




BMJ Open Protocol for EXICODE: the EXIstential health COhort DENmark – a register and survey study of adult Danes

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To cite: Stripp TK, Wehberg S, Büssing A, *et al.* Protocol for EXICODE: the EXIstential health COhort DENmark—a register and survey study of adult Danes. *BMJ Open* 2022;**12**:e058257. doi:10.1136/bmjopen-2021-058257

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-058257>).

Received 13 October 2021
Accepted 05 May 2022

ABSTRACT

Introduction We established the EXIstential health COhort DENmark (EXICODE) to examine how existential and spiritual needs, practices and orientations in a secular culture are linked to health outcomes, illness trajectory and overall cost of care in patients. Substantial literature demonstrates that existential and spiritual well-being has positive effects on health. While people turn to existential and spiritual orientations and practices during ageing, struggle with illness and approaching death, patients with severe illnesses like, for example, cancer similarly experience existential and spiritual needs. These needs are often unmet in secular societies leading to spiritual pain, unnecessary suffering, worse quality of life and higher medical costs of care.

Methods and analysis EXICODE is a national cohort comprising a 10% random sample of the adult Danish population with individual-level register and survey data. Specific patient subgroups are oversampled to ensure diseased respondents. The questionnaire used in the survey consists of a collection of validated instruments on existential and spiritual constructs suited for secular culture as well as some ad hoc questions compiled in the comprehensive EXICODE Questionnaire.

Ethics and dissemination The project is registered for legal and GDPR concerns by the University of Southern Denmark, journal number: 10.367. Ethical approval was not required by Danish law since EXICODE collects only interview, survey and register data, but due to institutional best-practice policy an ethical evaluation and approval were nevertheless obtained from the University of Southern Denmark Research Ethics Committee (institutional review board), journal number: 20/39546. The project follows The Danish Code of Conduct for Research Integrity and is carried out in accordance with the Helsinki Declaration. Results will be disseminated widely through publications in peer-reviewed scientific journals, international conferences, patient societies as well as mass and social media.

INTRODUCTION

People within secular cultures who suffer from serious illnesses experience existential and spiritual needs.¹ While many patients in general practice also have such needs and would like their doctor to inquire about

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study takes advantage of the comprehensive, valid and detailed longitudinal clinical and demographic information available in the Danish national registers that are based on administrative information established independently of the research questions.
- ⇒ The study is limited by the well-known risk for selection bias with the possibility of leaving out the most distressed, ill or low socioeconomic status patients, as well as low digital literacy participants as the survey is administered digitally.
- ⇒ Access to register data on non-responders will give the possibility to discuss results considering non-responder characteristics.
- ⇒ The combination of the questionnaire consisting of validated instruments on existential and spiritual constructs and the detailed longitudinal clinical and sociodemographic register data which can be linked at an individual level entails the possibility for an internationally unique, large, and high-quality cohort.

them, healthcare professionals rarely do.^{2–3} There are various reasons for this, one is a lack of knowledge on what effects existential and spiritual needs, engagement practices and orientations have in the secular culture and the implications of these for healthcare and cost of care.¹ Consequently, without the necessary knowledge to guide and back up societal and clinical policies, the administration of spiritual care is lacking.⁴ Being a highly secular country, this is also true for Denmark which has been called the least religious culture in the world.⁵ A culture in which 74% of the population are members of an organised church (the protestant Christian state church) that only 2% regularly visit.⁶ We established EXICODE to examine these relations to provide solid evidence on which to build clinical interventions, eHealth solutions and patient, relatives and



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healthcare professional support measures, which can aid in providing spiritual care.

Terminology

Since the field of faith and health is limited by a heterogeneous use of terms, a clarification of how EXICODE operationalises the concepts is in order.⁷ Various relevant frameworks could be used in this process, for example, the definitions used by Park, Breitbart, Folkman Schnell and others.^{8–11} In the manuscript ‘existential and spiritual’ (in Danish: *eksistentiel og ‘åndelig’*, not *‘spirituel’*) will be used to nominate the existential. Further, the definition by la Cour and Hvidt¹² of the term existential provides the framework of this manuscript as comprising three aspects of meaning-making, being: (1) religious, for example, related to specific religious connotation, community, theology, relation to God/higher power and so on; (2) spiritual, for example, often a more universal and subjective experience of the transcendent or salient/sacred features in the environment, with or without specific theology, and so on; or (3) secular, for example, related to personal values, meaning in life, relation to nature or other persons.^{12–13} The term ‘spiritual care’ refers to caring for existential and spiritual needs.¹⁴

EXICODE refers to EXistential health COhort DENmark, but the name bears more meaning than such. The project is also named thus as we are attempting to put the difficult to grasp constructs of existential and spiritual needs, orientations and practices on some sort of ‘code’—that we may address these issues and their impact on secular society quantitatively. This is done with the utmost respect that such concepts will for some people always remain larger than what may be embedded in even the most comprehensive survey.

Spirituality and health in secular culture

Links between religiosity, spirituality and health have been well established over the last decades.¹⁵ Generally, it has been shown that spiritual well-being, understood in terms of meaningfulness, hope, trust and coherence with a higher power, is a positive predictor of better physical, mental and social health including reduced morbidity, increased longevity, faster recovery and a happier life.¹⁵ Strong evidence from well-designed longitudinal studies supports that especially religious activity (ie, attendance)^{16–19} and meaningfulness and purpose in life²⁰ promotes various aspects of health. Spiritual needs or struggles may emerge from patients’ existential or spiritual convictions during a health crisis (or life crisis in healthy individuals).²¹ Also, people turn to existential and spiritual orientations and practices the more they age, struggle with illness or approach death.^{22–24} Some of these needs and struggles may be related to health impairment, well-being, depressive intention to escape from illness, and so on.^{25–30} A phenomenologically specific experience that may give rise to substantial spiritual needs, as it accompanies serious illness, is the near-death experience (NDE). Experienced in all cultures and throughout

all times, an NDE can be a life-changing event that may require professional support.³¹

Being diagnosed with cancer represents such a health crisis. North American studies with patients with cancer suggest that between 66% and 83% of patients want their physicians to inquire about religiosity or spiritual issues,^{2,32} and 21% of patients with cancer in a Danish study reported one or more ‘spiritual/religious concerns’.³³ In another Danish study among general practitioners, 45% of physicians reported that they addressed spiritual issues less than once a year or never.³ Conversely, spirituality has been found to be a positive resource in cancer coping, to be positively associated with quality of life, and to improve symptom tolerance in ageing populations with cancer.^{34–40} Also important to patients with cancer is spiritual well-being, which may explain some of the health-related quality of life above what can be ascribed solely to physical or mental health measures.⁴¹ Studies, also from Denmark, have even found spirituality to be associated with increased longevity and reduced risk of cancer.^{42–45} These findings have been replicated in various cultural settings.⁴⁶ It is noteworthy, that even in more secular European societies, spirituality is a relevant resource to cope with chronic and serious illnesses.^{47–58}

There is a large amount of research into various cardiac arrest survivor outcomes.^{59–64} However, there is limited knowledge about existential and spiritual needs related to surviving a cardiac arrest.⁶⁵ Research highlights the importance of attention to these needs.^{65–68} Many studies suggest that survivors have increased anxiety, depression and other psychological needs, and a comprehensive Danish study has shown an increased risk of suicide after cardiac arrest with successful resuscitation.^{69–70} Many patients with cardiovascular disease experience high levels of unfulfilled existential and spiritual needs, associated with poorer existential, mental, and physical well-being.⁷¹

Likewise, patients with chronic obstructive pulmonary disease (COPD), who suffer from dyspnoea as the major symptom, may have unmet spiritual needs. The risk of suffocation entails physical and psychological distress—distress that has been found to lead to existential and spiritual distress and prompt spiritual needs. Thus, a review regarding palliative and end-of-life care for patients with severe COPD identified spiritual care as one of the most neglected but important areas of care for COPD.^{72–73} A Danish study found similar spiritual needs in Danish patients with COPD. Existential or spiritual resources help patients with COPD cope with life and consider life valuable and beautiful, despite severe disease.⁷⁴ Nevertheless, patients with COPD across various cultural settings have few to talk to about spiritual issues, which may partly be due to stigma and a sense of self-blame.^{75–77}

While these tendencies pertaining to the links between health and existential, spiritual or religious aspects and care are relevant for patients with cancer, patients with COPD and cardiac arrest survivors, they may also be relevant to a much broader spectrum of patients. Such tendencies are similarly observed in patients with

chronic neurological diseases, for example, in patients with Alzheimer's disease^{78 79} and patients suffering from Huntington's disease, the latter having a relatively rapid decline compared with Alzheimer's disease and being rarer and ultimately lethal.⁸⁰

The pathophysiologic processes behind suffering from cancer, cardiac arrest or COPD are very different, resulting in different situations for the patient. Cancer diagnoses have very heterogeneous expressions, cardiac arrest is often a sudden event characterised among other things by the potential of (full) recovery (however, seldom recovery from the underlying cause), while COPD is a slowly progressing disease with no possibility of being cured, and with focus on coping, relief of symptoms and halting of disease progression. The latter may also be the case for some patients with cancer. Likewise, existential and spiritual needs and practices may also be very different across age groups.

Implications for secular Denmark

Secular societies are among other things characterised by a strong separation of church and state. This is also the case in Denmark where religion plays a minor role in public discourse and church attendance is unusually low.^{81–85} There are multiple reasons for this secularism of the Danish culture. In line with this, Danes consider 'faith and religion' to be the largest taboo just after 'mental illness'.⁸⁶ This attitude is reflected in the healthcare system with regards to the spiritual care administered. Health professionals are generally convinced existential, and spiritual resources have a positive impact on patients' health and handling of disease,^{87 88} just as they agree spiritual care should be administered.^{89 90} However, patients are largely not receiving such spiritual care.^{2 4 32 89–93} It is reasonable to expect that this is similar in other secular cultures as well. Studies from relatively more religious regions in North America show that palliative patients who experience low levels of existential and spiritual support have a lower quality of life, encounter more complications and higher overall medical care costs.^{94–96} Thus, a focus on alleviating existential and spiritual pain may embed a large financial potential for the health economy in secular cultures as well. Supporting researchers, clinicians and policymakers in providing existential and spiritual care for the patients and relatives in need of such, may also have a large impact on public health. The imaginable approaches and interventions are numerous, some already on their way. While in secular societies such as Denmark, the physical, psychological, and social aspects of health have for decades been utilised and exploited. With the proper evidence, perhaps it is time to invite existential and spiritual resources of patients and relatives to contribute to their health.

Objectives

This paper reports the protocol for EXICODE—the EXistential health COhort DENmark. The overall aim of the cohort is to examine existential and spiritual constructs

in the secular Danish setting and establish evidence on the links between existential and spiritual constructs of interest with clinical, economic and demographic variables.

METHODS AND ANALYSIS

Study design

EXICODE is designed as a national cohort based on register and survey data.

Registers

The Danish national health registers collect detailed administrative data on all Danish citizens, including sociodemographic data and data on healthcare utilisation, hospitalisation, medications used and so on.⁹⁷ All Danish citizens are registered in the Danish Civil Registration System (CRS) with a unique identification number enabling accurate linkage between registers at an individual level.⁹⁸

Participant selection and recruitment

All participants are identified through the CRS. Participants are a random selection of 10% of the adult (age >18 years) Danish population. Furthermore, to ensure diseased participation, three subsamples are invited: (1) patients with cancer diagnosed with either of the 10 most frequent cancer diagnosis groups in Denmark during 2020 (based on NORDCAN classification⁹⁹); (2) out-of-hospital cardiac arrest survivors (OHCAS) registered in 2016 through 2020; and (3) patients with COPD hospitalised for COPD in 2020 (table 1). Since timeliness of disease events is considered important with regards to the outcomes investigated, the latest available register data were sought. These diverse diagnosis categories are intended to contribute to nuanced understandings in the relation of health and existential needs as they span different age groups, disease progressions and severities and hope for a cure.

All participants are invited digitally via 'e-Boks' (a secure national online e-post service that most Danes utilise; a small portion of older Danes do not use e-Boks) through their Civil Registration System (CRS) number to participate and fill out a digital survey. e-Boks will automatically retain letters erroneously sent to CRS numbers of deceased individuals. The invitation letter includes information about how the individual was identified (thus, there are four slightly different letters), the study, information and legal notice on data management, consent to participate as well as a personal link to the questionnaire. e-Boks digital letters and the survey will be realised by Ramboll's SurveyXact, an online digital survey software.¹⁰⁰ Reminders will be sent after 3 weeks to non-responders. For respondents who agree to receive the questionnaire in the future, we will invite consecutive sampling at convenient time points. Due to institutional policy, no financial or lottery incitement will be provided.

Table 1 Yearly incident cases of the 10 most frequent cancer diagnoses, out-of-hospital cardiac arrest and COPD (hospitalised) in Denmark

	ICD-10	Men	Women	Total
Cancer (NORDCAN 2016)				
Colorectal	DC18–21	2904	2400	5304
Breast	DC50	46	4714	4760
Lung (including trachea)	DC33–34	2335	2367	4702
Prostate	DC61	4519	N/A	4519
Kidney, bladder and other urinary tract	DC65–68, DD09.0–1, DD30.1–9, DD41.1–9	2254	891	3145
Malignant melanoma of the skin	DC43	1220	1388	2608
Oesophagus, stomach, pancreas	DC15, DC16, DC25	1267	801	2068
Gynaecological	DC54, DC56.9, DC57.0–4	N/A	1862	1862
Brain and central nervous system	DC70–72, DC75.1–3, DD32–33, DD42–43	647	775	1422
Lip, oral and pharyngeal	DC00–14\DC10.1	711	298	1009
Total				31 399
Cardiac arrest (Danish Cardiac Arrest Register 2016)				
OHCA (30-day survival: 10.40%)	D146*	2230	1251	3481
COPD (Lash et al 2011)¹⁰⁶				
Mucopurulent bronchitis, chronic bronchitis, emphysema or COPD as primary diagnosis	J41–44* OR Primary: J96 + J13–18+Secondary: J41–44	~5980	~7020	~13 000
OR Pneumonia, respiratory insufficiency as primary with (J41–44) as secondary diagnosis				
COPD, chronic obstructive pulmonary disease; OHCA, out-of-hospital cardiac arrest.				

Population size

The sample size was selected to give sufficient power to detect subgroup differences. No formal sample size calculation was performed due to the various cohort outcomes examined. The sample of randomly selected adult Danes is estimated to contain around 460 000 individuals. The three subsamples also invited are estimated to contain approximately 40–50 000 patients with cancer, 20–25 000 patients with COPD and 2–2500 OHCAS. Unique CRS numbers are included. If any of the subsample participants are also drawn randomly in the 10% lot, they will only be included as subsample participants.

Eligibility

Inclusion is limited to adult (age ≥ 18 years) Danes with valid CRS numbers. Criteria for subgroup inclusion are relevant ICD-10 diagnoses (table 1). Participants are excluded if they are not alive at the time of data collection.

Data collection

The first wave of survey data was collected between the 1 November and 13 December 2021. Due to technical and feasibility reasons, 25% of the cohort was invited to participate. Register data were collected in January and February 2022.

Measurements

Questionnaire outcomes

The EXICODE Questionnaire totals six pages and includes seven internationally validated instruments, two subscales from validated instruments (table 2) and some ad hoc items tapping religious, spiritual, and existential affiliations and convictions.

The instruments are all suited for secular societies such as the Danish. The manuscript describing the selection of instruments, translation, cultural adaptation and qualitative pilot testing is in submission. However, results from this process indicated that the compiled questionnaire was comprehensible and that the digital design was feasible. We conducted a quantitative field test by convenience sampling to test the psychometric properties of instruments before distributing the EXICODE Questionnaire to the intended population.

Register outcomes

The Danish Health Data Authority (SDS), Statistics Denmark (DST) and the Danish Cardiac Arrest Register (DCAR) are data sources for independent register data outcomes (table 3) at individual levels coded by unique CRS numbers.

All register data will be pooled at DST's researcher server where data analysis will take place. Survey data

Table 2 The EXICODE Questionnaire

Instrument	Outcome	Items	Scoring	Item example
WHO-5 ¹⁰⁷	Well-being	5	6-point scale from '0—never' to '5—all the time'. Summed scores referred to 100% level.	<i>During the past two weeks... ...I have felt active and energetic.</i>
EQ-5D-5L ¹⁰⁸	Health status (five levels)	5	5-point scale of decreasing health status (1=good, 5=poor).	<i>Today... ...have you felt pain/discomfort?</i>
BMLSS ¹⁰⁹	Life and support satisfaction	18	7-point Likert scale from '0—very unsatisfied' to '7—very satisfied'. Score is mean ref. to a 100% level.	<i>How satisfied are you with... ...your family life?</i>
SpNQ ^{110 111}	Spiritual needs (four dimensions)	20	4-point scale from '0—not at all' to '3—very strong'. Scores are means per dimension.	<i>During the last month did you have the need... ...to be forgiven?</i>
SpREUK-P ¹¹² + GrAw-7 ¹¹³	Spiritual practices (four dimensions) + gratitude	25	4-point scale from '0—never' to '3—regularly'. Scores are means per dimension ref. to a 100% level.	<i>How often do you engage in the following: I meditate.</i>
AKU (RGH and escape subscales) ¹¹⁴	Adaptive coping (two dimensions)	8	5-point Likert scale from '0—does not apply' to '4—definitely applies'. Scores are means per dimension ref. to a 100% level.	<i>My faith is my foundation, even in difficult times.</i>
MAPS	Meaning and purpose (two dimensions)	6	6-point Likert scale from '0—don't agree' to '5—totally agree'.	<i>My life is meaningful.</i>
NDE-C ¹¹⁵	Near-death experience content (five dimensions)	20	5-point scale from '0—not at all' to '4—extreme'. Cut-off score of ≥ 37 is indicative of an NDE.	<i>You met a presence and/or an entity (ie, a deceased person).</i>
(S)FI ¹¹⁶	Human flourishing (five (six) dimensions)	12	Scored on 0–10 Visual Analogue Scale on different categories. Scores are means per dimension.	<i>How happy or unhappy do you usually feel?</i>

EXICODE, EXistential health COhort Denmark; NDE, near-death experience.

will be transferred to DST's researcher server from the University of Southern Denmark once collected. The cohort data construction is exemplified in [figure 1](#).

Patient and public involvement statement

The project is motivated based on previous studies and experiences with patients and public representatives. The project seeks to have a patient perspective as a central focus in all aspects of the research process. This process began by interviewing relevant end-users about their existential and spiritual needs, establishing the rationale and

content validity of the project aims. Public dissemination of results and project milestones is prioritised.

Statistical analysis plan

Various papers are expected from the cohort, and as such, the statistical analyses will be thoroughly described in each paper according to the relevant methods used. However, an overview of the major analytical approaches shall be outlined here. Multiple statistical approaches will be applied to both survey and register data according to the outcome data type

Table 3 Registries, tables and examples of register data variables

Register	Table	Examples of derived variables	Period (data collected yearly)
Statistics Denmark (DST)	Demographic	Civil status, family type, region, ethnicity, e/immigration, highest completed education, income, socio-economic status, work status and sick leave	1995–2020
	Clinical administrative outcomes	Date, diagnosis and type of healthcare service use in hospitals, out-patient clinic or general practitioners' clinic, Charlson Comorbidity Index	
	Municipal care	Home nursing, homecare	
Danish Health Data Authority (Sundhedsdatastyrelsen)	Drug use	ATC-codes, expiry date/price, volume, packages bought	1995–2020
	Clinical details on cancer patients	Date of diagnosis, ICD-10, TNM, treatment, NORDCAN-group	
	Rehabilitation	Date and type of rehabilitation training	
The Danish Cardiac Arrest Register (CAR)	Clinical details on cardiac arrest survivors	Date of arrest, heart-lung resuscitation done, first observed heart rhythm, status at arrival to the hospital	2016–2020

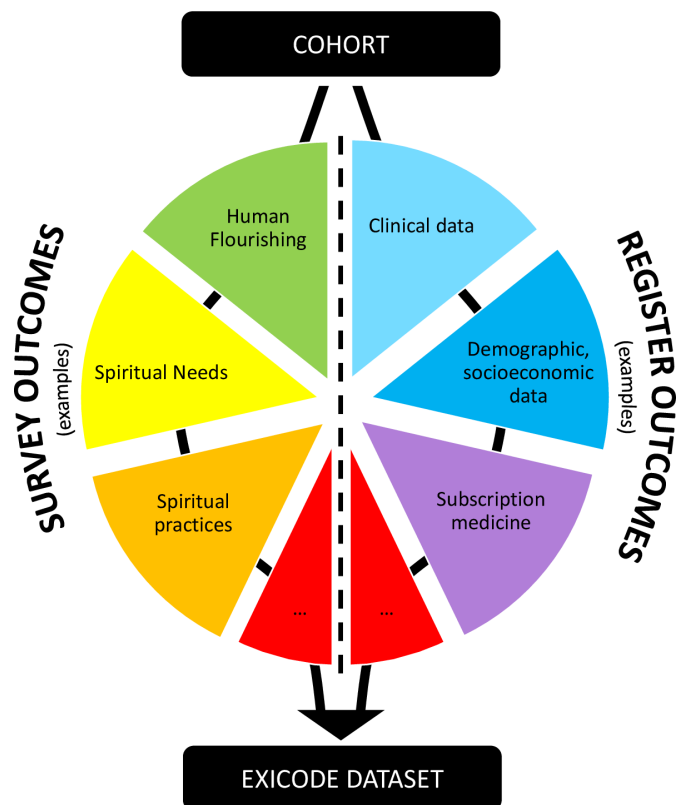


Figure 1 Exemplification of the data flow of survey and register variables.

(eg, continuous, binary, count, categorical). These approaches will primarily be regression modelling, structural equation modelling and causal mediation analysis. Responders will be presented using descriptive statistics. Responders/non-responders will be compared with a χ^2 -test based on gender, age, education, income, living status, region of living, work situation, marital status and comorbidity status to assess selection bias. The same covariates will serve in confounder control as well. Sensitivity analyses using e-values will be applied where applicable.¹⁰¹ In the digital survey, ‘validation rules’ were set up to avoid missing observations, that is, the respondent will have to answer each question before the software allows the respondent to move to the next page. Consequently, there will be no missing values internally in the survey dataset for responders who finish the questionnaire. However, it is expected that some participants drop off after having answered some of the questions (partial responders). Some missing values in the register data are expected. The survey responses of these participants will be included as ‘missings’.

Primary survey outcomes are spiritual needs, spiritual practices, well-being, health status, satisfaction with life and support, human flourishing, gratitude and awe and religious coping. These survey outcomes will be investigated with regression analysis with various register outcomes as explanatory factors, such as hospital admissions, medication use, mortality, visits

to a general practitioner or depression. Reverse regressions with the survey variables as explanatory factors for register outcomes may also be applied.

Subsamples of cases will be investigated in a matched setup where healthy Danes from the cohort will be matched to diseased subsample cases 1:5 based on age, gender, income, and educational level.

Health economic analyses will be conducted to investigate associations between the surveyed outcomes (eg, spiritual needs, spiritual practices, gratitude and awe etc) and register data variables proxying (1) healthcare cost, that is, prescribed medicine, use of healthcare services and so on; (2) loss of productivity, that is, sick leave, and so on and (3) social care costs, that is, home nursing and so on.

All statistical analyses will be carried out in STATA 16.0 or above with a significance level (α) of 5%.

Data management

A thorough data management plan has been prepared including a codebook on all outcomes. These are available on request. Although data will be FAIR,¹⁰² we will not be able to freely share all data collected in a repository due to legal and ethical limitations. Thus, we invite interested parties to reach out for collaborating projects on the data which will be available in EXICODE. The EXICODE questionnaire is available here: www.doi.org/10.5281/zenodo.6759958

ETHICS AND DISSEMINATION

Ethics and legal concerns

The project is registered for legal and GDPR concerns at the *University of Southern Denmark Legal Services* (SDU RIO), journal number: 10.367. The project has been evaluated by the *Danish Regional Scientific Ethical Committee*, journal number: 20202000-116, and the *Danish Authority for Patient Security* (STPS); these two institutions declared that the project did not require approval by Danish law due to EXICODE only collecting interview, survey, and register data and thus waived the applications. However, due to institutional best practices, the project was evaluated and approved by the institutional ethics review board *University of Southern Denmark Research Ethics Committee* (SDU REC), journal number: 20/39546. The project follows *The Danish Code of Conduct for Research Integrity*¹⁰³ and is carried out in accordance with the *Helsinki Declaration*.¹⁰⁴ The interviewers for the pilot test were well-trained in noticing unease on behalf of the interviewee. Some of the scripted probes in the cognitive interviews were addressing the burden/discomfort of filling out the questionnaire or unease emerging from answering for example, faith items. This is also the reason why we have obtained a rigorous ethical review of the protocol although it is not legally necessary to do so in a Danish context when conducting interviews

or surveys. Participant consent is obtained at participation, and data are handled according to Danish law.

Ethical approvals and development of the EXICODE Questionnaire began in May 2020. Access to register data has been delayed due to COVID-19.

Dissemination

The results of the project will be reported according to the Strengthening the Reporting of Observational Studies in Epidemiology statements,¹⁰⁵ and disseminated widely through publications in peer-reviewed scientific journals, international conferences, patient societies, mass and social media. A media strategy will be prepared together with publishers and funding organisations to increase public and academic reach. A website has been prepared for participants and other stakeholders to be able to follow the progress of EXICODE: www.sdu.dk/da/almenpraksis/exicode (currently only available in Danish).

Perspectives

EXICODE will be an internationally unique cohort with a large amount of data that are exceptionally rich and of high quality. The linkage of individual survey data to longitudinal register data represents a special opportunity for epidemiologic and public health research in the field of existential aspects and health in a secular culture. We anticipate that the project will establish the knowledge base on which to build future clinical interventions in secular countries like Denmark. The aim of such interventions should be to support patients and relatives in receiving existential and spiritual care, and to support healthcare professionals, such as oncologists, geriatricians and general practitioners among others, in providing such care.

We expect the results to translate into concrete interventions such as communication tools, communication courses with learning support measures, eHealth solutions and other patient support tools that can be included in healthcare practices—some of these interventions are already on the way. An interesting novel approach for the future would be to try and find meaningful ways to utilise artificial intelligence, Internet-of-Things (IoT) or computer-based learning to enhance and deliver spiritual care—a kind of care, which at the time of writing is predominantly provided through human interaction. The ultimate effects are expected to be reflected in a changed attitude to and practice of existential and spiritual care and patient-centred medicine. We believe that the project will have significant effects on patients, health professionals and the healthcare system in Denmark and similar secular countries.

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Contributors NCH, TKS and JS constructed the protocol and design. TKS made the first draft of this manuscript. NCH and JS contributed by a thorough evaluation and revising of the manuscript and all phases of the project. SW contributed with statistical advice and study design. SW, AB, LHJ, KA-R, FH and CBL contributed with a thorough evaluation of the design, method and manuscript. All authors accepted the final manuscript version.

Funding The work is supported by the Danish Cancer Society grant nr.: R247-A14755, The Jascha Foundation grant nr.: ID 3610, The Danish Lung Foundation grant nr.: not applicable, Academy of Geriatric Cancer Research (AgeCare) grant nr.: not applicable, and the University of Southern Denmark grant nr.: not applicable.

Disclaimer The funders had no influence on the design or methodology and will not have an influence on data collection or analysis.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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