cancer patients and their families living in Mainland China through qualitative interviews. Although I am not Chinese, I think the results are valid because they are consistent with what Chinese palliative care researchers have told me about this topic.

Although it is mentioned a little in Psychological symptoms, wasn't one of the main themes about future anti-cancer treatments? Today, there are various treatment options even for Stage III and IV patients. Especially, breast cancer patients are expected to survive for a long period even in Stage IV. The participants were those who have good performance status and can receive anticancer therapy.

Please emphasize the novelty. If there are really only two papers, it is understandable that the study itself has novelty. Really? What is the problem with cancer treatment in China that makes it different from the Western countries ? It is mentioned in the discussion, but it could be mentioned in "strength".

Wasn't one of the limitations that the participants were young compared to the average cancer patient?

Reviewer #2: Thank you for the opportunity to review this manuscript. It addresses an important area of palliative care practice in seeking to better understand the experiences and care needs of advanced cancer patients in China. However, I would recommend a major revision to address several methodological limitations as outlined in the following feedback:

Introduction
Paragraph 2 Sentence 1 – I suggest adding 'can' before "lead to significant distress".
Paragraph 2 – The authors communicate that "suffering is one of the primary concerns for patients at the terminal stage". Please define 'suffering' in this context to provide greater clarity. Similarly, the last sentence of this paragraph could be more clearly articulated – what 'wide range of problems' are attributed to suffering?
Paragraph 3 Sentence 1 – 'Preferences' appears twice so please delete one of them.
Paragraph 4 Sentence 1 – I suggest changing 'toward' to 'with' for clarity.
Paragraph 5 Sentence 1 – I suggest deleting the first 'cancer' so the sentence would read "In a recent qualitative systematic review of adult patients with cancer…"

Study Aims
There are a few aspects of the study aims which I would argue are not consistent with the data and main findings as communicated in this manuscript. Firstly, use of the term 'family' would be better replaced with the 'main family caregiver'. It is not entirely accurate to generalise these findings to the wider family. The study participants section within the methods refer to recruiting the 'main carer of a relative' and when I reviewed the topic guide for family members, the majority of questions referred to 'you' (the main carer) instead of encouraging participants to discuss the impact of symptoms and concerns on the wider family. Secondly, whilst this manuscript does communicate patient and carer experiences related to symptoms and care needs, a model of person-centred care for advanced cancer in China was not developed and I would argue there isn't a sufficient depth of data around experiences to be able to do this unfortunately. Instead, I would suggest the authors refer to the findings communicated in this manuscript as being able to contribute to and inform the development of person-centred care models.

Methods
The authors refer to reporting this work in accordance with the consolidated criteria for reporting qualitative research (COREQ) guidelines – Please submit a completed COREQ checklist as a supplementary file to communicate this.
Data collection – Paragraph 1 – Sentence 1 - I suggest changing 'pre-existed' to 'pre-existing' and adding 'with participants' after 'relationship.'
Data collection – Paragraph 2 – The term 'ideas for the future' is somewhat vague and I would suggest the authors consider an alternative term or phrase.
Analysis – Please provide a reference for the approach to framework analysis that was adopted. Framework analysis nicely lends itself to be able to analysis data both within a particular case/groups and across cases/groups. What was the authors' rationale for not analysing patient and main carer data separately to look for unique aspects of the cancer experience for each group of participants as well as

those themes that were identified across all data? If this wasn't done, it needs to be discussed as a limitation. It is important as, for example, pain is a highly subjective symptom and could be interpreted differently between the patient and their carer.

Results
The authors explain within the study participants section that patients and family members "did not have to match unless the family members expressed a strong willingness to participate", however, it is still important to clarify within the sample characteristics section if and how many of the patient and main carer participants were family/related. From table 1, it would seem they were related but a sentence to explicitly state this would be helpful to readers.
Qualitative findings – paragraph 1 – I suggest changing 'their' to 'participants' experiences.
Please re-consider how participants are referred to in the exemplar quotes. Providing so much information (age, cancer type, gender) could compromise the anonymity of participants. I suggest giving each participant a code and differentiating between whether they are a patient or carer (ie P1 – Patient; P5 Main Carer).
Throughout the qualitative findings section, I would encourage authors to provide further depth of analysis and interpretation of the data. I would also expect there to be some differentiation between issues unique to patients and carers as well as areas where there is a consistency and similarity in their care needs and experiences.
The topic guides referred to a section on seeking participants' comments on the Integrated Palliative Care Outcome Scale (IPOS). Could the authors please provide an explanation as to why this data was not reported?

Discussion
Paragraph 1 – Sentence 1/2 – Suggesting editing to "The findings from this study highlighted the multidimensional ramifications of advanced cancer for patients and their main family carer in China. Five themes of …"
As I explained earlier, this manuscript did not provide sufficient detail or depth of analysis to propose a model of care. It did communicate some of the experiences and perspectives of patients with advanced cancer in China which will be useful to inform future care.
Paragraph 4 – This paragraph does not make sense to me. It starts off by discussing spirituality yet the next sentence refers to cachexia? The link to spirituality needs further explained.
Implications – What does this study add to the evidence base? The authors started off in the introduction by suggesting that Chinese cultural beliefs may pose challenges in delivering patient-centred palliative and end of life care. I would have then expected this study to explore these cultural and spiritual issues in some depth but that wasn't the case. This needs to be communicated as a limitation – did patients and their carers not want to discuss this aspect of their cancer experience? If that is the case, this poses challenges for delivering palliative and end of life care that it aligned to principles of culture and spirituality that matter to Chinese patients.

6. PLOS authors have the option to publish the peer review history of their article (what does this mean?). If published, this will include your full peer review and any attached files.

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Reviewer #1: No

Reviewer #2: No

Appendix 17. Manuscript of paper 3

Translation and Cross-cultural Adaptation of the Chinese Version of Integrated Palliative care Outcome Scale: Expert Reviews and Cognitive Interviews

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Abstract

Background

Despite the burden of advanced cancer in China, there were no reliable and validated patient-reported outcome measures for use to measure the care needs and outcomes of patients with advanced cancers. The Integrated Palliative care Outcome Scale (IPOS) is a psychometrically sound and multidimensional measure that has been used worldwide for patients with advanced illnesses including cancer. This study aimed to translate and cross-culturally adapt IPOS to the Chinese context in advanced cancer care.

Methods

Chinese versions of IPOS Patient and IPOS Staff were translated and culturally adapted following the Rothrock guidance and the Palliative care Outcome Scale family of measures Manual for cross-cultural adaptation and psychometric validation. Five phases were included: (I) Conceptual definition; (II) Forward translation (translation from English to Chinese); (III) Backward translation (translation from Chinese to English); (IV) Expert review; (V) Cognitive debriefing.

Results

One new item was developed, and changes were made, agreed upon by the expert review meeting. The comprehension and judgement difficulties identified in the pre-final patient and staff versions were successfully solved during the cognitive interviewing process. IPOS was well accepted by both patients and staff, none of the items in the Chinese versions of IPOS were inappropriate, and all questions was judged relevant and important.

Conclusions

In this study, we translated and culturally adapted the patient and staff versions of IPOS and demonstrated content validity and acceptability of the scale through expert review and cognitive interviews with patients and staff.

Background

Patients with advanced cancer often experience complex symptoms and unmet needs varying according to cancer type, treatments an comorbidities.[1, 2] Cancer has become a leading cause of death in China, which is the most populous and rapidly aging country.[3] There were 4285033 new cases and 2865174 deaths recorded in 2018, with an increasing burden of cancer incidence and mortality observed over the past half century in China.[4-6] Despite significant improvement has been achieved in cancer care and palliative care provision and increasing funding on cancer registry and management, there is very limited evidence for outcomes of effectiveness of advanced cancer care in China, which is a common problem in counties where palliative care is absent, underdeveloped, and underfunded.[7, 8] Lack of appropriate and psychometrically sound outcome measures, logistical and methodological challenges in the setting and population are primary reasons for the dearth of evidence.[9]

The most commonly used palliative care outcome measures in China were quality of life questionnaires, which cannot capture all domains of palliative needs of advanced cancer patients and family members.[10] Furthermore, poor evidence of reliability and validity was found among the quality of life questionnaires in China due to unvalidated self-adapted instruments etc.[10] Systematic review found there is currently no patient reported outcome measure (PROM) with adequate psychometric proprieties for advanced cancer patients in China. The psychometric literature suggests that adaptation of existing measures that are appropriate for advanced cancer patients, address family and patient priorities, and contextually validated is the potential solution.[11-13]

The Integrated Palliative care Outcome Scale (IPOS; also referred to as the Integrated Patient care Outcome Scale) captures the full range of concerns prioritised by those with advanced illness themselves rather than only symptoms or overall quality of life, and developed specifically for use in advanced illness.[14] It is intended to provide multidimensional perspectives on a patient's situation, including physical, psychological, social, emotional, and spiritual concerns and information needs.[15]

The IPOS is comprised of ten items addressing patients' multidimensional concerns: symptoms, anxiety or low mood, family anxieties, overall feeling of being at peace, information needs, and practical concerns.[15] The first question is an open question concerning patients' main challenges. The second question is in the form of a list of 10 common symptoms and includes space for three free options of individual symptoms to be added if needed. The questions are scored using a 0–4 Likert scale, with numerical and descriptive labels. IPOS is available, in both a patient (self-report) and a staff (proxy rating) version (IPOS Patient and IPOS Staff, respectively) for reporting outcome measures. IPOS Patient version should be used when patients are able to answer the questions, while the staff version allow proxy report when the patient is unable to self-report.[16] IPOS Staff has one additional answer option, "cannot assess", and the 10th item, How did you complete this questionnaire? is excluded.[17] IPOS has been used widely in clinical practice and research, is validated, and has shown good responsiveness to change.[18-20] In order to expand clinical and research within palliative care in Chinese context, this study aims to translate and cross-culturally adapt IPOS to the Chinese advanced cancer care context.

Methods

Process of translation and adaptation of instruments were adapted for use for the translation.[21] Refinement of the original IPOS was undertaken following the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) taxonomy and guidance for relevance and comprehensiveness of PROMs to ensure content validity,[22-24] and Rothrock guidance on the development of valid PROMs in five phases (modified from the Rothrock guidance and The Palliative care Outcome Scale family of measures Manual for cross-cultural adaptation and psychometric validation):[25, 26] Phase I: Conceptual Definition; Phase II: Forward Translation (translation from the original English to Chinese); Phase III: Backward Translation (translation from Chinese to English); Phase IV: Expert Review; Phase V: Cognitive debriefing. The methods for each of these five phases are described below.

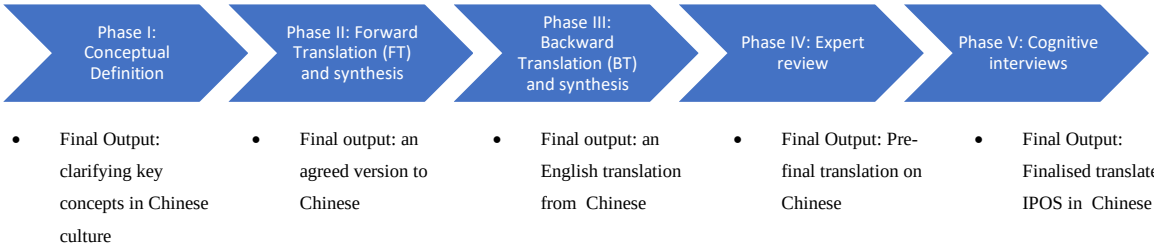

Figure 1. Overview of the phases in the translation and cultural adaptation process

Phase I: Conceptual Definition: In-depth Interviews with Patients and Families

The first stage of IPOS cross-cultural adaptation was to gather information from key stakeholders, to define concepts and construct a conceptual model to underpin the item refinement and establish the face and content validity of the new IPOS.[25, 27] This is important because the new IPOS need to reflect palliative care concepts appropriate and to avoid certain concepts are not recognised or meaningless in the Chinese culture.[28] Adhering to COSMIN guidance,[22-24] interviews were conducted with advanced cancer patients to explore experience, needs and priorities for people living with advanced cancer in China, as well as their brief opinions regarding the implement of IPOS. To ensure that the IPOS was relevant not only on patient level but also family level, main caregivers of advanced cancer patients were also interviewed regarding priorities from families' perspectives. 20 patients living with advanced cancer and 20 main caregivers of advanced cancer patients were recruited from Chaoyang Central Hospital, a large university affiliated teaching hospital in Northeast China, by research nurses. Interviews explored experience, needs and priority outcomes for people living with advanced cancer, as well as their perspectives of the implement of IPOS in China's clinical settings. Interviews were analysed using thematic analysis.[29, 30] Further details regarding the purposive sampling frame, inclusion and exclusion criteria, recruitment, conduct of the interviews and analysis, which formed the conceptual model will be published separately.

Phases II – III: Translation

The forward translation (phase II) was performed by two persons whose first language is Chinese and fluent in English, one with medical oncology and palliative care knowledge and

one naive in medicine. A third person, independent and naive in health care, acted as a mediator in a consensus discussion. This group generated a preliminary Chinese version of IPOS. The backward translation (phase III) was carried out by two persons whose first language is English and fluent in Chinese working independently. A third person, with knowledge of palliative care, was involved as mediator in consensus discussions. This group generated a back-translated version of the preliminary Chinese version of IPOS ready for expert review.

Phase IV: Expert review

Expert review was performed by researchers, oncology clinicians, nurses, and patient and public involvement (PPI) members from the UK and China. The meeting commenced with presentations in both English and Chinese providing an overview of IPOS, and their development and use in palliative care in research, teaching and clinic work. Following this, the findings from the in-depth interviews with patients and families were presented including themes and subthemes from the primary interview data to inform discussions of priority items for inclusion and potential missing items.

Discussion commenced with reviewing each item before moving into exploring priorities that were not emphasised in the original IPOS informed by the qualitative research findings, which led to new item generation. The following aspects of items were discussed and comments were raised: 1. Conceptual: degree to which a concept of the IPOS measure items exists in both cultures and the meaning is the same; 2. Semantic: sentence structure, colloquialisms or idioms which ensure the meaning of the text or idea of the items; 3. Experiential: items seeking to capture experience of daily life often vary in different countries and cultures; 4. Content equivalence: relevance or pertinence of the text or idea of the items in each culture.

The research team carefully reviewed the comments after the meeting. We agreed minor changes to wording for better comprehension should be made and restructure and reformat certain items were needed. At this stage, IPOS was finalised for cognitive interviews.

Phase V: Cognitive interviews

Cognitive interviewing or testing of a tool involves processes of 'think aloud' and 'verbal probing' to determine the acceptability and accessibility of the format and structure of a tool, interpretation of items, how responses are formulated, and whether any key concepts have been missed.[31] Registered nurses at an oncology ward recruited patients and staff based on the inclusion criteria, ask these individuals whether they are interested in participating, and provide an information sheet about the cognitive interviews. The contact details of those interested were passed on to and approached by the interviewer. Inclusion criteria for advanced cancer patients: 1. Diagnosed with advanced cancer (Stage III-IV), 2. Over 18 years of age, 3. Possess mental capacity to give informed consent as determined by the treating clinician, 4. Possess sufficient fluency in spoken Chinese. Inclusion criteria for staff: 1. Able to give the informed consent, 2. Available to participate in the study, 3. Have been caring for advanced cancer patients for at least six months or more. See Appendix 1 for topic guide of the cognitive interviews. Recruitment continued until thematic saturation was achieved and no new problems or concerns with the Chinese IPOS were emerging from subsequent interviews.

Interviews were audio recorded and comments captured by the researcher (HL). Each subject first completes the questionnaire and is then asked about their thoughts on what was meant by each item and their response. Both the meaning of the items and responses were explored. Cognitive interviewing or testing of a tool involved processes of 'think aloud' and 'verbal probing' to determine the acceptability and accessibility of the format and structure of a tool, interpretation of items, how responses are formulated, and whether any key concepts have been missed.

Interviews were analysed using inductive thematic analysis. All the questions and answers were checked in terms of wording, acceptability, ambiguous meaning, as well as format (including electronic or paper format) and layout issues. Any difficulties emerged during the filling of IPOS or in the discussion with participants were considered as a possible issue and code to be reviewed. The categories used to perform the analysis following:

comprehension, retrieval, judgement, response.[32, 33] All cognitive interview data of patient and staff participants were tabulated by item and participant, reviewed by the research team, and consensus reached regarding whether any change should be implemented.

Ethical approval

Ethical approval was attained from both Kings' College London (HR-20/21-12556) in the UK and the Chaoyang Central Hospital (Chaoyang Central Hospital Research Ethics Committees, approved on 8 October 2019) in China. Information sheets and consent forms were translated from English into Chinese. Participants gave written informed consent before the interview.

Results

Phase I: Conceptual Definition: In-depth Interviews with Patients and Families

Participants

Forty key stakeholders were recruited for in-depth qualitative interviews to inform the development and refinement of the IPOS: n=20 advanced cancer patients, n=20 family members. See Table 1 for participant characteristics.

Table 1. Participant characteristics. For patients (n=20) and family members

Variable	Patients		Family members	
	n	%	n	%
Age	Median 55.0	8.3, 36-75 (SD, range)	Median 41.0	SD, range 13.5, 24-72
Gender				
Male	8	40.0	11	55.0
Female	12	60.0	9	45.0

Marital status				
Single	0	0	4	20.0
Married	18	90.0	16	80.0
Divorced	1	5.0	0	0
Widowed	1	5.0	0	0
Education				
Primary school	4	20.0	1	5.0
Junior high school	11	55.0	8	40.0
High school	4	20.0	4	20.0
Undergraduate	1	5.0	6	30.0
Postgraduate	0	0	1	5.0
Employment Status				
Employed full-time	0	0	7	35.0
Employed part-time	0	0	2	10.0
Self-employed	1	5.0	7	35.0
Retired	7	35.0	1	5.0
Not employed	12	60.0	3	15.0
Participant’s relationship with patients				
Spouse	-	-	6	30.0
Child	-	-	14	70.0
Patient’s diagnosis				
Breast cancer	9	45.0	7	35.0
Lung cancer	4	20.0	6	30.0
Gastric cancer	1	5.0	2	10.0
Rectal cancer	2	10.0	1	5.0
Colon cancer	2	10.0	2	10.0
Prostate cancer	1	5.0	0	0
Sarcoma	1	5.0	0	0
Endometrial cancer	0	0	1	5.0
Hypopharyngeal cancer	0	0	1	5.0

Patient's stage				
III	6	30.0	6	30.0
IV	14	70.0	14	70.0
Patient's age at onset	Median	9.8, 30-75	Median	9.4, 42-74
	54.5	(SD, range)	59.0	(SD, range)
Time since diagnosis (years)				
< 1	12	60.0	12	60.0
≥1 & ≤5	3	15.0	4	20.0
> 5	5	25.0	4	20.0
Patient's KPS	Median	SD, range	Median	SD, range
	85.0	6.0, 70-90	80.0	7.6, 60-90
60	0		1	5.0
70	1	5.0	2	10.0
80	9	45.0	12	60.0
90	10	50.0	5	25.0

KPS: Karnofsky Performance Score

Analysis of in-depth qualitative interviews with patients and family members confirmed that original IPOS items mapped onto the main themes of identified need: (a) physical and psychological symptoms, (b) financial difficulties, (c) impacts on family, (d) practical impacts and coping, and (e) plans to the future.

Table 2. Mapping of priorities of participants identified from qualitative interviews and the original IPOS

Priorities of participants	**IPOS domains**	**IPOS items**
Physical and psychological symptoms	Physical symptoms	Q2. Below is a list of symptoms, which you may or may not have experienced. For each symptom, please tick one box that best

		describes how it has affected you over the past 3 days.
Physical and psychological symptoms	Emotional symptoms	Q3. Have you been feeling anxious or worried about your illness or treatment?
Physical and psychological symptoms	Emotional symptoms	Q4. Have any of your family or friends been anxious or worried about you?
Physical and psychological symptoms	Emotional symptoms	Q5. Have you been feeling depressed?
Physical and psychological symptoms	Emotional symptoms	Q6. Have you felt at peace?
Financial difficulties, practical impacts and coping, plans to the future	Communication /practical issues	Q7. Have you been able to share how you are feeling with your family or friends as much as you wanted?
Financial difficulties, practical impacts and coping, plans to the future	Communication /practical issues	Q8. Have you had as much information as you wanted?
Financial difficulties, practical impacts and coping, plans to the future	Communication /practical issues	Q9. Have any practical problems resulting from your illness been addressed? (such as financial or personal)
Impacts on family	--	--

However, "impacts on family" was identified as a core outcome which matters to the participants that was missing in the original IPOS. We decided to add a new item: ***Have you felt a burden to your family? / How much does the disease impact on your family?*** In addition, qualitative data indicated that practical problems, including financial difficulties,

had a great impact on overall life of participants, whereas original item 9 (***Have any practical problems resulting from your illness been addressed? (such as financial or personal***) was too generic and incomprehensible. Therefore, we decided to split item 9 into two questions: ***Have any financial problems resulting from your illness been addressed? (such as debt or lack of access to health care)*** and ***Have any practical problems resulting from your illness been addressed? (such as social disability or inability to work).***

Phase II and III – Translation

There were few obvious discrepancies in the forward translations. When the translators had chosen different terms, the options were discussed and negotiated. The main situations where this occurred were for the terms at peace (Q6); these have no equivalent terms in Chinese, and so the Chinese terms for calm/ quiet (平静) were chosen. The back-translations were compared, and no faulty or incorrect translations were discovered; only minor grammar discrepancies, which were adjusted.

Phase IV – Expert review

An expert group consists of six researchers experienced with PROMs, three oncologists, three nurses and two PPI members was organized. All members of the expert group agreed that the translations were generally clear and easy to understand. They agreed to add a new item regarding family burden and split the item 9 into two questions to improve clarification. Experts suggested item 1 was not clear that might mislead patients into thinking that this question is only about the patient's physical symptoms, rather than the main problems bothering them in their whole life (probably because the patient's inherent impression of PROMs, or the item 2 question which were physical problems on the same piece of paper interfering with the patient's understanding). We decided to add “in your whole life” in item 1, making it: ***What have been your main problems or concerns in your whole life over the past 3 days?***

Item 6 were considered confusing in Chinese context. Experts suggested participants would naturally assume this problem was about the overall psychological state, which should be

about spiritual wellbeing. After careful consideration of experts' suggestions, we decided to keep the current expression (calm/quiet, 平静) and gave several alternative expressions, such as "are you relaxed (放松)?" "Do you have a good mood (好心情)?" and leave this to be explored further in the cognitive interviews. Detailed comments from the expert review committee and how we addressed them were presented in Appendix 2. The expert group agreed on proposed Chinese versions of IPOS Patient and IPOS Staff are ready for cognitive interview.

Phase V: Cognitive interviews

Demographics of cognitive interviews

Interviews with six patients and six healthcare professional interviews (12-25 min long) were completed between March and April 2021. The mean age was 33.5 years in healthcare professional group (range 28–40 years) and 57 years in patient group (range 47–68 years). In healthcare professional group, 6/6 and in the patient group, 1/6 participants were female. Two patients had stage III while four patients had stage IV cancer. All participants were in-patients with disease duration of several months to 13 years. Details of each group are shown in the Table 2 and Table 3.

Table 3 Demographic of healthcare professional participants of cognitive interviews

No.	Gender	Age	Marital Status	Education	Profession	Duration of working
S-C-1	Female	35	Married	UG	Nurse	10
S-C-2	Female	35	Married	UG	Nurse	14
S-C-3	Female	40	Married	PG	Physician	16
S-C-4	Female	33	Married	PG	Physician	4
S-C-5	Female	28	Married	UG	Nurse	5
S-C-6	Female	30	Married	UG	Nurse	6

Table 4 Demographic of patient participants of cognitive interviews

Education

No.	Gender	Age	Marital Status	Employment Status		Diagnosis	Stage	Age at onset	Disease duration (years)	Patient's KPS
P-C-1	Female	47	Married	Not employed	Junior High School	Lung cancer	IV	34	13	80
P-C-2	Male	61	Married	Not employed	Junior High School	Gastric cancer	IV	59	2	90
P-C-3	Male	51	Married	Not employed	Junior High School	Lung cancer	III	50	< 1	90
P-C-4	Male	68	Married	Retired	UG	Colon cancer	III	67	1	80
P-C-5	Male	54	Married	Not employed	Junior High School	Gastric cancer	IV	53	< 1	80
P-C-6	Male	61	Married	Retired	UG	Gastric cancer	IV	60	< 1	80

Findings from cognitive interviews

The interviews in both groups demonstrated that for the majority of participants, most questions and answer options worked well. The identified difficulties were mainly comprehension problems. No problems were identified with retrieval or response formulation. See Appendix 3 for selected quotations from the cognitive interviews.

Patients were certain about their main problems and concerns (Item 1), and many described these as the things that are always on your mind. Positive comments about the symptom list in question 2 included the following: *This (item 1) includes all aspects, not just having disease, but also other trivial things in my daily life… They are easy to understand. These are basically routine questions, which are directly related to patients.* (Male, aged 61 years,

gastric cancer) *These questions have good generality. They are straightforward, easy to understand and answer.* (Male, aged 68 years, colon cancer)

Physical symptoms such as 'Pain', 'shortness of breath', 'nausea', 'poor appetite' and 'constipation' listed in item 2 were well understood by all participants. Comprehension of item 3 (anxiety/worries) was also good for all participants. Some comprehension problems were identified. For example, difficulties arose with the wording of specific questions. The term 'drowsiness' in question 2 was regarded as not plain language, and in contrast to the intent of the question, many patients misunderstand the word when answering it. We decided to use **sleepiness (昏昏欲睡)** to replace drowsiness. As for item 6, most participants preferred **calm/quiet (平静)** to express the meaning of "feel at peace".

Finally, format of questionnaire was asked. Most participants preferred to use paper format. *I like to put it on paper. As for people at my age, it's very convenient to use paper. I'm not familiar with tablets or mobile phones. However, along with the development and requirements of society, it is convenient and easy to store data in computers.* (Male, aged 68 years, colon cancer)

The final Chinese IPOS of patient version (see Appendix 4) and staff version (see Appendix 5) were really for further psychometric testing.

Discussion

In this study, we translated and culturally adapted IPOS Patient and IPOS Staff into Chinese and demonstrated face and content validity and acceptability of the scale through expert review and cognitive interviews with patients and staff. There were certain concepts where a direct translation from English to Chinese became misleading and in need of cultural adaptation. One new item was developed, and charges were made, agreed by the expert review meeting. The comprehension and judgement difficulties identified in the pre-final patient and staff versions were successfully solved during the cognitive interviewing process. The Chinese translation of IPOS has thus been shown to be acceptable for both

patients and staff. None of the items were considered inappropriate, and all questions were judged relevant and important.

Table 5. COSMIN criteria and rating system for evaluating the content validity of PROMs

Criteria	Assessment
Relevance	
Are the included items relevant for the construct of interest?	✓
Are the included items relevant for the target population of interest?	✓
Are the included items relevant for the context of use of interest?	✓
Are the response options appropriate?	✓
Is the recall period appropriate?	✓
Comprehensiveness	
Are all key concepts included?	✓
Comprehensibility	
Are the PROM instructions understood by the population of interest as intended?	✓
Are the PROM items and response options understood by the population of interest as intended?	✓
Are the PROM items appropriately worded?	✓
Do the response options match the questions?	✓

We assessed the IPOS against the COSMIN criteria for evaluating the content validity of PROMs, providing supporting evidence for the relevance, comprehensiveness and comprehensibility (content validity) of the Chinese IPOS.[1] (See Table 5) Importantly, the translation and cultural adaptation of the Chinese IPOS was achieved through the contribution of researchers, patients, families and healthcare professionals. Involving key stakeholders can potentially fit with broader sense of cancer care and palliative care, inform service evaluation, development and implementation and complement existing services and approaches.[2] It means the measure reflects the priorities of key stakeholders which established a sound face and content validity of the Chinese IPOS and improving this utility in routine clinical practice and research.[3]

The main problems with comprehension in the process of cross-cultural adaptation of IPOS involved finding an appropriate Chinese term for “at peace”, which in common issues reported worldwide.[4-6] The replacement terms (relaxed or in good mood) tested were understood as meaning satisfying/ comforting emotionally, and hence neither appropriate nor equivalent. The intention of the question is to measure spiritual wellbeing. The similar challenges of translation of “at peace” were identified in other languages/cultures. For example, Italian “feeling at peace” was confused with “not at war” or “only the dead are at peace”.[7] Beck et al. reported there was no equivalent terms so “satisfied” was chosen in Swedish.[8] In the Chinese version, we eventually found that both patients and staff considered the term for calm and quiet within themselves to be a suitable expression for feeling at peace in terms of spiritual wellbeing, without excluding either those that practice religion or those who do not.

Another problem with comprehension was identified for drowsiness since this was not seen as a feel asleep at daytime. Some patients confused this with “cannot sleep” as drowsiness is an academic word which causes misunderstand. Similarly, Laissaar et al. described disagreement in the translation of “drowsiness” in Estonian.[5] We changed it to plain language in the pre-final version. There were also inconsistencies related to the Chinese term for addressed in the question about practical problems (Q9). Both patients and staff considered this question to be an important one, which should allow participants having more opportunity to discuss it. The pre-final version included two items regarding participants’ financial issues and personal issues.

The need for person-centredness, focusing on what core outcome matters to people living with advanced cancer, has long been recognised.[9] However, to date there was no validated PROM that reflected the breadth of concerns for people living with advanced cancer in China.[10] Integrating the IPOS into routine cancer care and palliative care will support patients and family members to set their priorities, actively involve them in decision making, facilitate communication with healthcare professionals and improve quality of care.[11, 12]

IPOS measures core outcomes for patients in need of holistic palliative care.[13] Highlighting these questions is because non-physical aspects are easily neglected while physical symptoms are prioritized in advanced cancer patients, and so these areas are considered to be essential for both patients and staff.[14] It is crucial for a holistic palliative care to use measures that include multiple dimensions beyond physical symptoms, to ensure that other concerns are acknowledged and addressed.[15, 16] The next step, to further contribute to increased knowledge about outcomes within palliative care, is to psychometrically validate Chinese IPOS of patient and staff versions.

Strengths and limitations

The translation and cultural adaptation of the Chinese IPOS, a brief, comprehensive tool for use within palliative care, represents a significant step towards a person-centred approach in China. A major strength of this study is the methodological rigour with which it was undertaken, with transparent reporting of the PROM development process following both COSMIN and Rothrock guidance. Many reports of PROM development fail to describe the processes of item generation or cross-cultural adaptation in detail. Another strength is the meaningful engagement of patients and families (PPI members in expert review meeting phase) throughout this study.

Although we worked to ensure that the participants in the in-depth qualitative interviews and cognitive interviews represented the diversity of participants, there was underrepresentation of patients with low level of activity with high medical care requirements (low KPS), which could possibly lead to doubtful content validity of the Chinese IPOS when using it with seriously ill patients. Further exploration of priorities of critical conditions should be performed in the future.

Future perspectives

Next steps for the validation of the IPOS will include be completion of psychometric test to establish reliability, validity and responsiveness. Consideration will also be given at the time to the scoring system and any modifications to further consolidate IPOS that may be

required. In addition, further work to promote the implementation of Chinese IPOS in research and clinical practical practice within and beyond advanced cancer patients is required to broaden its use across the country. The remaining steps of validation have been undertaken at two sites in China (manuscript in preparation).

Conclusions

In this study, we translated and culturally adapted IPOS Patient and Staff versions into Chinese. Chinese IPOS is a brief outcome measure that reflects the breadth of symptoms and needs, concerns and practical issues experienced by people living with advanced cancer, translated and culturally adapted in accordance with recognised international methodological guidance. Informed by the priorities of key stakeholders captured with in-depth qualitative interviews, the Chinese IPOS has supporting evidence for face and content validity and high levels of acceptability following initial cognitive testing which reflects the range of multidimensional outcomes matters to people living with advanced cancer to drive and evaluate their care. The next step for the validation of the Chinese IPOS will be psychometric testing to establish reliability, validity and responsiveness.

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Appendix 1

Topic guide: Integrated Palliative care Outcome Scale (IPOS) Cognitive Interview

Objective:

To explore the cognitive processes used by respondents when reading, interpreting and responding to items on the IPOS questionnaire

Introduction:

- Study purpose, confidentiality, able to stop at any time, decline questions

- I'm going to show you a questionnaire and I want you to read & answer the questions one at a time
- We will stop and talk about each question before moving onto the next
- Please try to 'think out loud' as you read and answer the questions (DEMONSTRATE)
- I will also ask you some more specific things about each question

- Apologies of the questions get repetitive

- In this study we are less interested in your answers to the questions, but how you arrive at the answers – what you think the question means, and the things you were thinking about when you chose your answer.

- You can tell me any thoughts or views you might have about the questions

---------- START RECORDING ----------

General:

- What were you thinking about when you answered that question?

- I noticed you hesitated before giving your answer – what were you thinking about then?

Comprehension: **What does the respondent believe the question to be asking?**

- What does the question mean to you, in your own words?

- What does the word XXXXXX mean to you? (if certain words are thought to be problematic)

- How easy or difficult was it to understand this question?

- (If problem) How would you change this question?

Retrieval: **Could they recall the information required by the question? Was the time frame suitable?**

- How well could you remember your experience when answering this question?

- Was it easy or difficult to think about the past [week] when answering this question?

- Would there be a different time period that would be easier to understand?

Judgement: **Is the respondent able to make an evaluation based on the information recalled?**

- What were you thinking about when you answered this question?

- How did you arrive at your answer to that question?

- Was that easy or hard to arrive at your answer? Why do you say that?
- How sure are you of the answer to this question?

Response: Is the respondent able to map their internally generated answer to a response option?

- How did you choose your answer to this question?
- Was it hard or easy to select an answer from the options given?
- Did all options make sense for this question?

Other:

- Is there anything else you would like to say about this question? / The questionnaire as a whole?
- Did you find any of the questions upsetting? / embarrassing? / inappropriate?
- Are there any topics/questions that you would leave out of this questionnaire?

- Are there any topics/questions that you would add to this questionnaire?

- Do you have any thoughts about the way your answers were captured? (i.e. tablet/paper)

---------- THANKS + STOP RECORDING ----------

---------- COMPLETION OF DEMOGRAPHICS FORM ----------

Appendix 2

Table 1. Comments from the expert review committee and actions to address them

General comments	1.Any refinement/ adding/ remove of items should match the options of the original IPOS. 2.While being consistent to the original IPOS, we should pay attention to the Chinese culture and language habits based on faithfulness, expressiveness and elegance.	
Q1. What have been your main problems or concerns over the past 3 days?	Experts agreed that open questions are necessary. They thought expression of Q1 is not clear, which may mislead patients into thinking that this question is only about the patient's physical symptoms, rather than the main problems bothering them in their whole life (probably because the patient's inherent impression of PROMs, or the Q2 question on the same piece of paper interfering with the patient's understanding, etc.). Suggestions: Add an explanation in Q1 to help patients understand that this is about the main problem or concern in their whole life.	**Action 1 – add a phrase to Q1: "in your whole life"** **Revised Q1: What have been your main problems or concerns in your whole life over the past 3 days?**

Q2. Below is a list of symptoms, which you may or may not have experienced. For each symptom, please tick one box that best describes how it has affected you over the past 3 days.	Experts' discussion mainly focused on: (1) whether the order of symptoms listed should be ranked according to the degree of the impact of symptoms on the quality of life, or just keep the original order. (2) Nausea and vomiting are difficult to distinguish when asking patients clinically. Whether to consider the combination of nausea and vomiting into one item? Suggestions: (3) Keep the original order unchanged. The adjustment order will not have much significance in clinical use, as long as the symptoms are listed, the patients can clearly check according to their own situation. (4) Although nausea and vomiting are easily confused in clinical consultation by patients, patients can still understand in writing that these two words are different concepts. Experts believed that more importantly, there are essential differences between the clinical significance and treatment methods of nausea and vomiting. For example, vomiting can bring serious electrolyte disorder, while nausea cannot. Therefore, keep both two items: nausea and vomiting unchanged.	**Action 2 – Keep Q2 as original IPOS unchanged**

Please list any other symptoms not mentioned above, and tick one box to show how they have affected you over the past 3 days.	Experts thought it's good to set up an open question here. The expression in the Chinese version is appropriate.	
Q3. Have you been feeling anxious or worried about your illness or treatment?	The expression in the Chinese version is appropriate.	
Q4. Have any of your family or friends been anxious or worried about you?	The expression in the Chinese version is appropriate.	
Q5. Have you been feeling depressed?	Experts discussed that in the context of Chinese, the meanings of Q5 and Q6 are	**Action 3 – Keep Q5 as original IPOS unchanged**

Q6. Have you felt at peace?	repetitive to some content. For Q5, the question should be about the emotional/ psychological/ spiritual level of the patient. Q6 should be about patients' mentality/ mood/ spirituality. In the Chinese context, it is good and clear to use Q5 to explore patients' mood. But for the patients' mentality / mood / spirituality, there is less attention in Chinese culture. Patients would naturally assume the problem is to ask the overall psychological state. Suggestions: (1) Keep Q5 as original IPOS unchanged (2) As for Q6, keep the current wording in Chinese version. List several alternative questions, such as "Are you relaxed?" "Do you have a good mood?" In the cognitive interview, ask participants how do they understand these questions.	**Action 4 – Keep Q5 as original IPOS unchanged. As for Q6, keep the current expression in Chinese version. At the same time, list several alternative questions, such as "are you relaxed?" "Do you have a good mood?"** **In the cognitive interview, ask participants how do they understand these expressions.**
Q7. Have you been able to share how you are feeling with your family or friends as much as you wanted?	Experts thought that although Q7 has gone through the standardised process of forward and backward translation, it is still not accurate and does not reflect the concept "SHARE" which the question intend to capture.	**Action 5 –** **Revised Q7: Can you fully share your feelings with your family or friends?**

Q8. Have you had as much information as you wanted?	Experts thought it is important to consistent to the original IPOS. We cannot express the question as "do you know your condition?" or “What kind of information do you want?” In the current Chinese version, the meaning of "as much as you want" is not shown, so it is suggested to add the word "sufficient".	**Action 6 – add a word to Q8: "sufficient"** **Revised Q8: Have you had sufficient information?**
Q9. Have any practical problems resulting from your illness been addressed? (such as financial or personal)	Experts thought that the "practical problem" has a great impact on the overall life of patients. Q9 is too wide-ranging, and it will make it difficult for patients to understand what practical problems are. Suggestions: (4) Split Q9 into two parts, one is about financial problems, the other is about personal problems. (5) Give patients some tips, such as financial problems, including debt problems, medical insurance problems, etc. (6) In the cognitive interview, ask participants how to understand these questions, and know how to further optimise the items.	**Action 7–** **Split Q9 into two questions.** **" Have any financial problems resulting from your illness been addressed? (such as debt or lack of access to health care) "** **and** **"Have any practical problems resulting from your illness been addressed? (such as social disability or inability to work) "** **And in the subsequent cognitive interview, ask participants how to understand these questions.**
Q10. How did you complete this questionnaire?	The expression in the Chinese version is appropriate.	

Add a new item?	Experts agreed that family burden has a great impact on the overall needs of patients according to the qualitative data and the characteristics of Chinese culture. Adding a new item related to family burden is suggested. Considering the comparability of the Chinese version of IPOS with other languages, we could consider putting the newly added question before the last one.	**Action 8–** **Add items:** **Have you felt a burden to your family?** **/How much does the disease impact on your family?** **And in the subsequent cognitive interview, ask participants how to understand these questions.**

Appendix 3

Table 2 Selected quotations from cognitive interviews with patients and staff

Item	Quotations in English (translated)
1	<PATIENT-1> I think it (item 1) is about the patient's personal life or financial problems, or what they worry about in the hospital. As for myself, I think that financial hardship is the biggest issue. <PATIENT-4> I'm not worried about the disease a lot. It seemed to be horrifying in the past few years, and the cure rate is not ideal. Many people get cancer. Now, I found the cure rate is relatively high. I'm a little worried that I won't be cured, but I still have confidence. This is how I felt when I got sick. I'm afraid that I won't be fixed. <PATIENT-5> I always thought about income, and money for medication. I was distraught and panicked. But I got a lot of healthcare reimbursement afterwards. <PATIENT-6> This includes all aspects, not just having disease, but also other trivial things in my daily life. For example, in a family, children and immediate family members' attitude and concern influence your life. Impacts are multifaceted, which also including environmental factors. Some environment is not good. Even people around may impact the disease. <STAFF-1> (Item 1) is about how are you doing in your daily life. It's also about psychological impacts, right? Some trivial things in life also count. There is a phrase "in every aspect of your life" in this question. Can you be more specific, such as work and so on? I find that every aspect of your life is too general and there are no details. Can you refine the item by listing some examples which could give more details? <STAFF-2> (Item 1) maybe about medication, diet, eating, drinking, sleeping, the effectiveness of the drug, finance, etc. <STAFF-3> After diagnosed, the patient's mind focuses on the disease. They would keep thinking about cancer, and all his behaviours would be related to the disease, such as diet. <STAFF-4> I think it's about daily life, such as some activities after getting up, including cleaning, cooking, going out for a walk or having everyday conversations.
2	<PATIENT-2> Interviewee: what is this? Interviewer: drowsiness. Interviewee: what does drowsiness mean? <PATIENT-4> Interviewee: Drowsiness is mild. Interviewer: How did you feel? Interviewee: It means almost no sleep. My sleep is very light. Usually 6-7 hours in a day. Interviewer: how do you understand the word drowsiness? Interviewee: I don't understand it well. <PATIENT-5> Interviewer: how do you understand the word drowsiness? Interviewee: my understanding is I am able to fall asleep. <STAFF-1> Interviewer: How would you change this drowsiness item? Interviewee: sleep condition.

	Interviewer: Do you find drowsiness or insomnia a common symptom (in cancer patients)? Interviewee: insomnia is common. I think it is better to change this into insomnia. Many patients in the oncology department do have insomnia. <STAFF-2> Interviewer: how do you understand the word drowsiness? Interviewee: always sleeping, but I can wake the patient up. Interviewer: I interviewed some patients a few days ago. Some thought that drowsiness and insomnia had the same meaning. They can't be distinguished. Interviewee: "Drowsiness" is not commonly used in daily life. I think it is academic language. Interviewer: what would you say in plain language? Interviewee: do you sleep more or less? From my point of view, I don't think we need to change it. If we ask patients to fill in the scale, we can explain it to them. Or we can add a bracket to clarify it means sleep longer than usual during the day. Interviewer: Which way do you prefer to ask this question? Interviewee: I think it's enough to explain it when I send out the scale. <STAFF-3> Interviewee: drowsiness, as we have learned to define it, means feeling abnormally sleepy during the day and can be weakened up and communicate normally. Interviewer: I interviewed six patients a few days ago. Some thought that drowsiness means not sleeping, which is the same as insomnia. Interviewee: So, from the patient's perspective, they might not be able to understand what drowsiness is. Interviewer: what would you ask in your own words? Interviewee: I would ask if your sleep were disturbed. Some people sleep more, but in fact, some people less. They sleep even worse because of the disease's pressure and side effects due to chemotherapy. <STAFF-4> Interviewee: shortness of breath, to what degree? I think "shortness of breath" gives me a sense that the symptom is severe. When you feel shortness of breath, it feels like you cannot breathe at all. Most people may just feel a little panting, not in such a very urgent situation. Interviewer: what do you think of the word sleepiness? Is it easy to understand? Interviewee: drowsiness is easy to understand because we are healthcare workers. We can understand the meaning of drowsiness. However, some patients may not understand it. When we make rounds, we may ask them how they sleep. Some patients may say that they can't sleep at night. Interviewer: do you think it's better to change the words? Interviewee: more sleep? Some people may not understand "drowsiness" as a medical term. I think "more sleep" is understandable. <STAFF-5> Interviewer: what do patients say if they sleep more than usual? Interviewee: patients would say that they are sleepy all day. Patients who take anti-allergy medications before chemotherapy would say that they can't wake up all days. <STAFF-6> increased sleep? we can say mild increase, moderate increase, severe increase.
3	<PATIENT-1> I'm worried that I won't be cured. I'm afraid that I'll run out of my money and I won't be cured. I have to go that step (die) in the end—cancer patients like me (would definitely choose) most of the time or always. <PATIENT-3> No, because I felt that the effect was very significant after the second chemotherapy. <STAFF-5> When you talk with him, you will find that he is not satisfied with his care workers. I felt that he was in an anxious and irritable mood.
4	<PATIENT-1>

	Yes, especially with my mother, husband, children, immediate family, and friends. They definitely feel worried for me. They always chat with me to help me to have a good attitude to face the disease. <PATIENT-3> Occasionally worry. My families are very anxious, to be honest. They are distraught as I have cancer. <PATIENT-4> My choice is "always". I feel that my relatives and friends are worried about me all the time. <PATIENT-6> They all have (been anxious or worried about me), but I don't think they worry a lot. Now I have a good recovery. I was a little concerned at the beginning (of the treatment), but now I have to face it. <STAFF-5> His family rarely visited after hiring a care worker. If the patient lacks company, I think he will feel that his families don't care about him.
5	<PATIENT-2> It's impossible not to be depressed. My mood before and after getting sick is definitely different. Anyway, I have to relax. It is not good to worry about it all the time. <PATIENT-3> Yes, sometimes. When I have nothing to do, I would think about why I got cancer at a young age. I'm only 51 years old, right? I definitely feel depressed. <PATIENT-6> Occasionally depressed, but not severe. Anyway, I have to face it seriously.
6	<PATIENT-2> I would say, "are you relaxed? "It's plain language. <PATIENT-3> If I would say, "are you in a good mood? "I am not educated, but the most common way is to ask your mentality, right? <PATIENT-4> My understanding of this problem is that you will feel at peace if you are not feeling burdensome or worried. I choose "occasionally", which means to worry occasionally, but I feel at peace most of the time. If you have a good attitude, you will be happy. If you have a bad attitude, you will be unhappy. <PATIENT-5> This means always be happy and not think of the disease. Be happy and stay calm. Relax your mind and don't think about bad things. <PATIENT-6> (Peace means) not take it (cancer) too seriously, and don't take it as a mental pressure. If you worry and think about it every day, you still have to face it. So, I practice calligraphy now. When I'm tired, I will sleep for a while without thinking about my disease. <STAFF-3> My understanding of "peace" is not to have mental ups and downs. Peace is not the same as relaxation. It just means that you can accept things for the moment, but it can't be pleasant. <STAFF-4> Peace of mind means to accept the reality, and not to be in a very low mood. I think “have you felt at peace” is a good statement.
7	<PATIENT-1> Yes, I love to talk. My voice is not pleasant because my lungs and lymph nodes oppress the vocal cords. I chatted and shared with cancer patients like me at home and in the hospital regardless I know them before. <PATIENT-3> Occasionally. I talk with my family about the disease. <STAFF-3>

	Some patients have good communication with doctors. Doctors in my department may have done a great job. Anyway, patients always want to communicate with us about their discomfort and concerns. <STAFF-5> His family and friends didn't often visit because of the pandemic. He has been hospitalised and unable to communicate. I seldom hear patients have video calls. Care workers are taking care of him. Their families ask their subordinates to visit. It's hard for him to share.
8	<PATIENT-1> Occasionally, for example, when the examination results come out, I never see them. My responsibility is to cooperate with the doctor. My husband and doctors will see the results, while I don't want to see them. <PATIENT-3> Occasionally. I overhear something. Doctors always discuss things with my families. And they don't tell me basically. Most of them keep it from me, and I don't ask them. Cancer is not like headaches or colds. Families do not tell me, and I do not want to ask either. Anyway, I feel that the effect of these two chemotherapies is quite remarkable. <STAFF-3> It's intuitive to think whether the doctor told me everything. But if we think about it carefully, more information such as information on the Internet would come to my mind. <STAFF-6> It's mainly about asking the patients about the things related to disease and treatment. For example, understanding what chemotherapy drugs are used and side effects are is comprehensive information that patients want.
New Family item	<PATIENT-1> I personally find it's very clear to use the word "burden" because it's a real problem. I've borrowed a lot of money, which will definitely cause a burden. Sometimes my partner says, "everyone else has a car, and we can't afford it.". Then I would think that I spent all the money and couldn't afford anything. This made me feel like a burden to my family. Sometimes I feel bad, but my husband is in a bad mood too. Interviewer: do you think this question is important? Interviewee: it's important. I think it's crucial. My child just started to work. I don't have enough money to spend so I can't support him. When he gets married, I can't buy him an apartment. I feel that the burden is really heavy. <PATIENT-3> I think "burden" is reasonable. I feel that there is still a significant burden. I can't get much reimbursement (from medical insurance). Besides, children have to take care of me. Isn't it burdensome? The "burden" is a more unambiguous statement. <PATIENT-4> The term "impact on the family" is appropriate. Because an "impact" is enough to cover all my family's circumstances, including impact on finance and work. Everything in my family will be affected in the future. <PATIENT-5> I think "burden" is more appropriate. It must be a burden to pay for treatment when you are sick. Once you have no income, the family must have a heavy burden. <PATIENT-6> This does not affect me for the moment. My wife has a salary. My daughter and her husband earn a lot, and I earn a lot. This is not a problem for me. But it depends on specific situations. Those who come from rural area must have a heavy burden. I have no burden, no matter how much money I spend. <STAFF-1> "Burden" is more appropriate. It is general and intuitive. <STAFF-4> "Burden" is more appropriate and easier to understand. Because ("burden" is the word we would use when) we chat, most people know the meaning of burden, which is easy to understand. <STAFF-5>

	"A burden on the family" is more appropriate. It's intuitive and easy to understand. <STAFF-6> "Burden" is easier to understand. Because I think it is simple and straight. Patients have a more intuitive feeling after reading it.
9	<PATIENT-1> It's better to split it into two questions. It will be easier to answer and understand. I chose "not addressed". My financial issues are not addressed. In terms of work, I can't do anything considering my physical condition now. When I go downstairs for a walk, It's fine when I walk, but it's too hard to go up to the sixth floor. I was better last year. Now my physical strength is too weak. <PATIENT-3> It's more comprehensive to ask one question. Both financial and social issues are included. <PATIENT-4> It's right to split it into financial and personal problems. Personal problems include whether you can work and what you can do. It is different from your financial situation. Split to make it understandable and easy to answer. <PATIENT-5> It's better to split it into two questions. I can't solve my working problem. I lost my job after I was sick, so my financial situation will definitely be affected. But in terms of medical insurance, the country has solved it well. Now the medical insurance in this country is standardised. <PATIENT-6> This needs to be split into two questions. These are two aspects, really. <STAFF-1> It is good to ask one single question. I don't feel good talking about debt directly, which might cause psychological pressure on patients and make them feel depressed. Because patients in the oncology department are always in debt, they are more pessimistic when admitted. <STAFF-3> It's more appropriate to split it into two questions. If you ask in one single question, the question is too big. It's hard to answer big questions. When it's not easy to respond, the patient will not think through. They may choose an option randomly. The answer will be not accurate. The more direct the problem, the better. <STAFF-4> I think these two aspects are different. <STAFF-5> It's better to split it into two questions. I think it's more detailed. <STAFF-6> I think these are two independent issues. One is social problems, and the other is debt. I think it's two aspects. So, I think it should be taken apart. When I read it (the original problem), I had doubts about how to choose.
10	<PATIENT-1> This item is very clear. <PATIENT-5> It was completed by myself. This question is easy to understand and answer.
General comments	
Comprehension	<PATIENT-4> These questions have good generality. They are straightforward, easy to understand and answer. <PATIENT-6> They are easy to understand. These are basically routine questions, which are directly related to patients.
Recall	<PATIENT-2> Three or seven days is appropriate. If you can't think back on the past seven days, your mental capacity is too bad.

	<PATIENT-3> I am clear about what happened over the past seven days as I am always in hospitalisation. I don't think there is much difference between seven days and three days. I can't forget (how I felt). <STAFF-4> It's easy to recall the past seven or three days.
Paper / Tablet format	<PATIENT-1> I think the paper format is better. Let alone the elderly, sometimes I can't even understand tablets and mobile phones. It's not convenient for the elderly. They don't use mobile phones well and surf the Internet. It's inconvenient for them, so it's better to use paper format. <PATIENT-2> It depends on the level of education. I don't know how to use a tablet or a mobile phone. I use a phone designed for the elderly. I am an old people who come from the old era. It's more convenient to take the paper up and read it, which is more convenient. <PATIENT-3> Mobile phone format. Mobile phones are common now. It is good to fill in the blanks on mobile phones, tick the right ones and cross the wrong ones. I think it's convenient to use mobile phones. <PATIENT-4> I like to put it on paper. As for people at my age, it's very convenient to use paper. I'm not familiar with tablets or mobile phones. However, along with the development and requirements of society, it is convenient and easy to store data in computers. <PATIENT-5> I won't use mobile phones or computers. I have to use paper questionnaires. <PATIENT-6> Paper format. Some people are old and can't understand the computer. It's hard for them to use tablets or mobile phones. I met two people (in the hospital) who come from rural areas, and (scales of another research project) were all filled in by their children. <STAFF-1> I think we should keep both formats. Because the patients are old, some of them don't use mobile phones at all. But for young patients, it's entirely possible to use mobile phones. <STAFF-2> I think the paper format is suitable. It's convenient to read. Because some people use phones designed for elderly. If you put it on smartphones, I don't think they can read it. The font size on mobile phones is small. The font size on the papers can be bigger and easier to read. <STAFF-3> I like paper. Usually, I enjoy reading on papers while I don't want to read on electronic screens. When I read the paper version of the questionnaire, I feel that I will be more serious. Because I am using my mobile phone every day, I feel a little numb when I fill in scales through my mobile phone and not take it seriously. <STAFF-4> I think the paper format is more suitable. Because there are some old patients, they don't use mobile phones. They don't have smartphones. For example, suppose you want patients to be added to a WeChat group to contact us at any time, in this case, they will possibly say they cannot because they do not have a smartphone. I think the paper version is better. Most people are literate. <STAFF-5> Both tablet and paper. Now, most people like to use mobile phones. It's very convenient to read on mobile phones and tablets. Even if there are only a few items in the IPOS and it is clear, some people still may not have the patience to choose. People may be willing to read on mobile phones while unwilling to read on papers although they have the same content. The paper version is not as convenient as the mobile phone, which may lead to miss items when filling in the questionnaire. <STAFF-6>

	The paper version is better because many of our patients still use phones designed for the elderly, or they cannot use mobile phones at all. When using the paper version, the patient may not understand some items. We (medical staff) will read and explain for the patient, and they will be able to answer them.

Appendix 4 Simplified Chinese IPOS patient version

IPOS 患者版本

www.pos-pal.org

姓　　名：……

日期 (年-月-日)：……

病 历 编 号：…… *(医务人员填写)*

填 表 用 时：……*分钟 (医务人员填写)*

问题 1. 在过去 3 天内，在您的整个生活中曾存在的主要问题或担忧是什么?

1. ……
2. ……
3. ……

问题 2. 下表所列症状，有的可能您经历过，有的可能您没有。在对应症状后打钩，标记出过去 3 天您所受这种症状困扰的程度。

	根本没有	*轻度*	*中度*	*重度*	*超重度*
疼痛	0☐	1☐	2☐	3☐	4☐
气短	0☐	1☐	2☐	3☐	4☐
虚弱或乏力	0☐	1☐	2☐	3☐	4☐
恶心（感到想要呕吐)	0☐	1☐	2☐	3☐	4☐
呕吐	0☐	1☐	2☐	3☐	4☐
食欲差	0☐	1☐	2☐	3☐	4☐
便秘	0☐	1☐	2☐	3☐	4☐
口疮或口干	0☐	1☐	2☐	3☐	4☐
昏昏欲睡	0☐	1☐	2☐	3☐	4☐
行动不便	0☐	1☐	2☐	3☐	4☐
请列出以上没有提及的其他症状，然后在对应方框中打勾以显示它们在过去三天内对您的影响。					
1.	0☐	1☐	2☐	3☐	4☐
2.	0☐	1☐	2☐	3☐	4☐
3.	0☐	1☐	2☐	3☐	4☐

在过去的 3 天内：

	根本没有	*偶尔*	*有时*	*大多数时间*	*总是*
问题 3.您对您的病情或治疗感到焦虑或担心吗?	0☐	1☐	2☐	3☐	4☐
问题 4.您的家人或朋友感到焦虑或为您担心吗?	0☐	1☐	2☐	3☐	4☐
问题 5. 您感到情绪低落吗?	0☐	1☐	2☐	3☐	4☐
	总是	*大多数时间*	*有时*	*偶尔*	*根本没有*
问题 6.您感到平静安宁吗?	0☐	1☐	2☐	3☐	4☐
问题 7.您是否能充分地与家人或朋友分享您的感受?	0☐	1☐	2☐	3☐	4☐
问题 8.您能充分地获得您想知道的信息吗?	0☐	1☐	2☐	3☐	4☐
问题9.您感到对家庭构成负担吗?	0☐	1☐	2☐	3☐	4☐
	已解决/没有问题	*大部分解决*	*部分解决*	*几乎没有解决*	*没有解决*
问题 10-1. 由您的病情所导致的财务问题，已得到解决了吗? （比如债务或无法获得医保）	0☐	1☐	2☐	3☐	4☐
问题 10-2.由您的病情所导致的个人问题，已得到解决了吗? （比如社交障碍或无法工作）	0☐	1☐	2☐	3☐	4☐

	自己独立完成	*在朋友或家人的帮助下完成*	*在工作人员帮助下完成*
问题 11.您是如何完成本问卷的?	☐	☐	☐

如果您对本问卷中的任何问题感到担忧

请与您的医生或护士联系

Appendix 5 Simplified Chinese IPOS staff version

IPOS 医务人员版本

患　者　姓　名: .....

日期 (年-月-日): .....

病　历　编　号: .....

问题 1. 在过去 3 天内，在患者的整个生活中曾存在的主要问题是什么?

1. .....
2. .....
3. .....

问题 2. 请在您认为最能准确描述下列症状在过去 3 天内对患者产生了怎样的影响的对应方框内打勾。

	根本没有	*轻度*	*中度*	*重度*	*超重度*	*无法评估(例如，患者意识不清)*
疼痛	0☐	1☐	2☐	3☐	4☐	☐
气短	0☐	1☐	2☐	3☐	4☐	☐
虚弱或乏力	0☐	1☐	2☐	3☐	4☐	☐
恶心（感到想要呕吐)	0☐	1☐	2☐	3☐	4☐	☐
呕吐	0☐	1☐	2☐	3☐	4☐	☐
食欲差	0☐	1☐	2☐	3☐	4☐	☐
便秘	0☐	1☐	2☐	3☐	4☐	☐
口疮或口干	0☐	1☐	2☐	3☐	4☐	☐
昏昏欲睡	0☐	1☐	2☐	3☐	4☐	☐
行动不便	0☐	1☐	2☐	3☐	4☐	☐
请列出以上没有提及的其他症状，然后在对应方框中打勾以显示您认为它们在过去三天内对患者构成怎样的影响。						
1.	0☐	1☐	2☐	3☐	4☐	☐

2.	0☐	1☐	2☐	3☐	4☐	☐
3.	0☐	1☐	2☐	3☐	4☐	☐

在过去的 3 天内：

	根本没有	*偶尔*	*有时*	*大多数时间*	*总是*	*无法评估（例如，患者意识不清）*
问题 3.患者对他/她的病情或治疗感到焦虑或担心吗?	0☐	1☐	2☐	3☐	4☐	☐
问题 4.患者的家人或朋友感到焦虑或为患者担心吗?	0☐	1☐	2☐	3☐	4☐	☐
问题 5. 您认为患者感到情绪低落吗?	0☐	1☐	2☐	3☐	4☐	☐
	总是	*大多数时间*	*有时*	*偶尔*	*根本没有*	*无法评估（例如，患者意识不清）*
问题 6. 您认为患者感到平静安宁吗?	0☐	1☐	2☐	3☐	4☐	☐
问题 7.患者是否能充分地与家人或朋友分享他/她的感受?	0☐	1☐	2☐	3☐	4☐	☐
问题 8.患者能充分地获得他/她想知道的信息吗?	0☐	1☐	2☐	3☐	4☐	☐
问题9.您认为患者感到对家庭构成负担吗?	0☐	1☐	2☐	3☐	4☐	☐
	已解决/没有问题	*大部分解决*	*部分解决*	*几乎没有解决*	*没有解决*	*无法评估（例如，患者意识不清）*

问题 10-1. 由患者的病情所导致的财务问题，已得到解决了吗？（比如债务或无法获得医保）	0☐	1☐	2☐	3☐	4☐	☐
问题 10-2.由患者的病情所导致的个人问题，已得到解决了吗？（比如社交障碍或无法工作）	0☐	1☐	2☐	3☐	4☐	☐

Appendix 18. Manuscript of paper 4

Psychometric validation of the Chinese version of the Integrated Palliative care Outcome Scale: A person-centred outcome measure for advanced cancer

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Abstract

Background

Cancer is a leading cause of death in China. As palliative care provision expands, it is essential to ensure quality through a focus on patient-centred outcomes. Currently, no such measure has been reported with adequate psychometric properties.

Objective

The study aimed to evaluate the psychometric properties (validity, reliability, and responsiveness to change) of the Integrated Palliative care Outcome Scale in China.

Method

A multi-centre validation study was conducted to test the psychometric properties of the novel patient self-report and staff proxy-report Chinese Integrated Palliative care Outcome Scale. We tested i) construct validity (factor structure and convergent validity), ii) reliability (internal consistency, test-retest reliability and inter-rater reliability), and iii) responsiveness (longitudinal evaluation of change) among adults with advanced cancer.

Results

We consecutively recruited n=308 participants from two medical oncology units. We confirmed i) a three-factor structure (Physical Symptoms, Emotional Symptoms/Communication, Practical Issues). ii)Good convergent validity to hypothesised items and subscales of the Edmonton Symptom Assessment System was demonstrated (IPOS and total EASA, r=0.76, 95% CI 0.681-0.819). iii) Good internal consistency (α=0.83), acceptable to good test-retest reliability (κw=0.59), inter-rater reliability (κw=0.48) and responsiveness was demonstrated.

Conclusion

The Chinese Integrated Palliative care Outcome Scale is a reliable and valid outcome measure for use in patients with advanced cancer in both patient self-report and staff proxy-report versions. It is suitable for assessing needs, symptoms and concerns in advanced cancer, and monitoring the change of health status over time. It offers new

potential, determining the impact of healthcare interventions, and demonstrating the quality of care.

Keywords
patient-reported outcome measures, validation studies, reliability, psychometrics, China, advanced cancer, palliative

Background

Cancer is one of the leading causes of death in China, with an estimated 4.82 million new diagnoses and more than 3.21 million cancer deaths in 2022 [1]. Cancer is predicted to be the most common cause of health-related suffering at the end of life by 2060[2]. Although advanced cancer patients and their families report a high burden of pain and other symptoms[3], palliative care services in mainland China are scarce.[4-6] In the global response to the 40 million people who need palliative care each year,[7, 8] China ranked 53rd out of included 81 countries in the 2021 Quality of Death and Dying Index. It was reported to be “facing difficulties from slow adoption of palliative care and a rapidly ageing population”.[9, 10]

Variations in healthcare quality can be addressed by improving the delivering outcomes-focused care.[11] Patient-reported outcome measures (PROMs), elements of patient-centred care, comprise standardised validated questionnaires that are completed by patients to measure their perceptions of their health status and wellbeing.[12] Routine use of PROMs in palliative care (i.e. capture, transfer, and feedback of patient-centred outcomes data in routine palliative care clinical practice) can improve symptom recognition, increase discussion of quality of life, increased referrals based on PROMs reporting, and improve emotional and psychological patient outcomes.[13, 14]

A systematic review found no PROM with adequate psychometric properties for palliative care from China.[15] The Integrated Palliative care Outcome Scale (IPOS) is a brief and valid PROM that evaluates the most burdensome symptoms and concerns such as physical and

psychological symptoms, information needs, spiritual and practical concerns of people living with advanced serious illness within a timeframe of three days (for inpatient settings) or seven days (for ambulatory settings).[16] It has sound psychometric properties (validity, reliability and responsiveness) and has been adapted and validated in many regions of the world.[17-21]

We previously conducted qualitative interviews to develop face and content validity of a Chinese IPOS translated IPOS into Chinese and undertook cross-cultural adaptation and cognitive interviewing. In this study, we aimed to evaluate the psychometric properties (validity, reliability, and responsiveness) of the patient self-report and staff proxy-report versions of the novel Chinese IPOS.

Methods

The testing and reporting of the measurement properties of the Chinese IPOS followed the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) recommendations,[22, 23] following the quality criteria for measurement properties of health status questionnaires.[24]

This paper reports the psychometric testing of construct validity, reliability and responsiveness. The study establishing face and content validity, involving conceptual mapping, forward and backward translation, expert review and cognitive interviews, will be published separately. The design was a multi-centre validation study of two versions of the Chinese IPOS: patient report and staff report.

Population and settings

Inclusion/exclusion criteria

Inclusion criteria for patient participants were: ≥18 years old, inpatients diagnosed with advanced cancer (stage III-IV, as determined by their treating clinician), capacity to give written informed consent (determined by treating clinician), and able to speak and read Chinese. Exclusion criteria for patient participants were: too unwell and/or without mental

capacity to give informed consent (determined by treating clinician) and/or unable to understand written and verbal communication in Chinese. Inclusion criteria for staff participants: experience of delivering clinical care for patients with advanced cancer for at least six months at the participating sites.

Setting

Patients with advanced cancer were consecutively recruited from two inpatient medical oncology units in two university-affiliated hospitals in China within three days of admission. Staff caring for participating patients were also recruited for proxy rating.

Data collection

Demographic data and clinical information (i.e., primary diagnosis, KPS) were collected through self-report and electronic medical record review at baseline, respectively. There were two time points of patient data collection: T1 0-3 days from admission and T2 5-7 days after admission (Table 1). At T1, patients were asked to self-complete the IPOS patient version (3-day recall period, with assistance as required from research nurses) and ESAS, and their allocated primary nurses completed the IPOS staff version, KPS, and ESAS (see measures' description below). At T2, IPOS patient version and global change question 'Has your condition changed?' were collected for patient participants. For staff participants, the IPOS staff version and KPS were collected.

Measures used

- Integrated Palliative care Outcome Scale (IPOS)

IPOS is a 10-question, 17-item brief PROM of symptoms and concerns across the four domains of palliative care (physical, psychological social and spiritual).[16] Each item is scored on a 5-point Likert scale (0–4), with higher scores indicating an overwhelming presence of symptoms and needs not addressed. Open items allow patients to list their main symptoms and concerns. We used the seven-day patient version recommended for use in community-based services, with three previously identified three sub-scales of IPOS Physical Symptoms, Emotional Issues and Support (Social issues and Quality of Care).[25]

-The Edmonton Symptom Assessment System (ESAS)

ESAS was developed to measure the most common symptoms in cancer patients. It consists of nine visual analogue scales measuring physical symptoms (each scored from 0-10). Initially, ESAS. Higher scores indicate worse symptoms. The ESAS has been validated for assessing the symptoms of patients with an advanced progressive illness in China.[26]

-Karnofsky Performance Status (KPS)

A single score between 0% and 100% (in 10% bands) reflects a patient's ability to perform common tasks relating to activity, work and self-care.[27] A KPS score of 100% signifies normal physical abilities with no complaints and no evidence of disease. Decreasing numbers indicate reduced performance status. The Australia-modified Karnofsky Performance Status (AKPS) is a better version for this research but not available in China.[28]

-Global change question

At T2, a single item asked patient participants to report overall change in their symptoms and concerns since T1: 'Over the last seven days, has your condition changed/ would you say that things have got better /worse / there has been no change?'. This item informs assessment of responsiveness.

Analysis

Analysis was undertaken using IBM SPSS Statistics 28.0 and R 3.6.0 (Bell Laboratories, Oakland).

Reliability

Internal consistency was evaluated using Cronbach's alpha for IPOS total scores and subscales, with a Cronbach's alpha between 0.70 and 0.95 indicating good internal consistency without homogeneity.[24]

Test-retest reliability was calculated between repeated IPOS–Chinese measures in stable patients, i.e. those who at T2, answered "no" to the question: "*Over the last three days has your condition changed*?".

Inter-rater reliability was assessed between independent patient and staff ratings at each time point. Cohen's weighted kappa was calculated, and the Spearman correlation was

calculated to test the association between patient/ staff ratings. For interpretation, the Landis and Koch[29] and Fleiss'[30] criteria of k > 0.4 for fair to good and k > 0.75 for substantial to excellent agreement were used.

Validity

For structural validity, exploratory factor analysis (EFA) was used to initially identify the dimensions of the measure. The EFA was conducted using the principal components extraction method with varimax oblique rotation. The number of factors was determined by Scree plot and Kaiser's criterion of an Eigen value>1.[31, 32] A factor loading greater than 0.30 was considered significant.[33]

The EFA output was used to inform confirmatory factor analysis (CFA). The CFA model fit was assessed using fit indices. We used robust maximum likelihood estimation to accommodate the ordinal nature of the data[34]. The fit of each solution was evaluated using chi-square, ratio of chi-square and degrees of freedom, confirmatory fit index, Tucker-Lewis index (TLI), Standardised Root Mean Squared Residual (SRMR), and root mean square error of approximation (RMSEA)[35]. Contrasting models were compared regarding fit indices, standardised parameter estimates, and local strains (low loadings, high standard error)[36]. The following thresholds were used to indicate a good fitting model: RMSEA < 0.05, CFI > 0.95, TLI > 0.95 and SRMR < 0.08.[37, 38] The modification indices command was used to identify any further factor loadings or covarying error terms that would improve model fit; these were then added to the model. Correlation coefficients were used to assess the correlation of factors with parameters classified weak (<0.4), moderate (0.4 – 0.6) and strong (>0.6) correlations.[8]

Convergent validity was tested by correlating individual IPOS items and subscales with respective items and subscales from ESAS,[39] using Spearman's correlation coefficients (r)[40] with associated p-values, where $0 \leqslant r < 0.20$ indicated weak, $0.20 \leqslant r < 0.40$ low, $0.40 \leqslant r < 0.60$ moderate and $0.60 \leqslant r < 0.80$ strong relationship given statistical significance. We hypothesised:

(1)strong correlations ($r \geqslant 0.60$) of identical or near-identical single items relating to the physical and psychological symptoms from ESAS and IPOS;
(2)moderate correlations ($0.40 \leqslant r < 0.60$) between total ESAS scores and ESAS subscale scores (not covering the spectrum of spiritual and family issues covered by the IPOS) and total IPOS scores (including domains beyond symptoms).

Responsiveness

We assessed responsiveness by comparing IPOS-Chinese scores at timepoint 1 and timepoint 2 using the Wilcoxon signed-rank test, among patients who indicated that their clinical condition has changed at Time Point 2. We compared mean changes and respective standard deviations of change descriptively in the six categories of change given by the global change rating (ranging from much better to much worse).

Interpretability

More than 15% of respondents reporting the highest (4) or lowest (0) possible value at T1 may be considered a measure ceiling or floor effect.[24]

Feasibility

Completion time was recorded. Means, standard deviations and ranges of completion time were calculated.

Sample size

It is highly recommended to use at least ten subjects per instrument item [41-44]. Comrey and Lee[45] provided the following guidance: 100 = poor, 200 = fair, 300 = good, 500 = very good, ≥1000 = excellent. We aim to recruit 300 patients and their primary nurses in this study.

Ethical approval

Ethical approval was attained from Kings' College London (HR-20/21-18713) in the UK and the Chaoyang Central Hospital (Chaoyang Central Hospital Research Ethics Committees, approved on 8 October 2019) and Peking University Shenzhen Hospital (Peking University

Shenzhen Hospital Research Ethics Committees, approved on 15 July 2020) in China. Information sheets and consent forms were translated from English into Chinese. Participants gave written informed consent before data collection.

Results

Sample characteristics

Study recruitment took place from January to September 2021. 753 individuals were screened at admission and of those 609 were eligible for this study. A total of 308 patients (50.6% of those eligible) were recruited. The number of screened, eligible, approached and consented participants, plus those who completed the first (n=308) and second (n=186) assessments, with reasons for non-completion, are shown in Figure 1.

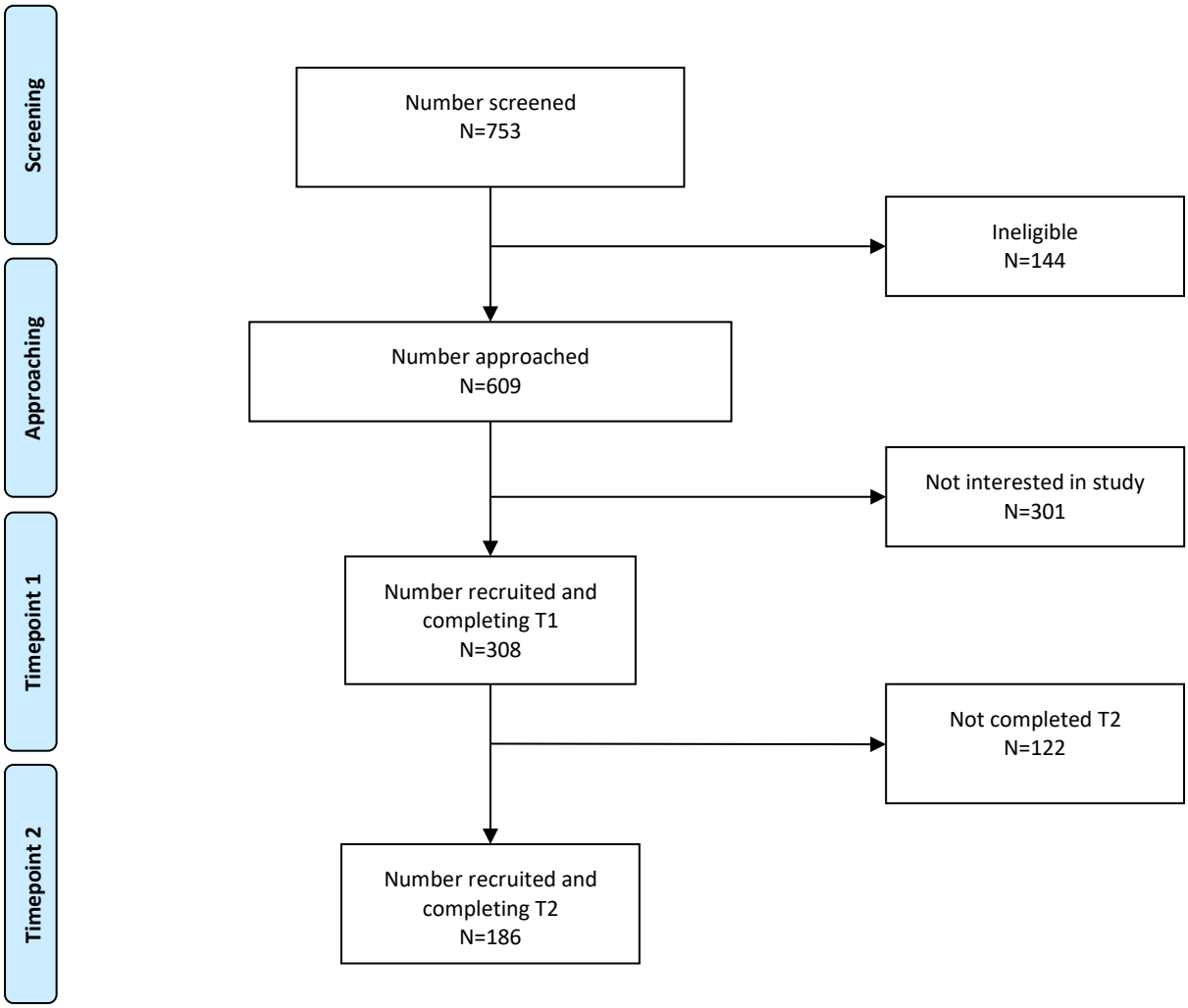

Figure 1. Sample size at each stage of screening, recruitment and analysis

The median age of patient participants was 57.0 years (SD 11.0, range 24-79), and 48.4% of the sample identified as male and 51.6% female. Most participants were married (91.6%) and unemployed (41.2%). The most common cancer type was colorectal cancer (CRC) (n=97, 31.4%), followed by lung cancers (n=75, 24.4%), breast cancer (n=47, 15.2%) and gastric cancer (n=25, 8.1%). Most of the patients were at stage IV (60.1%). In terms of IPOS administration, n=106 (51.9%) patients completed IPOS alone while 109 (35.4%) had staff help and 39 (12.7%) with family help. (See Table 1)

Table 1. Patient sample demographic and clinical characteristics (n=308)

Variable	n	%
Age	Mean 55.6 (Median 57.0)	(SD 11.0, 24-79)
< 60 years	196	63.6
≥60 years	112	36.4
Gender		
F	159	51.6
M	149	48.4
Marital Status		
Divorced	3	1.0
Married	282	91.6
Single	16	5.2
Widowed	7	2.3
Employment Status		
Employed Full-Time	46	14.9
Employed Part-Time	3	0.1
Not Employed	127	41.2
Self Employed	23	7.5
Retired	104	33.8
Missing	5	1.6
Primary diagnosis		
CRC	97	31.4
Lung	75	24.4
Breast	47	15.2
Gastric	25	8.1
Oesophageal	11	3.5

H&N	10	3.2
Ovarian	8	2.6
Liver	7	2.3
Cervical	5	1.6
Pancreatic	5	1.6
Bladder	4	1.3
Endometrial	4	1.3
Sarcoma	4	1.3
Neuroendocrine	3	1.0
Prostate	2	0.6
Gallbladder	1	0.3
Stage		
III	123	39.9
IV	185	60.1
Karnofsky performance status	Mean 87.66	(SD 8.715, 50-100)
50	1	0.3
60	2	0.6
70	8	2.6
80	115	37.3
90	113	36.7
100	69	22.4
IPOS completion		
Completed IPOS alone	160	51.9
Completed IPOS with family help	39	12.7
Completed IPOS with staff help	109	35.4
Time between timepoint 1 & 2 (in days)	Mean 7.1 (Median 6)	(SD 2.6, 4-9)

Table 2 shows the distribution of IPOS scores at T1. The full range of the 5-point Likert scale levels was used. The five most burdensome items (i.e. scored three or four) were: Family burden (46.8%), Sharing feelings (25.3%), Family anxiety (25%), Personal issues (19.1%) and Information (17.9%). There was no missing data as research nurses were trained to review the IPOS responses with patients and to clarify any missing responses.

Table 2. Descriptive statistics and distribution for IPOS items at T1 (n=308)

	Not at all (0)	%	Slight (1)	%	Moderate (2)	%	Severe (3)	%	Overwhelming/ all the time (4)	%
Physical symptoms										
1-Pain	197	64	78	25.3	25	8.1	6	1.9	2	0.6

2- Shortness of breath	217	70.5	78	25.3	11	3.6	2	0.6	0	0
3- Weakness or lack of energy	149	48.4	127	41.2	24	7.8	6	1.9	2	0.6
4- Nausea	242	78.6	45	14.6	17	5.5	2	0.6	2	0.6
5- Vomiting	263	85.4	30	9.7	11	3.6	4	1.3	0	0
6- Poor appetite	185	60.1	83	26.9	28	9.1	10	3.2	2	0.6
7- Constipation	223	72.4	65	21.1	13	4.2	3	1	4	1.3
8- Sore or dry mouth	209	67.9	79	25.6	16	5.2	2	0.6	2	0.6
9- Drowsiness	242	78.6	45	14.6	16	5.2	3	1	2	0.6
10- Poor mobility	249	80.8	36	11.7	15	4.9	8	2.6	0	0
Emotional and communication issues										
11- Patient anxiety	123	39.9	92	29.9	58	18.8	23	7.5	12	3.9
12- Family anxiety*	87	28.2	67	21.8	77	25	44	14.3	33	10.7
13- Depression	144	46.8	89	28.9	56	18.2	17	5.5	2	0.6
14- Feeling at peace	108	35.1	113	36.7	44	14.3	33	10.7	10	3.2
15- Sharing feelings*	100	32.5	58	18.8	72	23.4	49	15.9	29	9.4
16- Information*	124	40.3	75	24.4	54	17.5	39	12.7	16	5.2
Practical issues										
17- Family burden*	48	15.6	54	17.5	62	20.1	64	20.8	80	26
18- Financial issues	115	37.3	82	26.6	76	24.7	22	7.1	13	4.2
19- Personal issues*	150	48.7	55	17.9	44	14.3	26	8.4	33	10.7

*The five most burdensome items (ie scored three or four)

i) Validity

Structural validity

As expected for IPOS (a multidimensional measure), the goodness-of-fit indices of the initial EFA suggest no adequate fit to the single factor model, with fit indices CFI (0.58) and RMSEA (0.15). The three-factor solution showed a better fit than the two-factor and one-factor solutions. The EFA indicated a three-factor structure, with factor one loaded with ten items physical subscale, factor two with 6 items (emotional and communication subscale) and factor three with three items (practical issues subscale). (See online Appendix Table 1 for result of EFA and online Appendix Table 2 for standardised factor loadings)

The first factor, Physical Symptoms, comprised 10 items and explained 31.46% of the variance. The second factor, Emotional Symptoms and communication issues, consisted of 6 items and explained 13.55% of the variance. The third factor, Practical Issues, contained 3

items and explained 7.15% of the variance. (We refer to these factors as Physical, Emotional/Communication and Practical subscales, see Table 3).

In this three-factor model, CFA fit indices CFI=0.80, TLI=0.76 and RMSEA=0.11 indicated poor fit of the model to the data ($\chi 2=652.25$, df=148.00, $\chi 2/df=4.41$, $p < 0.0001$). Even though the CFI and SMRM parameters approached the minimums, they were not within the required defined parameters recommended for small samples. For this reason, the CFA was inconclusive and cross-cultural validity could not be confirmed or negated. The standardised parameter estimates of the modified model are shown in online Appendix Figure 1.

Convergent validity

Correlations between IPOS and ESAS were confirmed. Pain (r=0.77), drowsiness (r=0.61), nausea(r=0.766) and poor appetite(r=0.61) were highly correlated between IPOS single symptom items and the corresponding Edmonton Symptom Assessment Tool items. Weakness or lack of energy/tiredness (r=0.57), depression (r=0.49) and anxiety or worry about illness or treatment/anxiety were moderate correlated. Only one pair of items (shortness of breath) had low correlation (r=0.35). In terms of overall score and subscale score, the Chinese IPOS was highly correlated with total ESAS (r=0.76, 95% CI 0.681-0.819), with physical (r=0.76) subscale and emotional/ communication subscale (r=0.57) highly to moderately correlated. IPOS practical issues subscale had low correlation with total ESAS (r=0.20). R values were in the hypothesised range of direction and magnitudes. (See online Appendix Table 3 and 4)

Table 3. Descriptive statistics and distribution for IPOS total and subscale scores at T1 (n=308)

	#items	Range	Mean	SD	Skew	Cronbach's α	Eigenvalue	% variance
IPOS Total Score	19	0-58	15.76	9.39	1.11	0.83		
IPOS Physical symptoms	10	0-27	3.96	4.92	2.16	0.89	5.98	31.46
IPOS Emotional/ Information Issues	6	0-20	7.27	4.94	0.32	0.79	2.57	13.55
IPOS Practical Issues	3	0-12	4.53	2.86	0.40	0.55	1.36	7.15

Reliability

Internal consistency

IPOS total score had a very good internal consistency (Cronbach's α was 0.83). For the subscales, both physical and emotional/ information issues had very good internal consistency (Cronbach's α was 0.89 and 0.79, respectively), whereas practical issues subscale had poor internal consistency (Cronbach's α was 0.55).

Test-retest Reliability

According to the participant-reported change question at T2, n=85 patients reported no change on the global change rating. For these stable patients, test-retest reliability weighted kappa values showed fair to good agreement (range 0.40 to 0.75) except for the items 'Nausea' (κw=0.39), 'Constipation' (κw=0.30), 'Sore or dry mouth' (κw=0.36), 'Feeling at peace' (κw=0.36) and 'Burden to family' (κw=0.39). The proportion agreement within one score between assessments was generally fair to good with only 'Pain' achieving substantial to excellent agreement (κw=0.80). (See Table 4). The agreement of total IPOS scores between two timepoints was fair to good with κw=0.59.

Inter-rater reliability: patient and staff

The level of agreement between independent patient and staff ratings measured by weighted Kappa scores was good (≥ κw=0.40) for 14/19 IPOS items, with the highest levels of agreement being achieved for the items 'Pain' (κw=0.73), 'Shortness of breath' (κw=0.66) and 'Poor mobility' (κw=0.64). Lower levels of agreement were observed for items 'Patient anxiety', 'Family anxiety', 'Feeling at peace', 'Sharing feelings' and 'Burden to family'. The agreement of total IPOS score between patient and staff reported was fair to good with κw=0.48.

Table 4. Test-retest reliability (n=85): weighted kappa (κw) between T1 and T2 and Inter-rater reliability (n=251): weighted kappa (κw) between patient and staff ratings at T1

	Test-retest (n=85)	Inter-rater (n=251)
	Cohen's weighted kappa	

1-Pain	0.80	0.73
2- Shortness of breath	0.73	0.66
3- Weakness or lack of energy	0.55	0.51
4- Nausea	0.39	0.60
5- Vomiting	0.43	0.47
6- Poor appetite	0.48	0.56
7- Constipation	0.30	0.60
8- Sore or dry mouth	0.36	0.55
9- Drowsiness	0.51	0.42
10- Poor mobility	0.51	0.64
11- Patient anxiety	0.60	0.34
12- Family anxiety	0.43	0.39
13- Depression	0.48	0.42
14- Feeling at peace	0.36	0.36
15- Sharing feelings	0.58	0.35
16- Information	0.49	0.41
17- Burden to family	0.39	0.26
18- Financial issues	0.59	0.43
19- Personal issues	0.68	0.49
IPOS Physical symptoms	0.46	0.60
IPOS Emotional and communication issues	0.28	0.39
IPOS Practical issues	0.55	0.31
Total IPOS	0.59	0.48

Responsiveness to change

SD at baseline for the total IPOS score was 9.11 (4-58). Mean change scores for the total score were as large as -3 in the “much better” group and even larger (4.36) for the group that described themselves as ‘a little wors’ (Table 5). Total IPOS score discriminated between patients who indicated that their health improved, got worse, or remained unchanged between the two assessment timepoints.

Table 5. Mean total IPOS score changes (between T1-T2) by global change scale (a negative change scores indicates deterioration).

Has your condition changed?	n	IPOS $Mean_{change} \pm SD_{change}$
Things have got		
Much better	22	-3.00±8.36

A little better	62	-1.02±7.07
No significant change	85	0.76±6.62
A little worse	11	4.36±8.31
Much worse	0	0
Do not know	0	0

Interpretability

The ceiling effect was evident in only one item (*Q9: Have you felt a burden to your family?*) with 15.6% patients soring 4. The floor effect was present for all items, with 26.0 – 85.4% of the patients reported the lowest possible score (0).

Time to complete

The mean time to complete at timepoint 1 and timepoint 2 was 6.23 min (1-25, SD=3.97) and 5.54 min (1-26, SD=4.14).

Discussion

This study provides strong evidence that Chinese IPOS is a valid and reliable global outcome measure for use with people with advanced cancer in China. The psychometric evaluation shows Chinese IPOS has good internal consistency, structural validity, with three underlying factors – physical symptoms, emotional/ communication symptoms, and practical issues – and appropriate convergent and discriminant validity when compared with ESAS (validated in China). Most individual IPOS items show good agreement when re-tested in stable patients. There is also acceptable or good agreement between the majority of patient self-reported and staff proxy-reported items. Most importantly, the total IPOS score showed a change in keeping with patient-report of the overall change in their symptoms and other concerns, both in direction and magnitude of change.

Among the tested solutions, the 3-factor solution performed best. This solution is very similar to the one obtained on the original IPOS and APCA African POS, with the difference of the emotional items now clustering with the communication items.[16, 46] The item 'burden to family', loading on the symptom factor, was the only item with a factor loading

below 0.30. This suggests that 'burden to family' may not be collapsed into the construct of 'practical issues'. As this item was newly developed for Chinese IPOS informed by qualitative research, these results warrants further exploration, particularly given the diversity of settings and patients included. It may be explained by underlying heterogeneity in the sample which could be explored by latent mixture modelling. It should also be investigated whether burden to family forms an overarching factor, affecting and explaining the other factors and subscales in the IPOS.

In terms of test-retest reliability, we found mostly fair to excellent agreement demonstrated by weighted kappa values ranging from 0.40 to 0.80. These values are similar or higher than similar studies of test-retest reliability of IPOS in other cultures. However, some items demonstrated low weighted kappa values, namely 'Constipation' (κw=0.30), 'Sore or dry mouth' (κw=0.36) and 'Feeling at peace' (κw=0.36). These are also the items showing very low agreement in comparing patient and staff ratings. The low agreement for the information item had also been observed. The Czech IPOS validation study found a weighted kappa value as low as 0.33 for this item.[47, 48] Several explanations can account for this result. A qualitative study accompanying low agreement scores of the Palliative care Problem Severity Index, identified reasons and features of the raters (e.g., new staff member with new patient), patient characteristics (e.g., communication problems, dementia, drowsiness or immigrant), family characteristics (e.g., lacking interaction with family, appropriate distress in face of advanced illness), or features of the item itself (e.g., time frame of question not matching the assessment time frame) as impeding high agreement scores.[49] It is likely that these features may also have been present in the Chinese IPOS validation study. Specifically, lack of familiarity with patients and their families and IPOS assessment occurring prior to taking the first, comprehensive history at admission of the patient. These features may also well explain the low agreement scores observed with items asking about family issues.

The Chinese IPOS is innovative as burden to family (n=1 item) and practical issues (n=2 items) were newly developed or refined. It enables healthcare professionals to assess the multidimensional outcomes of palliative care contextually. Importantly, patients were an integral part of the entire development process, with more than 300 patients involved

throughout to shape the scope of the Chinese IPOS. It is flexible because it has developed a staff-reported version for patients unable to self-report their symptoms and concerns.

Limitations

Firstly, the findings from this oncology sample should be reproduced in non-cancer palliative populations that also bring serious health-related suffering at the end of life.[50] In addition, 96.4% of the sample reported good functional status (KPS≥80). Lastly, only two study sites were included across China, and there are regional differences in the Chinese language and a large and diverse geography.

Clinical and research implications

This study has demonstrated that IPOS is valid, reliable and responsive. Because it is brief and underpinned by the symptoms and concerns of people with advanced illness, it will be invaluable for clinical practice (both clinical care delivery and audit) and research. Focus shod now be twofold. Firstly, the evidence base for palliative care in China is currently limited, and Chinese IPOS will enable health outcomes to be appropriately measured. [6]. Second, the health system should plan locally acceptable ways of implementing the measure into routine clinical practice.[51-53]

Conclusions

The Chinese IPOS is a valid and reliable outcome measure for use with people with advanced illness, ready to be used both in its patient self-report and staff proxy-report versions. It is suitable for assessing and monitoring symptoms and concerns in advanced cancer, monitoring change over time, determining the impact of healthcare interventions, and demonstrating the quality of care in China.

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Appendix Table 1

Table 1. Result of EFA

Index of fit	One-factor	Two-factor	Three-factor
Chi-Square	1196.92	740.91	652.25
df	152.00	151.00	148.00
p-value	<0.001	<0.001	<0.001
Chi-Square/df	**7.87**	**4.91**	**4.41**
CFI	0.58	0.76	0.80
TLI	0.52	0.73	0.76
RMSEA	**0.15**	**0.11**	**0.11**

Appendix Table 2

Table 2. Result of factor loadings for all Chinese IPOS items from structure matrix

Items	Factor 1	Factor 2	Factor 3
Pain	**.64**		
Shortness of breath	**.63**		.34
Weakness or lack of energy	**.81**		
Nausea	**.75**		
Vomiting	**.71**		
Poor appetite	**.81**		
Constipation	**.54**		
Sore or dry mouth	**.66**		
Drowsiness	**.69**	.31	
Poor mobility	**.78**		
Patient anxiety	.31	**.73**	.38
Family anxiety		**.69**	.41
Depression	.39	**.54**	.52
Feeling at peace		**.70**	
Sharing feelings		**.67**	
Information		**.70**	
Burden to family			**.37**
Financial issues			**.71**
Personal issues		.468	**.61**

Appendix Figure 1

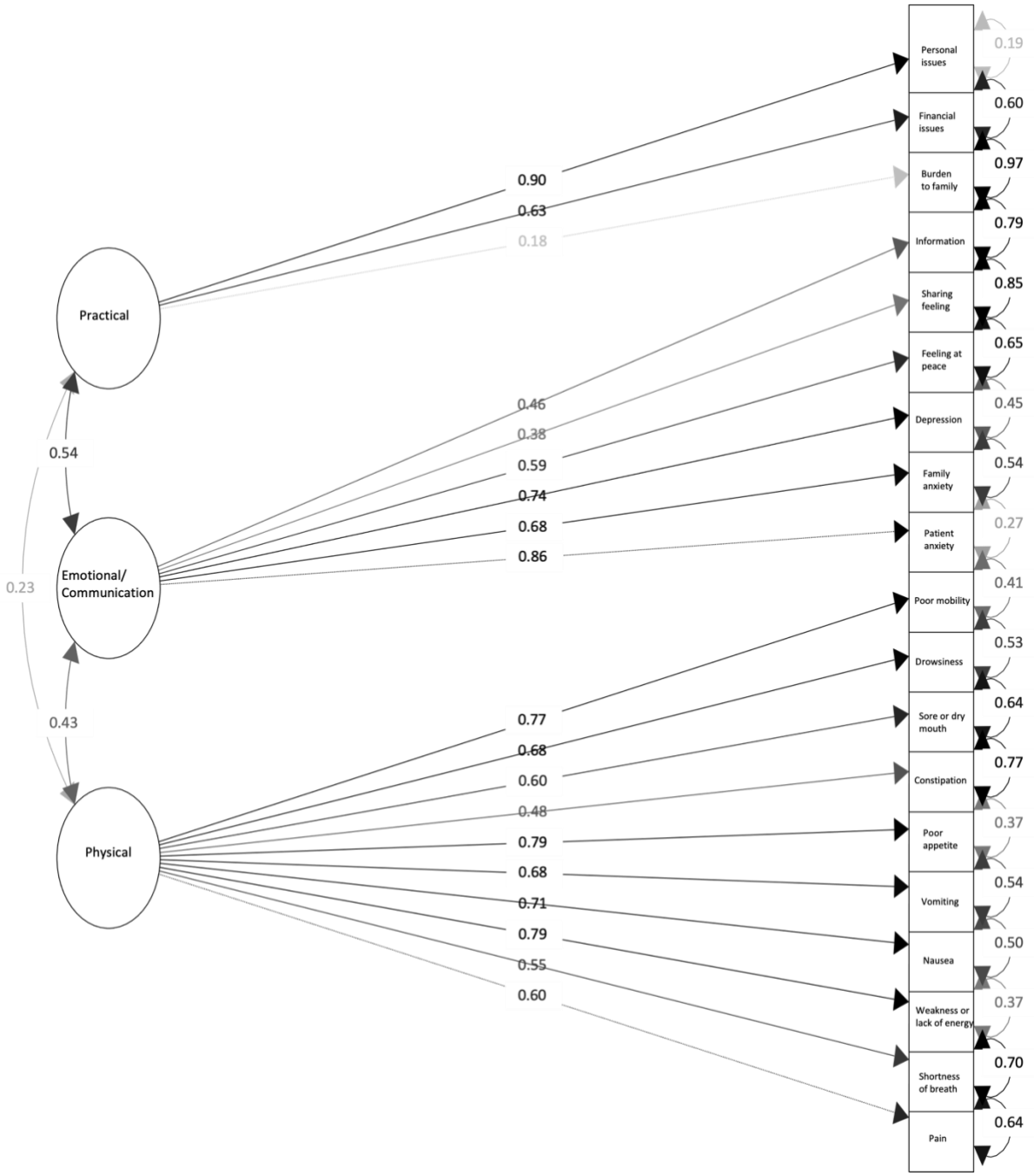

Figure 1. Standardised measurement model for Confirmatory Factor Analysis (n = 308)

Appendix Table 3

Table 3. Correlations between IPOS single symptom items and the corresponding Edmonton Symptom Assessment Tool items (n=308)

IPOS	ESAS	r	95% CI
Pain	Pain	0.77	0.69-0.84
Weakness or lack of energy	Tiredness	0.57	0.47-0.667
Drowsiness	Drowsiness	0.61	0.46-0.73
Nausea	Nausea	0.76	0.64-0.85
Poor appetite	Lack of appetite	0.61	0.49-0.71
Shortness of breath	Shortness of breath	0.35	0.20-0.50
Depression	Depression	0.49	0.36-0.60
Anxiety or worry about illness or treatment	Anxiety	0.52	0.40-0.63

Appendix Table 4

Table 4. Correlations between IPOS (Total and subscales) and ESAS (Total) (n=308)

	Total IPOS		IPOS Physical		IPOS Emotional/ Communication		IPOS Practical issues	
	r	95% CI	r	95% CI	r	95% CI	r	95% CI
Total ESAS	0.76	0.681-0.819	0.73	0.635-0.801	0.57	0.48-0.65	0.20	0.08-0.30