The Construct Validity of the Social and Spiritual Items of the Utrecht Symptom Diary – 4 Dimensional

Abstract

Context

Patients facing a life-limiting illness experience multidimensional symptoms, problems, and needs requiring personalized care. The Utrecht Symptom Diary – 4 Dimensional (USD-4D) is a Patient Reported Outcome Measure (PROM) that supports daily multidimensional symptom management through identification, monitoring and discussing of multidimensional symptoms and care needs. The construct validity of this PROM has yet to be established.

Objective

This study aimed to assess the construct validity of the social and spiritual items of the USD-4D in a population of Dutch patients in the palliative phase of their illness.

Methods

Construct validity is defined as the "degree to which the scores of a PROM are consistent with hypotheses based on the assumption that the PROM validly measures the construct to be measured." Since the USD-4D does not measure one construct, the construct validity of the social and spiritual items was assessed through hypotheses testing following the criteria of the COSMIN initiative (COnsensus-based Standards for the selection of health Measurement Instruments).

This study comprised patients coming from two distinct observational cohorts: a hospice cohort and the MuSt-PC cohort, a national cohort of patients across several care settings. Patients included in the hospice cohort were adult patients with an estimated life-expectancy of 3 months or less and any underlying disease. The MuSt-PC cohort comprised adult patients with an estimated life-expectancy of 12 months or less and any underlying disease in the home, care home, hospital, or hospice setting. Patients unable or unwilling to self-assess their symptoms were excluded. Construct validity was assessed by means of hypothesis testing for every individual item and was established when ≥75% of the formulated hypotheses were confirmed. Hypotheses were literature and expert driven. A total of 19 hypotheses were formulated and tested.

Results

897 patients were included in the final analysis. Of these patients 53% was female, 81% had cancer as their primary diagnosis and 85% received care in a hospice. For every item, at least 75% of hypotheses were confirmed. One hypothesis for the item 'I can let my loved ones go' was rejected.

Conclusions

This study confirmed the construct validity on the social and spiritual items of the USD-4D for Dutch hospice patients in the palliative phase of their illness. The USD-4D is suitable for signaling and monitoring multidimensional symptoms and needs. Generalizability to other settings is challenging due to lack of patient outcome data from these settings.

Introduction

Patients facing a life-limiting illness experience multidimensional symptoms, problems, and needs which require personalized care to maintain and improve their Quality of Life (QoL).[1] Optimal personalized care can only be delivered after a careful assessment and understanding of patients' symptoms and needs.[2, 3] Patients themselves can give the best indication of their symptom presence and intensity. Use of Patient-Reported Outcome Measures (PROMs) supports structural multidimensional symptom management, thus contributing to relieving suffering and optimizing the QoL of patients and their loved ones.

The Utrecht Symptom Diary – 4 Dimensional (USD-4D) (Appendix 1) supports daily multidimensional symptom management in all four dimensions of palliative care: physical, psychological, social, and spiritual. It consists of 21 items which are assessed using an 11-point numerical intensity scale (0 = no symptom, best possible; 10 = worst intensity, worst possible). It is designed for patients to structurally self-assess the severity of their symptoms and needs and enables patient-driven dialogue to explore and/or understand their underlying wishes and care needs. Furthermore, patients are stimulated to prioritize their symptoms and needs. Concentrating on the concept of total pain, it helps explore patients' multidimensional symptoms and needs. Using the USD-4D requires patients to fill-in the items and having the opportunity to go into dialogue with HCP to explore and/or understand underlying wishes and care needs.

The USD-4D is an extension of the Utrecht Symptom Diary (USD). The USD is a validated PROM to help signal physical and psychological symptoms and problems of patients in the palliative phase of their illness.[4] It is designed for patients to structurally self-assess their multidimensional symptoms and needs. The Netherlands Quality Framework for Palliative Care recommends use of the USD in clinical palliative care.[5]

Based on the Diamond Model (DM) for spiritual assessment, an operationalization of the Ars Moriendi tradition, the USD was supplemented with five expert-based items to cover the social and spiritual dimensions. The DM is a frequently used conversation aid in Dutch and Belgian palliative care.[6] The DM is a hermeneutic instrument that focuses around the concept *inner space*. Inner space is a metaphor that refers to a state of mind that allows one to relate to immediate emotions and attitudes evoked by a situation in complete freedom and tranquility. Five anthropological polarities control whether or not inner space can be experienced: myself versus the other, doing versus undergoing, holding on versus letting go, remembering versus forgetting, and knowing versus believing.[6]

Central to the DM is that is does not measure a construct. Rather it is a model that is easy to use in clinical palliative care for exploring and discussing patients' needs concerning the spiritual dimension and is operationalized in a fluid, open, and hermeneutic fashion. A recent systematic review found that patients' expressions of needs concerning the social and spiritual dimensions are linguistically alike.[7] Although developed for spiritual assessment, the DM could also be used for exploring patients' needs considering the social dimension.

The five polarities influencing one's perception of inner space were reworked into five items that were to supplement the USD (Figure 1). These items enable patients to self-assess potential care needs considering the social and spiritual dimensions and potentially function as stepping stones for patient-driven dialogue.

The USD-4D is being used in several healthcare settings across the Netherlands and has proven to be feasible in assessing and discussing patients' multidimensional symptoms and needs. However, the validity of this PROM

has yet to be established. The COSMIN methodology (Consensus-based Standards for the selection of health Measurement Instruments) distinguishes three categories of validity: content validity, criterion validity, and construct validity. The content validity from the perspective of patients has been established in a prior study. Since there is no reference standard concerning the assessment of the socio-spiritual items, criterion validity cannot be assessed.
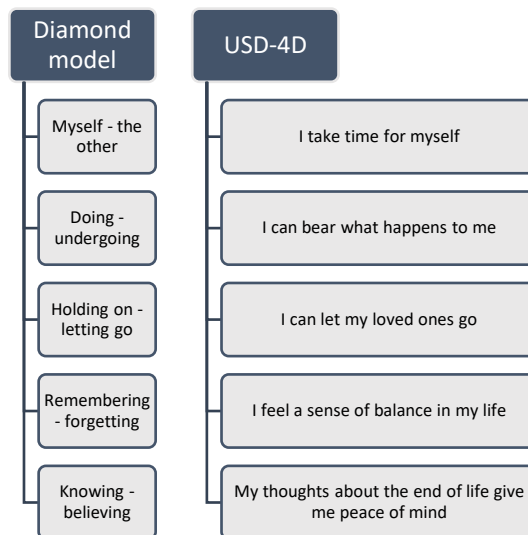

Figure 1: The anthropological polarities of the Diamond Model and their respective reworked items in the USD-4D.

This study set out to assess the construct validity of the social and spiritual items of the USD-4D in a population of Dutch patients in the palliative phase of their illness. The COSMIN methodology defines construct validity as the 'degree to which the scores of a PROM are consistent with hypotheses based on the assumption that the PROM validly measures the construct to be measured.' In other words: do these items of the USD-4D measure what they intend to.

METHODS

An observational cohort study was conducted using patient outcome measures. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement was used to ensure completeness of this report.[13] Criteria of the COSMIN (Consensus-based Standards for the selection of health Measurement Instruments) were used in defining methods and quality criteria.[12, 14, 15]

Study outcome

The study outcome is the construct validity of the social and spiritual items of the USD-4D. Following the underlying mechanisms of the DM, these five socio-spiritual items do not measure one predefined construct. Henceforth, for every item the construct validity needs to be assessed separately.

The five social and spiritual items do not measure a construct. Every item on its own forms a standalone score. Therefore, each score represents a certain construct – albeit broad – and should consequently be considered as a separate PROM. Hence, the construct validity of each individual item will be assessed.[12]

Setting, participants and data collection

Patient-outcome data came from patients belonging to two distinct cohorts. The first concerns a cohort of hospice patients. It comprised patients admitted to Dutch hospices between June 2015 and August 2020 using the Madenco electronic patient record. This database collected demographic and disease-related patient data and information. In addition, all information about symptoms is collected using the USD-4D. All data have been collected as part of routine care. Patients included in this database were ≥ 18 years of age and had an estimated life-expectancy of 3 months or less. Patients consented to their USD-4D outcomes being used for research purposes.

The second cohort is the MuSt-PC cohort. This cohort comprised anonymized data collected within the scope of the MuSt-PC study (A Multidimensional Strategy to improve quality of life of patients with multiple symptoms and Palliative Care needs, NCT 201800366). The MuSt-PC study cross-sectionally assessed symptom burden of patients in the palliative phase of their illness using the USD-4D across all healthcare settings. Two nation-wide data collection weeks were organized from September 10th – 14th and from September 24th – 28th 2018. In these two weeks HCPs were invited to offer the USD-4D to patients in the palliative phase of their illness. Patients' eligibility was assessed using the surprise question: when the HCP answered "no" to question "Would I be surprised if this patient died in the next 12 months?" a patient was eligible to participate. Adult patients with any underlying disease at home, care home, hospital, or hospice could participate. Patients unable or unwilling to self-assess their symptoms were excluded. The Medical Ethics Review Board of the University Medical Center Groningen determined that the study did not fall within the scope of the Medical Research Involving Human Subjects Act (2018/307).

Hypotheses

Prior to the analysis, hypotheses were formulated concerning the five social and spiritual items of the USD-4D. The inherent subjective nature of the concepts "sociality" and "spirituality" made formulating solid hypotheses complex. Hence, relevant literature was discussed within the research team until consensus was met regarding the theoretical assumptions on which hypotheses would be based. Literature suggests a connection between spiritual well-being (SWB) and the social and spiritual dimensions.[16, 17] Based on this connection four theoretical assumptions were formulated that informed potential hypotheses:

    I.   There is a positive correlation between pain and the social and spiritual dimensions.[18, 19]
    II.   There is a positive correlation between anxiety and the social and spiritual dimensions.[20]
    III. There is a positive correlation between depression and the social and spiritual dimensions.[21]
    IV.   There is a positive correlation between sociality and spirituality and well-being.[22]

These theoretical assumptions were the basis on which the research team formulated hypotheses for each of the five social and spiritual items in the USD-4D. These hypotheses were then presented to a multiprofessional panel of experts in the field of palliative care. This panel consisted of 2 medical specialists, 2 nurse specialists and 2 healthcare chaplains. The experts assessed the hypotheses for their plausibility in clinical practice. Some had experience in using the USD-4D, some did not. Up to four hypotheses per item were considered in the analysis when ≥75% of the experts perceived them to be plausible. Table 1 shows the hypotheses that were analyzed in this study.

Table 1. USD-4D items and the respective hypotheses.

USD-4D item	Number	Hypothesis
I take time for myself.	1	Patients **with pain** report higher scores on the item 'I take time for myself' than patients **without pain**.
	2	Patients **with anxiety** report higher scores on the item 'I take time for myself' than patients **without anxiety**.
	3	Patients **with a depressed mood** report higher scores on the item 'I take time for myself' than patients **without a depressed mood**.
	4	Patients that report higher scores on the item 'I take time for myself' experience **less well-being** than patients that score lower on the item 'I take time for myself'.
I can bear what happens to me	5	Patients **with pain** report higher scores on the item 'I can bear what happens to me' than patients **without pain**.
	6	Patients **with anxiety** report higher scores on the item 'I can bear what happens to me' than patients **without anxiety**.
	7	Patients **with a depressed mood** report higher scores on the item 'I can bear what happens to me' than patients without a **depressed mood**.
	8	Patients that report higher scores on the item 'I can bear what happens to me' experience **less well-being** than patients that score lower on the item 'I can bear what happens to me'.
I can let my loved ones go	9	Patients **with anxiety** report higher scores on the item 'I can let my loved ones go' than patients **without anxiety**.
	10	Patients **with a depressed mood** report higher scores on the item 'I can let my loved ones go' than patients **without a depressed mood**.
	11	Patients that report higher scores on the item 'I can let my loved ones go' experience **less well-being** than patients that score lower on the item 'I can let my loved ones go'.
	12	Patients that have a **longer life expectancy** report higher scores on the item 'I can let my loved ones go' than patients that are **close to their impending death**.
I feel a sense of balance in my life	13	Patients **with pain** report higher scores on the item 'I feel a sense of balance in my life' than patients **without pain**.
	14	Patients **with anxiety** report higher scores on the item 'I feel a sense of balance in my life' than patients **without anxiety**.
	15	Patients **with a depressed mood** report higher scores on the item 'I feel a sense of balance in my life' than patients **without a depressed mood**.
	16	Patients that report higher scores on the item 'I feel a sense of balance in my life' experience **less well-being** than patients that score lower on the item 'I feel a sense of balance in my life'.
The thought about the end gives me peace of mind	17	Patients **with anxiety** report higher scores on the item 'The thought about the end gives me peace of mind' than patients **without anxiety**.
	18	Patients **with a depressed mood** report higher scores on the item 'The thought about the end gives me peace of mind' than patients **without a depressed mood**.
	19	Patients that report higher scores on the item 'The thought about the end gives me peace of mind' experience **less well-being** than patients that score lower on the item 'The thought about the end gives me peace of mind'.

Statistical analysis

Patient characteristics were summarized using descriptive statistics. For all hypotheses, except number 12, the first completed USD-4D per unique patient was selected for the analyses when more than one USD-4D per patient was present in the databases. For hypothesis 12, paired groups of USD-4D score were made per unique patient

consisting of the first completed USD-4D and a completed USD-4D within 2 weeks before the patient passed away.

Except for hypotheses considering the item "well-being", we compared groups based on low and high outcome scores. Literature did not deliver information on ideal cutoff points for no and severe symptom intensity.[23] We considered scores ≥6 as severe.[24-26] We compared the absence of a relevant symptom (score 0) to the prevalence of a severe symptom (score ≥6) using a Chi-squared test. In line with prior research, the item well-being was analysed as a continuous variable, since grouping this variable in the same way as other symptoms was considered non-informative. A non-parametric Mann-Whitney U test was employed to analyse hypotheses concerning this item. A Wilcoxon paired signed rank test was used to analyse hypothesis 12 considering paired groups of a first USD-4D and a USD-4D close to a patient's death.

Following the COSMIN methodology, construct validity of an item was established when ≥75% of the formulated hypotheses was confirmed.[15] A hypothesis was confirmed when tested significant with p ≤ 0.05. The statistical analyses were conducted using SPSS Statistics 26.[27]

Ethical issues

This study was conducted in accordance with the principles of the Declaration of Helsinki and the General Data Protection Regulation.[28, 29] This research was not considered subject to the Medical Research Involving Human Subjects Act by the institutional review board of the UMC Utrecht (18-499/C, July 2018).

RESULTS

897 patients completed at least one USD-4D in any given care setting. Table 2 summarizes the characteristics of these patients. Most patients, 75%, were part of the hospice cohort. Looking at all patients, 53% was female and 82% had cancer as their primary diagnosis.

As shown in tables 3 and 4, all hypotheses except for hypothesis 12 were confirmed. For every item ≥ 75% of the hypotheses was confirmed.

Table 2. Participants' characteristics

	Total		Madenco		MuSt-PC	
Patients, N (%)	897	(100.0)	676	(100.0)	221	(100.0)
Age, N (%)						
≤ 29 years	8	(.9)	8	(1.2)	0	(0.0)
30 – 45 years	21	(2.3)	13	(1.9)	8	(3.6)
46 – 67 years	274	(30.5)	188	(27.8)	86	(38.9)
68 – 80 years	316	(35.2)	236	(34.9)	80	(36.2)
≥ 81 years	269	(30.0)	225	(33.3)	44	(19.9)
Missing (%)	9	(1.0)	6	(.9)	3	(1.4)
Gender female – N (%)	473	(52.7)	374	(55.3)	99	(44.8)
Missing (%)	10	(1.1)	7	(1.0)	3	(1.4)
Philosophy of life, N (%)						
None	141	(15.7)	56	(8.3)	85	(38.5)
Religious	234	(26.1)	125	(18.5)	109	(49.3)
Spiritual	58	(6.5)	39	(5.8)	19	(8.6)
Non-practising	167	(18.6)	167	(24.7)	0	(0.0)
Unknown[a]	283	(31.5)	283	(41.9)	0	(0.0)
Missing (%)	14	(1.2)	6	(.9)	8	(3.6)
Diagnosis, N (%)						
Cancer	734	(81.8)	535	(79.1)	199[b]	(90.0)
Organ failure	62	(6.9)	48	(7.1)	14	(6.3)
Cancer + organ failure	38	(4.2)	26	(3.8)	9	(4.1)
Missing (%)	67	(7.5)	67	(9.9)	0	(0.0)
Performance score, N (%)						
Restricted activity	173	(19.3)	74	(10.9)	99	(44.8)
<50% of the day in bed	273	(30.4)	233	(34.5)	40	(18.1)
>50% of the day in bed	325	(36.2)	263	(38.9)	62	(28.1)
Completely disabled	70	(7.8)	56	(8.3)	14	(6.3)
Missing (%)	56	(6.2)	50	(7.4)	6	(2.7)
Location of care, N (%)						
At home	97	(10.8)	0	(0.0)	97	(43.9)
Hospital	31	(3.5)	0	(0.0)	31	(14.0)
Nursing home	2	(.2)	0	(0.0)	2	(.9)
Hospice	760	(84.7)	676	(100.0)	84	(38.0)
Other	3	(.3)	0	(0.0)	3	(1.4)
Missing (%)	4	(.4)	0	(0.0)	4	(1.8)

[a] In the hospice database this category reflects patients not knowing how to reflect on their philosophy of life. [b] Participants in the MuSt-PC study could indicate more than 1 disease; MuSt-PC and total numbers add up to >100%.

Table 3. Hypothesis testing of the social and spiritual items of the USD-4D – Pain, anxiety, depressed mood, and time to death.

		N	USD-4D score ≥6 N (%)		P-value
I take time for myself					
1	Severe pain (≥6)	131	30	(23)	.002[†]
	No pain (0)	327	37	(11)	
2	Severe anxiety (≥6)	91	33	(36)	<0.001[†]
	No anxiety (0)	501	60	(12)	
3	Severe depressed mood (≥6)	97	34	(35)	<0.001[†]
	No depressed mood (0)	442	41	(9)	
I can bear what happens to me					
5	Severe pain (≥6)	134	38	(28)	<0.001[†]
	No pain (0)	331	33	(10)	
6	Severe anxiety (≥6)	90	35	(39)	<0.001[†]
	No anxiety (0)	508	51	(10)	
7	Severe depressed mood (≥6)	99	45	(46)	<0.001[†]
	No depressed mood (0)	446	27	(6)	
I can let my loved ones go					
9	Severe anxiety (≥6)	91	58	(64)	<0.001[†]
	No anxiety (0)	490	207	(42)	
10	Severe depressed mood (≥6)	102	65	(64)	<0.001[†]
	No depressed mood (0)	426	180	(42)	
11	USD-4D ≤ 2 weeks before death	163	63	(39)	.076[‡]
	First USD-4D	163	72	(44)	
I feel a sense of balance in my life					
13	Severe pain (≥6)	127	40	(32)	<0.001[†]
	No pain (0)	316	39	(12)	
14	Severe anxiety (≥6)	88	39	(44)	<0.001[†]
	No anxiety (0)	483	60	(12)	
15	Severe depressed mood (≥6)	98	45	(46)	<0.001[†]
	No depressed mood (0)	423	44	(10)	
The thought about the end of life gives me peace of mind					
17	Severe anxiety (≥6)	57	34	(60)	<0.001[†]
	No anxiety (0)	290	95	(33)	
18	Severe depressed mood (≥6)	66	43	(65)	<0.001[†]
	No depressed mood (0)	252	78	(31)	
† Chi square ‡ Wilcoxon					

Table 4. Hypothesis testing of the social and spiritual items of the USD-4D – Well-being.

			Median well-being score [IQR]	P-value*
4	I take time for myself	score ≥6	5 [4-7]	<0.001
		score 0-5	3 [0-5]	
8	I can bear what happens to me	score ≥6	5 [4-7]	<0.001
		score 0-5	3 [1-5]	
12	I can let my loved ones go	score ≥6	4 [2-5]	0.041
		score 0-5	4 [1-5]	
16	I feel a sense of balance in my life	score ≥6	5 [3-6]	<0.001
		score 0-5	3 [1-5]	
19	The thought about the end of life gives me peace of mind	score ≥6	4 [2-5]	0.037
		score 0-5	4 [1-5]	
	* Mann Whitney U, *IQR interquartile range*			

Discussion

This is the first study to assess the construct validity of the social and spiritual items of the USD-4D in a population of Dutch patients in the palliative phase of their illness. The results of this study show that 18 of 19 hypotheses have been confirmed, and for every item ≥ 75% of hypotheses have been confirmed. Data were insufficient to draw conclusions for a population of Dutch patients in the palliative phase of their illness across all healthcare settings. Although the data suggest similar results could be found in the home care, hospital, and nursing home settings, the data had insufficient power to make any strong claims concerning these settings. Therefore, this paper concludes that construct validity of the social and spiritual items of the USD-4D was established for Dutch patients in the palliative phase in the hospice setting.

Results display that for the item 'I can let go of my loved ones' one hypothesis was rejected. As 75% of the hypotheses was confirmed, it is unlikely that the rejection of this hypothesis would hint towards lack of validity of this item. Since there was no literature suggesting a cut-off point after which patients might have less problems letting go of their loved ones, the research team settled on a period of 14 days prior to death. The turning point, however, might have occurred later in the process. Yet, there was little to no outcome data close to patients' death: patients do not fill in a USD-4D in their last days of life. Hence, lack of data might be the cause of the rejection of this hypothesis.

This study illustrates the challenges when assessing the construct validity of a PROM that does not measure one prespecified construct. Examples of PROMs that do measure one construct within social and spiritual care were given in the introduction of this paper. In contrasts to these PROMs, the social and spiritual items of the USD-4D are formulated in such a way that they offer the opportunity to be interpreted the way patients seem fit. Although patients interpret the social and spiritual items in their own way, these individual interpretations still fall within the pretended scope of the items.[8] Knowledge on the construct being measured is therefore fluid. This made formulating solid hypotheses challenging. Combining theoretical driven assumptions and expert opinion has proven to be feasible in formulating hypotheses.

Strengths and limitations

Due to the nature of the USD-4D it was impossible to formulate hypotheses solely based on research literature. However, formulating hypotheses based on both literature and multiprofessional collaboration of researchers and experts in the field of palliative care was considered a strength of this study. It warranted the most appropriate hypotheses for assessing the construct validity of the social and spiritual items of the USD-4D.

A limitation, as was mentioned before, was that the study population mainly comprised hospice patients who were of Dutch origin. Hence, it remains unclear how generalizable the results are to other settings. Looking at the study population, patients from the hospital and home care setting are underrepresented. When the USD-4D is to be used in these settings or any other new population, it should be validated again for this setting and target population.

Implications for clinical practice

Established construct validity of the social and spiritual items of the USD-4D could facilitate use of this PROM in clinical practice. This study shows these items measure what they intend to and that their outcomes are in line with

hypotheses. Results should not be interpreted to prove hypotheses or determine causality. The USD-4D is suitable for signaling, monitoring, and discussing patients' problems and needs concerning the social and spiritual dimensions.

There is no data on cutoff points signaling symptom intensity for the social and spiritual items and there will probably never be any. Personal differences and development of the disease process influence acceptance of symptom burden which affect outcome scores. Therefore, assumptions should never be made based solely on outcome scores. Hence, for the interpretation of the outcome scores, dialogue between patient and HCP is indispensable.

Implications for future research

This study focused on an autochthonous Dutch population of patients in the palliative phase of their illness. For the USD-4D to be adequately used in other cultures, future studies should focus on cross-cultural validity.

Moreover, validation should always be regarded as a continuous process. Future research should, therefore, employ the growing understanding of the constructs being measured and the growing body of empiric evidence to further validate the USD-4D in new situations, settings, and populations. Since validation of a measurement instrument cannot be regarded as separate from underlying theories also advocates for these underlying theories to be validated continuously.[12]

Conclusion

This study confirmed the construct validity on the social and spiritual items of the USD-4D for Dutch hospice patients in the palliative phase of their illness. Thus, the USD-4D measures that what it intends to measure. As such, the USD-4D supports signaling and monitoring social and spiritual symptoms and needs on an individual patient level which is a perquisite for patient-tailored care in day-to-day healthcare practice. Generalizability to other settings is challenging due to lack of patient outcome data from these settings.

1.   World Health Organization. Cancer-Fact sheet [Available from: https://www.who.int/en/news-room/fact-sheets/detail/cancer.

2.   Richardson A, Medina J, Brown V, Sitzia J. Patients' needs assessment in cancer care: a review of assessment tools. Support Care Cancer. 2007;15(10):1125-44 DOI: https://10.1007/s00520-006-0205-8.

3.   Tian L, Cao X, Feng X. Evaluation of psychometric properties of needs assessment tools in cancer patients: A systematic literature review. PLoS One. 2019;14(1):e0210242 DOI: https://10.1371/journal.pone.0210242.

4.   van der Baan FH, Koldenhof JJ, de Nijs EJ, Echteld MA, Zweers D, Hesselmann GM, et al. Validation of the Dutch version of the Edmonton Symptom Assessment System. Cancer Med. 2020;9(17):6111-21 DOI: https://10.1002/cam4.3253.

5.   IKNL. Meetinstrumenten: multidimensioneel 2017 [Available from: https://www.pallialine.nl/index.php?pagina=/richtlijn/item/pagina.php&id=41817&richtlijn_id=1078.

6.   Leget C. Art of Living, Art of Dying. Spiritual care for a good death. London/Philadelphia: Jessica Kingsley Publishers; 2017.

7.   Lormans T, de Graaf E, van de Geer J, van der Baan F, Leget C, Teunissen S. Toward a socio-spiritual approach? A mixed-methods systematic review on the social and spiritual needs of patients in the palliative phase of their illness. Palliat Med. 2021;35(6):1071-98 DOI: https://10.1177/02692163211010384.

8.   de Vries S, Lormans T, de Graaf E, Leget C, Teunissen S. The Content Validity of the Items Related to the Social and Spiritual Dimensions of the Utrecht Symptom Diary-4 Dimensional From a Patient's Perspective: A Qualitative Study. J Pain Symptom Manage. 2021;61(2):287-94 e2 DOI: https://10.1016/j.jpainsymman.2020.07.036.

9.   Damen A, Visser A, van Laarhoven HWM, Leget C, Raijmakers N, van Roij J, et al. Validation of the FACIT-Sp-12 in a Dutch cohort of patients with advanced cancer. Psychooncology. 2021;30(11):1930-8 DOI: https://10.1002/pon.5765.

10.   Snowden A, Telfer I. Patient Reported Outcome Measure of Spiritual Care as Delivered by Chaplains. J Health Care Chaplain. 2017;23(4):131-55 DOI: https://10.1080/08854726.2017.1279935.

11.   Büssing A, Recchia D, Koenig H, Baumann K, Frick E. Factor Structure of the Spiritual Needs Questionnaire (SpNQ) in Persons with Chronic Diseases, Elderly and Healthy Individuals. Religions. 2018;9(1) DOI: https://10.3390/rel9010013.

12.   de Vet HCW, Terwee CB, Mokkink LB, Knol DL. Validity. Measurement in Medicine: Cambridge University Press; 2011. p. 150-201.

13.   Von Elm E, Altman D, Emmer M, al. e. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Prev 2007;335(7624):806-8 DOI: https://10.1136/bmj.39335.541782.AD.

14.   Mokkink L, Terwee C, Patrick D, Alonso J, Stratford P, Knol D, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res. 2010;19(4):539-49 DOI: https://10.1007/s11136-010-9606-8.

15.   Prinsen CAC, Mokkink LB, Bouter LM, Alonso J, Patrick DL, De Vet HC, et al. COSMIN methodology for systematic reviews of Patient-Reported Outcome Measures (PROMs). Qual Life Res. 2018.

16.   Monod S, Brennan M, Rochat E, Martin E, Rochat S, Bula CJ. Instruments measuring spirituality in clinical research: a systematic review. J Gen Intern Med. 2011;26(11):1345-57 DOI: https://10.1007/s11606-011-1769-7.

17.   Sharma RK, Astrow AB, Texeira K, Sulmasy DP. The Spiritual Needs Assessment for Patients (SNAP): development and validation of a comprehensive instrument to assess unmet spiritual needs. J Pain Symptom Manage. 2012;44(1):44-51 DOI: https://10.1016/j.jpainsymman.2011.07.008.

18.   Siddall P, McIndoe L, Austin P, Wrigley P. The impact of pain on spiritual well-being in people with a spinal cord injury. Spinal Cord. 2017;55:105-11 DOI: https://1362-4393/17.

19. Aydin Yildirim T, Kes D. Relation between Coping with Pain & Spiritual Wellbeing in Chronic Pain Living Individuals. Soc Work Public Health. 2021:1-10 DOI: https://10.1080/19371918.2021.1991543.

20. Feng Y, Liu X, Lin T, Luo B, Mou Q, Ren J, et al. Exploring the relationship between spiritual well-being and death anxiety in patients with gynecological cancer: a cross-section study. BMC Palliat Care. 2021;20(1):78 DOI: https://10.1186/s12904-021-00778-3.

21. Musa AS, Pevalin DJ, Al Khalaileh MAA. Spiritual Well-Being, Depression, and Stress Among Hemodialysis Patients in Jordan. J Holist Nurs. 2018;36(4):354-65 DOI: https://10.1177/0898010117736686.

22. Agnieszka Bożek A, Nowak P, Blukacz M. The Relationship Between Spirituality, Health-Related Behavior, and Psychological Well-Being. Front Psychol. 2020;11(1997) DOI: https://10.3389/fpsyg.2020.01997.

23. Yamaguchi T, Morita T, Nitto A, Takahashi N, Miyamoto S, Nishie H, et al. Establishing Cutoff Points for Defining Symptom Severity Using the Edmonton Symptom Assessment System-Revised Japanese Version. J Pain Symptom Manage. 2016;51(2):292-7 DOI: https://10.1016/j.jpainsymman.2015.09.011.

24. Oldenmenger WH, de Raaf PJ, de Klerk C, van der Rijt CC. Cut points on 0-10 numeric rating scales for symptoms included in the Edmonton Symptom Assessment Scale in cancer patients: a systematic review. J Pain Symptom Manage. 2013;45(6):1083-93 DOI: https://10.1016/j.jpainsymman.2012.06.007.

25. Seow H, Sussman J, Martelli-Reid L, Pond G, Bainbridge D. Do high symptom scores trigger clinical actions? An audit after implementing electronic symptom screening. J Oncol Pract. 2012;8(6):e142-8 DOI: https://10.1200/JOP.2011.000525.

26. Selby D, Cascella A, Gardiner K. A single set of numerical cutpoints to define moderate and severe symptoms for the Edmonton Symptom Assessment System. J Pain Symptom Manage. 2010;39(2):241-49 DOI: https://10.1016/j.jpainsymman.2009.06.010.

27. IBM Corp. IBM SPSS Statistics for Windows, Version 26.0. Released 2019.

28. World Medical Organization. Declaration of Helsinki – ethical principles for medical research involving human subjects 2018 [Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

29. Shabani M, Borry P. Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation. Eur J Hum Genet. 2018;26(2):149-56 DOI: https://10.1038/s41431-017-0045-7.