

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Long-term physical and mental outcomes after out-of-hospital cardiac arrest– Protocol for a national cross-sectional survey of survivors and their relatives (the DANCAS survey)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-045668
Article Type:	Protocol
Date Submitted by the Author:	07-Oct-2020
Complete List of Authors:	Joshi, Vicky; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Tang, Lars; Slagelse Hospital, Department of Physiotherapy and Occupational Therapy; University of Southern Denmark, The Department of Regional Health Research Borregaard, Britt; Odense University Hospital, Department of Cardiology; University of Southern Denmark, Department of Clinical Research Zinckernagel, Line; University of Southern Denmark, National Institute of Public Health; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Mikkelsen, Tina; Odense University Hospital, REHPA, The Danish Knowledge Centre for Rehabilitation and Palliative Care Taylor, Rod; University of Glasgow, MRC/CSO Social and Public Health Sciences Unit & Robertson Centre for Biostatistics, Institute of Health and Well Being; University of Exeter, College of Medicine and Health Christiansen, Sofie; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Nielsen, Jørgen ; Regional Hospital Hammel Neurocenter; Aarhus University, Department of Clinical Medicine Zwisler, Ann Dorthe; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care; Odense University Hospital, Department of Cardiology
Keywords:	Adult cardiology < CARDIOLOGY, REHABILITATION MEDICINE, EPIDEMIOLOGY

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3
4 **Long-term physical and mental outcomes after out-of-hospital cardiac arrest– Protocol for**
5 **a national cross-sectional survey of survivors and their relatives (the DANCAS survey)**
6
7

8 Vicky L Joshi, PhD student¹ (victoria.louise.joshi@rsyd.dk)

9
10 Lars H Tang, Assistant professor^{2,3} (larta@regionsjaelland.dk)

11 Britt Borregaard, Post doc^{4,5} (britt.Borregaard@rsyd.dk)

12
13 Line Zinckernagel, PhD student^{1,6} (lizi@niph.dk)

14
15 Tina Broby Mikkelsen, Data manager¹ (tina.Broby.mikkelsen@rsyd.dk)

16
17 Rod S Taylor, Professor^{7,8} (rod.taylor@gla.ac.uk)

18 Sofie Raahauge Christiansen, researcher¹ (sofie.Raahauge.Christiansen@rsyd.dk)

19
20 Jørgen Feldbeck Nielsen, Professor⁹ (joerniel@rm.dk)

21
22 Ann-Dorthe Zwisler, Professor^{1,4} (ann.dorthe.olsen.zwisler@rsyd.dk)

23
24
25 ¹REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care, University of Southern
26 Denmark, and Odense University Hospital, Denmark

27
28 ²Department of Physiotherapy and Occupational Therapy, Næstved-Slagelse-Ringsted Hospitals

29
30 ³The Department of Regional Health Research, University of Southern Denmark

31
32 ⁴Department of Cardiology, Odense University Hospital, Odense, Denmark

33
34 ⁵Department of Clinical Research, University of Southern Denmark, Odense, Denmark

35
36 ⁶The National Institute for Public Health, University of Southern Denmark, Copenhagen, Denmark

37
38 ⁷MRC/CSO Social and Public Health Sciences Unit & Robertson Centre for Biostatistics, Institute of
39 Health and Well Being, University of Glasgow, UK

40
41 ⁸College of Medicine and Health, University of Exeter, UK

42
43 ⁹Hammel Neuro Center, Hospitalsenhed Midt, Viborg, Denmark

44
45 Corresponding author: Vicky L Joshi, address: Studiestræde 6, 1455 Copenhagen. email:
46 victoria.louise.joshi@rsyd.dk. Tel: +4550229798.
47
48

49
50 Word count abstract: 298

51
52 Word count manuscript: 3842

53
54 Key words: Out-of-hospital cardiac arrest survivor, relatives of out-of-hospital cardiac arrest
55 survivors, cross-sectional survey, self-report.
56
57
58
59
60

ABSTRACT

Introduction

The number of out-of-hospital cardiac arrest (OHCA) survivors is increasing. However, there remains limited knowledge on the long-term physical and mental problems suffered by survivors and their relatives. The aims of the DANCAS (DANish cardiac arrest survivorship) survey are to describe the prevalence of physical and mental problems, identify predictors associated with suffering them and to determine unmet rehabilitation needs in order to make recommendations on the timing and content of future rehabilitation interventions.

Methods and analysis

The DANCAS survey has a cross-sectional design involving a survey of OHCA survivors and their relatives. OHCA survivors will be identified through the Danish Cardiac Arrest Registry as having suffered an OHCA between 1st January 2016 and 31st December 2019. Each survivor will be asked to identify their closest relative to complete the relatives' survey. Contents of survivor survey: EQ-5D-5L, Hospital Anxiety and Depression Scale, Two Simple Questions, Modified Fatigue Impact Scale, 12-item World Health Organisation Disability Assessment Scale 2.0, Nordic Physical Activity Questionnaire Short, plus questions on unmet rehabilitation and information needs. Contents of relatives' survey: World Health Organisation-Five Well-Being Index, Informant Questionnaire on Cognitive Decline in the Elderly – Cardiac Arrest and the Modified Carer Strain Index. Self-report outcome data collected through the surveys will be enriched by data from Danish national registries including: demographic characteristics, circumstances of cardiac arrest and co-morbidities. The survey will be completed either electronically or by post December 2020-February 2021.

Ethics and dissemination

The study will be conducted in accordance with the Declaration of Helsinki. Surveys and registry-based research studies do not normally require ethical approval in Denmark. This has been confirmed for this study by the Region of Southern Denmark ethics committee (20192000_19). Results of the study will be disseminated via several peer-reviewed publications and will be presented at national and international conferences.

Article Summary

Strengths and limitations of this study:

- Denmark has markedly improved the survival rate among OHCA survivors during the last five years.
- This will be one of the largest nationwide surveys of OHCA survivors to date with data collected from survivors and relatives up to five-years after cardiac arrest.

- 1
2
3 -Data will be derived from both self-report measures and national registries providing a
4 comprehensive picture of the problems experienced by OHCA survivors and the risk factors
5 associated with suffering them.
6
7 -The response rate from OHCA survivors suffering from cognitive problems and/or fatigue may be
8 lower due to difficulties completing the survey compared to those without these problems to
9 counter this the survey will be available both electronically and on paper.
10
11 -The change in physical and mental problems over time may be influenced by a treatment cohort
12 effect and other unknown time-dependent modifying factors.
13
14
15
16
17

18 INTRODUCTION

19
20 The number of people surviving an out-of-hospital cardiac arrest (OHCA) is increasing every year due
21 to advances in pre-hospital and acute medical care.^{1 2} In Denmark, thirty-day survival after OHCA
22 improved from 4-16% between 2001 and 2018.³ This amounts to at least 800 new survivors every
23 year.³ Still, after the acute phase ends, the physical and mental impact of OHCA may continue.⁴ Most
24 OHCA survivors will have a new or ongoing cardiac condition.^{5 6} They may suffer from mental trauma
25 due to surviving a near-death experience.⁷ Further, reduced oxygen levels to the brain during an
26 OHCA can cause cognitive deficits in up to 50% of survivors.⁸⁻¹⁰ Due to this combination of factors,
27 OHCA survivors have been shown to suffer anxiety and depression, fatigue and reduced
28 participation in society.^{7 8 11 12} General health, return-to-work rates and quality of life do, however,
29 appear to improve over time¹³⁻¹⁵ but data regarding: health measures, return-to-work patterns and
30 unmet rehabilitation needs beyond 12-months after OHCA are limited.^{7 11 14 16 17}
31
32
33
34
35
36
37
38
39

40 As most OHCA occur in private homes, relatives are likely to witness the event.¹⁸ Combined with the
41 changes in both physical and mental status of many OHCA survivors, quality of life and mental health
42 among relatives might be influenced. It has previously been described how relatives of OHCA
43 survivors suffer from emotional problems including anxiety, depression and post-traumatic stress,
44 due to becoming a carer for their loved one or fear of the cardiac arrest recurring.^{19 20} Likewise, lack
45 of control, feelings of insecurity, mood and sleep disturbances have been reported among
46 relatives.^{21 22} Yet, very few research studies have investigated the consequences of OHCA for
47 relatives in the longer term,^{23 24} or how these are associated with witnessing the event or with the
48 physical, mental problems suffered by the OCHA survivor.
49
50
51
52
53
54

55
56
57 Rehabilitation for OHCA survivors is recommended in international guidelines^{4 25} but the specific
58 content and timing of these interventions has not been established. Survivors will commonly be
59
60

1
2 offered cardiac rehabilitation related to their new or ongoing cardiac condition,^{4 26} but it has been
3 suggested that the psychological and neurological rehabilitation needs of OHCA are not met to the
4 same degree.²⁷ Hence, the aims of this national cross-sectional study are to 1) describe the long-
5 term prevalence of physical and mental problems for OHCA survivors and their relatives 2) identify
6 predictors associated with increased risk of suffering these problems and 3) determine unmet
7 rehabilitation needs in order to make recommendations on the timing and content of future
8 rehabilitation interventions. Specific objectives for each aim will be defined in future publications.
9
10
11
12
13
14
15
16

17 **METHODS AND ANALYSIS**

18 **Study design**

19 The DANCAS (DANish Cardiac Arrest Survivorship) survey aims will be achieved through a cross-
20 sectional study design.
21
22
23
24

25 **Setting and participants**

26 In Denmark, pre-hospital care, hospital care and all cardiac treatment and rehabilitation are funded
27 via the tax system and are free of charge for patients. The Danish Out-of-Hospital Cardiac Arrest
28 (DHRCA) registry will be used to identify the Danish personal identification numbers of people who
29 have suffered an OHCA from 1st January 2016 to 31st December 2019 and were alive 30-days after
30 their cardiac arrest (figure 1). All patients in Denmark who have suffered an OHCA, where
31 bystanders or paramedics attempted treatment are included in the DHRCA registry. Data is recorded
32 electronically immediately after the OHCA in the pre-hospital patient record by paramedics from one
33 of the five regional ambulance services and collected in the DHRCA.
34
35
36
37
38
39
40
41

42 The DHRCA started collecting data in 2001, however, before 2016, this was recorded by hand on
43 paper and hence significant gaps in the data exist³. In addition, pre-hospital and medical
44 management of OHCA has changed significantly in the period 2001-2015.²⁸ Consequently, the
45 proposed timeframe of 1-5 years since OHCA provides both a long-term perspective and ensures
46 data is relevant to the contemporary OHCA survivor population.
47
48
49
50
51

52 The extracted Danish personal identification numbers will be matched by the Danish National Health
53 Digital Board to data in the Danish National Patient Registry to remove any people who have died,
54 and to retrieve names, and addresses.
55
56
57
58
59
60

1
2
3 The information letter received by the OHCA survivors will ask them to identify their closest relative
4 and ask them to complete the relatives' survey. This method of recruitment has been tested in the
5 development of the survey and is feasible. Closest relative is defined as a partner, spouse, sibling, or
6 parent that is closest to the survivor.
7
8
9

10 11 **Eligibility criteria**

12 OHCA survivor participants included in the survey will have a Danish personal identification number,
13 be alive at least ten-months post-cardiac arrest, resident in Denmark, over 18-years of age and able
14 to read and write in Danish and not protected from receiving inquiries during scientific surveys.
15
16
17

18
19 Relative participants must have a relative who has survived an OHCA, be over 18 years of age and be
20 able to read and write in Danish. The relatives do not need to have a Danish personal identification
21 number, as they will be invited to complete their survey via the information letter to the OHCA
22 survivor participants. However, they will be asked to provide their Danish personal identification
23 number to allow linkage with Danish national registries.
24
25
26
27
28

29 30 **Data collection**

31 All OHCA survivor participants that meet the eligibility criteria will receive an invitation to participate
32 in the survey via REDCap (Research Electronic Data Capture) software to their E-boks (government
33 electronic mail account) or via post if they do not have an E-boks address. Based on the age profile
34 of OHCA survivors over the last 5-years and the age-profile of Danes with E-boks addresses it is
35 estimated that 20% of participants will require a postal survey.
36
37
38
39
40

41 The invitation to participate will include a link for the relatives of the survivor to complete the
42 separate relatives' survey. Invitations via post will include a paper copy of both surveys, two
43 stamped addressed envelopes (for survivor and relative) and information on how to complete the
44 surveys online rather than by post if they wish. A participant information sheet will be included with
45 all invitations to participate in the survey. This will detail the purpose of the research study, how
46 data will be used and will explain that by returning the survey, they are consenting to take part. The
47 information sheet will include a telephone number to call a member of the research team if
48 participants have any questions. Participants who receive the E-boks survey will have the option to
49 request a paper survey by post. A reminder invitation will be sent via E-boks/post after two-weeks.
50
51
52
53
54
55
56
57

58 Additional data from the DHRCA will provide information on circumstances of the OHCA (Table 1).

59 Table. 1 Data on circumstances of OHCA from DHRCA
60

Table. 1 Data on circumstances of OHCA from DHRCA

Location of cardiac arrest (Private/public)

First observed heart rhythm (shockable/not shockable)

Cardiopulmonary resuscitation was given before the arrival of the ambulance (Yes/No)

Defibrillated before the arrival of the ambulance (Yes/No)

Time to return of spontaneous circulation (minutes:second)

Development of the DANCAS surveys

The outcome domains for the two DANCAS surveys were developed from a public and patient involvement (PPI) event held in Denmark²⁹ (see PPI section below) and from the outcomes identified as important by participants in the COSCA (core outcome set for cardiac arrest) initiative.³⁰ For each of these outcome domains, appropriate existing self-report outcome measures were chosen. For domains where no outcome measure existed, questions from other patient groups were adapted for OHCA survivors or new questions were developed.

The PPI group participants tested individual outcome measures for acceptability and face validity where there was more than one outcome measure available (for example, in the domain 'function and disability'). The PPI group also gave feedback on draft versions of the whole DANCAS surveys, and the participant information sheet. Feedback was received from eight survivors, three relatives, and three clinicians with experience of treating OHCA survivors and relatives. Based on this feedback, we reduced the number of questions, removed any outcome measures where the item content overlapped and improved the clarity of the participation information sheet.

Self-report outcome measures in the DANCAS surveys

Full details on the self-report outcome measures, scoring, and Danish translations can be found in the Supplementary data.

The following self-report outcome measures will be completed by OHCA survivors:

EQ-5D-5L: This is a six-item standardised instrument for measuring current health status.³¹ The questionnaire covers five-dimensions of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is divided into five-levels: no problems, slight, moderate, severe or extreme problems. The sixth-item, a Visual Analogue Scale, 0-100, allows the respondent to provide a self-rating of his or her health. A higher score signifies a better health status.

1
2
3
4 *Hospital Anxiety and Depression Scale (HADS):* The HADS consists of a seven-item subscale
5 measuring symptoms of anxiety (HADS-A) and a seven-item subscale measuring symptoms of
6 depression (HADS-D).³² Each item has a four-choice response, with scores ranging from 0 (no
7 symptoms) to 3 (maximum number of symptoms). The total scores on each subscale range from 0 to
8 21. A score of less than 8 indicates no psychological distress, 8 to 10 mild psychological distress and
9 over 10 definite psychological distress. It has recently been shown to be a valid measure of anxiety
10 and depression in a Danish cardiac disease population.³³
11
12
13
14
15
16

17
18 *Two Simple Questions (TSQ):* Consists of three-items. Developed to assess the survivor's own
19 perception of mental recovery and dependency in daily activities after cardiac arrest.^{34 35}
20
21

22
23 *Modified Fatigue Impact Scale (MFIS):* The MFIS assesses impact of fatigue on performance of
24 functional activities and consists of 21-items in three-sub-scales (physical, cognitive and
25 psychosocial). Total scores range from 0 to 84 with a score of 30 or more signifying a fatigued
26 individual. It has been validated in people with multiple sclerosis and traumatic brain injury.^{36 37}
27
28
29

30
31 *12-item World Health Organisation Disability Assessment Schedule 2.0 (12-item WHO DAS 2.0):* This
32 assesses disability and functioning in the prior month on six adult life tasks. There are twelve-items
33 scored from 0=no difficulty to 4=extreme difficulty, total score 0 to 48 with higher scores indicating
34 greater difficulty. Used extensively to research rehabilitation and disability in a wide range of disease
35 populations³⁸ and validated in patients with chronic diseases³⁹ including traumatic brain injury.⁴⁰
36
37
38
39

40
41 *The Nordic Physical Activity Questionnaire Short (NPAQ-Short):*

42 The NPAQ-short assesses whether WHO recommendations on weekly exercise are met⁴¹.
43 Participants under 65 years of age are asked if they are physically active at a moderate-to-high
44 intensity (≥ 30 minutes a day) and at physically active at a high-level for ≥ 20 minutes twice a week.
45 Participants over 65 years of age are asked about being physically active ≥ 30 minutes a day, and if
46 they undertake strength or balance training. It has been found to be sufficiently reliable and valid to
47 monitor physical activity levels in a Danish population.⁴¹
48
49
50
51
52

53
54 *REHPA scale:* A linear analogue self-assessment scale, where participants indicate how close they are
55 to living the life they desire after their OHCA, indicating rehabilitation need. The scale is rated
56 between 0 (goal reached) to 9 (infinitely far from).
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Questions on unmet rehabilitation needs have been adapted from the Danish Cancer Society questionnaire 'The experiences of cancer patients during diagnosis and treatment'.^{42 43}. Participants are asked if they received the help they needed after their cardiac arrest in 6 areas: emotional reactions, cognitive problems, physical activity, peer-support and family (supplementary data). Questions on unmet information needs after cardiac arrest were adapted from a questionnaire evaluating experiences of healthcare quality in Denmark among patients with heart disease.⁴⁴ Participants are asked if they felt informed after their cardiac arrest on seven subjects: treatment of heart condition, medication for heart condition, emotional reaction, cognitive problems, physical activity, return-to-work and impact on family.

In addition to the HADS, the relatives' survey includes:

World Health Organisation Five Well-Being Index: The WHO-5 is a self-report measure of current mental well-being⁴⁵ that has been shown to be a valid tool across a wide range of study fields.⁴⁶ The tool consists of five statements with six responses on a scale from 'At no time' to 'All of the time' scoring 0-5. Scores are totaled and multiplied by 4 with 0 representing the worst imaginable well-being and 100 representing the best imaginable well-being. The WHO-5 was chosen as a generic global measure of health for the survey, as opposed to using the EQ-5D-5L as in the OHCA survivor survey. This choice was based on feedback from a PPI workshop asking relatives to fill-in and provide feedback on individual questionnaires. The relatives felt the EQ-5D-5L was about medical problems and was for their relative (who had suffered the OHCA) to complete and they were unsure how to answer the questions. Conversely, they understood why the WHO-5 might be relevant to their life situation and felt able to complete it.

The Informant Questionnaire on Cognitive Decline in the Elderly – Cardiac Arrest (IQCODE-CA): This is a modified version of the observer-reported questionnaire designed to measure global cognitive decline in the dementia population.⁴⁷ Informants, defined as relatives or close friends are requested to compare current cognitive function with pre-cardiac arrest cognitive function. The tool contains 26-items scored on a five-point scale with higher scores indicating greater impairment. It has been shown to identify cardiac arrest survivors with possible cognitive problems.⁴⁷

Modified carer strain index (MCSI): This is a self-reported questionnaire that screens for caregiver strain in long-term caregivers.⁴⁸ The tool has 13 questions scoring 2 points for 'yes', 1 point for 'sometimes' and 0 for 'no'. Scores range from 26-0 with higher scores indicating a higher level of caregiver strain. The MCSI has been found to be easily administered and a reliable test of strain in an informal caregiver population.⁴⁸

1
2
3
4 Further, one question derived from the Danish National Health Survey 2017⁴⁹ on loneliness and four
5 questions on support received in the post-cardiac arrest period (created for this survey,
6 supplementary data). Seven questions on educational level, labour market status and sick leave are
7 also asked in the relatives section as their survey answers can only be connected to Danish labour
8 market registry data if relatives choose to provide their Danish personal identification number in
9 their survey response.
10
11
12
13
14
15

16 **Data enrichment from registries**

17
18 Following data collection via the two surveys, data enrichment will occur via Danish national
19 registries for both survivors and relatives. The Danish Civil Registration System will provide gender,
20 age and marital status. The Danish Education Register:⁵⁰ education level and the Danish Register on
21 personal income⁵¹: income.
22
23
24
25

26
27 The Danish National Patient Register,⁵² provides data on 19 selected somatic co-morbidities scored
28 on a 3-point scale. This data will be used to calculate the Charlson Comorbidity Index,⁵³ based on the
29 10 years previous to the date of the surveys. The Charlson Comorbidity Index has three categories:
30 0, 1-2 and ≥ 3 . This registry will also provide data on hospital admissions and healthcare use for the
31 potential sub-study on societal costs after surviving OHCA.
32
33
34
35

36
37 Current and pre-OHCA employment status for the working-age population will be obtained from the
38 Danish Register for Evaluation of Marginalization.(DREAM)⁵⁴ Participants who are not on any social
39 benefits or participants who are on State Education Fund grants, maternity leave pay, or leave-of-
40 absence schemes will be classified as being part of the workforce.⁵⁵ Accordingly, patients receiving
41 unemployment benefits, being on paid sick leave, on early retirement payment or disability pension
42 will be defined as being on social benefits. Pre-OHCA employment status will be assessed in a 5-
43 week span before cardiac arrest to classify patients as either working or receiving social benefits.
44
45
46
47
48
49

50 Information from the DHRCA and other national registries will be collected for all eligible study
51 participants both responders and non-responders to the survey (figure 1).
52
53
54

55 **Data handling and record-keeping**

56
57 The study has been registered on the Region of Southern Denmark's record of data processing
58 activities (19/8559). A license agreement has been made with Odense Patient Data Explorative
59
60

1
2
3 Network (OPEN) (OP_843) to establish the REDCap system, secure data storage, data analysis and
4 data linkage with national registries. REDCap will be used to import Danish personal identification
5 numbers for survey distribution via E-boks. Postal surveys received will be scanned, and the data
6 imported into REDCap and destroyed.
7
8

9 10 11 **Sample size considerations**

12 Each year approximately 800 people are alive 30-days after surviving an OHCA in Denmark.³ Hence,
13 we estimate the survey will be sent to approximately n=3200 survivors. Based on similar studies in
14 heart diseases,^{17 56} we are assuming a 20% (n=640) loss due to a person having moved out of
15 Denmark, being protected from inquiries or having died,¹⁶ and a response rate of 60%. Hence, the
16 estimated total study population would be approximately n= 1540 OHCA survivors with
17 approximately n=380 in each of the four time interval groups. The response rate to the relatives'
18 survey is likely to be less as not all survivors will have a relative able to complete the survey. Hence,
19 estimated 50% (1200) of relatives will respond and 50% (600) of responders will provide CPR
20 numbers.
21
22
23
24
25
26
27
28
29

30 **Planned analysis**

31 Continuous data will be checked for normality and described as mean and standard deviation (SD) or
32 median with 25th and 75th quartiles [IQR, interquartile range], as appropriate. Categorical variables
33 will be described as number and frequencies (n (%)). To investigate changes over time, participants
34 will be stratified into four groups: those suffering an OHCA in 2016, 2017, 2018 and 2019 (figure 2).
35 Differences in the prevalence of self-report problems between the groups will be determined by Chi-
36 squared test or Fisher's Exact test as appropriate. The OHCA survivor and relatives' surveys will be
37 linked via a unique identifying number to discover if associations exist between each groups' self-
38 report outcomes.
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Predictors of physical and mental problems will be identified from self-report outcomes,
demographic characteristics, circumstances of OHCA and unmet rehabilitation/information needs
using univariate binary logistic regression. All univariate predictors with p<0.10 will be entered into a
multivariate binary logistic regression, with description of odds ratios or β and 95% confidence
intervals. In all regression analyses, both crude and adjusted models will be presented. Level of
statistical significance will be set at p<0.05.

1
2
3 A potential sub-study is planned to calculate the total societal costs (healthcare costs and
4 absenteeism from work) of surviving OHCA using the EQ-5D-5L data and registry data (National
5 Prescription Registry,⁵⁷ and DREAM database).
6
7
8

9 **Ethics and dissemination**

10 The study will be conducted in accordance with the Declaration of Helsinki. Surveys and registry-
11 based research studies do not normally require ethical approval in Denmark. This has been
12 confirmed for this study by the Region of Southern Denmark ethics committee (20192000_19).
13 Participants will be informed about the study via the participant information sheet. Consent to
14 participate will be implied through the return of the completed survey.
15
16
17
18

19
20
21 Results of the study will be disseminated via several peer-reviewed publications and will be
22 presented at national and international conferences. The results of the proposed study will be
23 reported with reference to the international statement in the Strengthening the Reporting of
24 Observational studies in Epidemiology (STROBE) checklist for cross-sectional studies⁵⁸. Health
25 professionals will be informed of the study results through professional literature via new national
26 clinical guidelines on rehabilitation after OHCA. Finally, the survey is part of a larger project on
27 rehabilitation after surviving a cardiac arrest and all results, including the survey results, will be
28 presented at a project-closing event to which all participants, stakeholders and interested parties
29 will be invited.
30
31
32
33
34
35
36
37

38 **Patient and public involvement**

39 The themes for the survey were developed from a PPI event involving OHCA survivors, relatives and
40 clinicians.²⁹ A further group of survivors and relatives have helped to develop the survey by testing
41 individual questionnaires and by providing feedback on the whole survey. At the end of the study,
42 the research advisory group and PPI group will discuss and comment on the findings and contribute
43 to how the results will be disseminated and implemented in the next stage of the research.
44
45
46
47
48
49

50 **Discussion**

51
52
53 Recovery after OHCA can be complicated by a new or ongoing cardiac condition, mental trauma
54 from surviving a near-death experience or possible anoxic brain injury. Small scale, short term
55 studies suggest these complications can lead to an increased mental and physical burden for both
56 survivors and their relatives. However, little is known about the long-term prevalence of physical
57 and mental problems or who is at most risk of developing them. Rehabilitation has been
58
59
60

1
2 recommended to meet the secondary physical and mental consequences of OHCA but more
3 knowledge is needed including establishing the perceived unmet rehabilitation and information
4 needs from OHCA survivors and their relatives themselves.
5
6
7
8

9 The results from this study will be used to identify the most prevalent problems suffered by OHCA
10 survivors and their families and those at most risk of suffering them. This will allow researchers and
11 managers within the Danish healthcare system to design assessment tools to ensure problems are
12 detected early after OHCA, and survivors and relatives are offered rehabilitation plans tailored to
13 their needs. Further, currently there are few high quality studies investigating the effectiveness of
14 rehabilitation interventions for OHCA survivors. Results from the DANCAS survey will provide
15 researchers with specific information to design the content and timing of new rehabilitation
16 interventions for OHCA survivors and their relatives.
17
18
19
20
21
22
23

24 Although this study will be one of the largest surveys involving OHCA survivors and one of the first to
25 survey both survivors and relatives, with the ability to link between the two, there are several
26 potential limitations. The majority of the self-report questionnaires have undergone some validation
27 testing. However, not all these tools have been validated in Danish or in the OHCA survivor
28 population and some questions have been written specifically for this survey (see supplementary
29 data).
30
31
32
33
34
35

36 The survey uses questionnaires based on self-report. However, approximately 50% of OHCA
37 survivors suffer from cognitive deficits and/or fatigue, leading to difficulties completing the survey
38 and hence potentially a lower response rate from survivors with these problems. To counter this,
39 the survey will be available both electronically and on paper, survivors will be allowed to have help to
40 complete the survey and asked to state if they had help. In addition, the relatives' section of the
41 survey will include an observer-reported cognitive questionnaire and relatives will be asked to
42 complete this even if the survivor questionnaire is not completed. However, it remains possible that
43 those with cognitive deficits and/or fatigue will be underrepresented in the survey response group
44 and this has to be accepted as a limitation of the self-report method chosen to gain data from as
45 many OHCA survivors as possible. Surveys will only be received by OHCA survivors able to access
46 Eboks or living at home, so we are very unlikely to receive responses from any survivor living in long-
47 term residential care. Further, the DHRCA only records OHCA and therefore people who have
48 suffered an in-hospital cardiac arrest will not be included in this study.
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 One aim of the survey is to describe how the prevalence of physical and mental problems suffered
4 by survivors and their relatives changes over time since OHCA. Ideally, this would be investigated
5 using a prospective longitudinal study with data from the same population at multiple follow-up
6 points. The disadvantage of this design is the results would not be available for five-years, and
7 participants are asked to complete multiple surveys. The design of our survey groups participants
8 dependent on time since OHCA to describe changes over time. However, as these are not the same
9 participants in each time interval group, there is a risk of an unknown time-dependent confounding
10 factor effecting one of the groups more than another. Further, the cross-sectional design, by
11 definition, does not allow the formation of solid conclusions but the generation of hypotheses based
12 on associations between variables.
13
14
15
16
17
18
19
20
21
22

23 **Acknowledgements**

24 We would like to thank the member of the DANCAS network for their support in designing this
25 study: (Anette Marianne Fedder, Anette Rasmussen, Bo Gregers Winkel, Camilla Kofoed Dichman,
26 Charlotte Brun Thorup, Christian Hassager, Christina Marr Andersen, Elin Petersen, Frank Humle,
27 Hanne Balle, Hanne Kruise Rasmusen, Hanne Skovgaard Petersen, Helle Westberg, Irene Hallas,
28 Jens-Jakob Eifer Møller, Jette Nørr Møllebjerg, Jørgen Feldbeck Nielsen, Klaus Nikolaisen, Lars
29 Thrysoe, Lene Mønsted Nielsen, Lisa Gregersen Østergaard, Lone Andersen, Malene Hollingdal,
30 Malene Missel, Mette Stougaard, Mette Wagner, Mogens Hørder, Morten Jensen, Nina Rottmann,
31 Rikke Mols, Rikke Tornfeldt Martens, Steen Pehrson, Susanne Budin Holst, Susanne S Pedersen, Tina
32 L.B. Andersen, Dorte Qvistgaard).
33
34
35
36
37
38

39 LHT is currently funded by a grant from the Danish Regions and The Danish Health Confederation
40 through the Development and Research Fund for financial support (project nr. 2703) and a grant
41 from Region Zealand, Denmark (Exercise First).
42
43
44
45

46 **Author contributions** VJ, LHT and ADZ conceived the study; VJ and LHT designed the study with ADZ,
47 BB, LZ, TMB, RS, SRC and JFN. VJ led the writing of the manuscript, which was revised by all authors.
48 The final manuscript was approved by all authors.
49
50
51

52 **Funding** This project will be supported by infrastructure provided by REHPA, Danish Knowledge
53 Centre for Rehabilitation and Palliative Care, University of Southern Denmark.
54

55 This study is part of a PhD partially funded by the University of Southern Denmark and the Region of
56 Southern Denmark, which receive funding from the Danish Government.
57
58
59
60

1
2
3 **Competing interests** None declared
4
5

6 **Patient consent** Not required
7
8

9 **Data statement:** Within the boundaries of Danish legislation, the anonymised data from the study
10 will be available for other researchers upon reasonable request when the results have been
11 published.
12
13
14

15
16 **Figure legends:**
17

18
19 Figure 1. Flow chart of Survey Population
20
21

22 Figure 2. Design of DANCAS survey and grouping according to time since OHCA
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

REFERENCES

1. Wissenberg M, Lippert FK, Folke F, et al. Association of national initiatives to improve cardiac arrest management with rates of bystander intervention and patient survival after out-of-hospital cardiac arrest. *JAMA* 2013;310(13):1377-84. doi: 10.1001/jama.2013.278483
2. Berdowski J, Berg RA, Tijssen JGP, et al. Global incidences of out-of-hospital cardiac arrest and survival rates: Systematic review of 67 prospective studies. *Resuscitation* 2010;81(11):1479-87. doi: 10.1016/j.resuscitation.2010.08.006
3. Ringgren KB, Christensen HC, Schønau L, et al. Out of hospital cardiac arrest in Denmark 2018. *Danish Cardiac Arrest Registry*
4. Sawyer KN, Camp-Rogers TR, Kotini-Shah P, et al. Sudden Cardiac Arrest Survivorship: A Scientific Statement From the American Heart Association. *Circulation* 2020;141(12):e654-e85. doi: 10.1161/CIR.0000000000000747 [published Online First: 2020/02/23]
5. Andrew E, Nehme Z, Wolfe R, et al. Long-term survival following out-of-hospital cardiac arrest. *Heart* 2017;103(14):1104-10. doi: 10.1136/heartjnl-2016-310485
6. Hawkes C, Booth S, Ji C, et al. Epidemiology and outcomes from out-of-hospital cardiac arrests in England. *Resuscitation* 2017;110:133-40. doi: 10.1016/j.resuscitation.2016.10.030
7. Schaaf KPW, Artman LK, Peberdy MA, et al. Anxiety, depression, and PTSD following cardiac arrest: A systematic review of the literature. *Resuscitation* 2013;84(7):873-77. doi: 10.1016/j.resuscitation.2012.11.021
8. Lilja G. Follow-Up of Cardiac Arrest Survivors: Why, How, and When? A Practical Approach. *Seminars in Neurology* 2017;37(1):88-93. doi: {10.1055/5-0036-1593859}
9. Maciel CB, Barden MM, Greer DM. Neurologic Recovery After Cardiac Arrest: a Multifaceted Puzzle Requiring Comprehensive Coordinated Care. *Current treatment options in cardiovascular medicine* 2017;19(7):52. doi: 10.1007/s11936-017-0548-0
10. Cronberg T, Greer DM, Lilja G, et al. Brain injury after cardiac arrest: from prognostication of comatose patients to rehabilitation. *The Lancet Neurology* 2020;19(7):611-22. doi: 10.1016/s1474-4422(20)30117-4
11. Lilja G, Nielsen N, Bro-Jeppesen J, et al. Return to Work and Participation in Society After Out-of-Hospital Cardiac Arrest. *Circulation: Cardiovascular Quality and Outcomes* 2018;11(1) doi: {10.1161/CIRCOUTCOMES.117.003566}
12. Kim YJ, Rogers JC, Raina KD, et al. An intervention for cardiac arrest survivors with chronic fatigue: A feasibility study with preliminary outcomes. *Resuscitation* 2016;105:109-15. doi: 10.1016/j.resuscitation.2016.05.020
13. Elliott VJ, Rodgers DL, Brett SJ. Systematic review of quality of life and other patient-centred outcomes after cardiac arrest survival. *Resuscitation* 2011;82(3):247-56. doi: 10.1016/j.resuscitation.2010.10.030
14. Kragholm K, Wissenberg M, Mortensen RN, et al. Return to Work in Out-of-Hospital Cardiac Arrest Survivors: A Nationwide Register-Based Follow-Up Study. *Circulation* 2015;131(19):1682-90. doi: 10.1161/CIRCULATIONAHA.114.011366
15. Viktorissov A, Sunnerhagen KS, Johansson D, et al. One-year longitudinal study of psychological distress and self-assessed health in survivors of out-of-hospital cardiac arrest. *BMJ Open* 2019;9(7):e029756. doi: 10.1136/bmjopen-2019-029756 [published Online First: 2019/07/06]
16. Caro-Codon J, Rey JR, Lopez-de-Sa E, et al. Long-term neurological outcomes in out-of-hospital cardiac arrest patients treated with targeted-temperature management. *Resuscitation* 2018;133:33-39. doi: 10.1016/j.resuscitation.2018.09.015 [published Online First: 2018/09/27]
17. Viktorissov A, Sunnerhagen KS, Pöder U, et al. Well-being among survivors of out-of-hospital cardiac arrest: a cross-sectional retrospective study in Sweden. *BMJ Open* 2018;8(6):e021729. doi: 10.1136/bmjopen-2018-021729

18. Ann-Britt T, Ella D, Johan H, et al. Spouses' experiences of a cardiac arrest at home: an interview study. *Eur J Cardiovasc Nurs* 2010;9(3):161-7. doi: 10.1016/j.ejcnurse.2009.12.005 [published Online First: 2010/01/15]
19. Wallin E, Larsson I-M, Rubertsson S, et al. Relatives' experiences of everyday life six months after hypothermia treatment of a significant others cardiac arrest. *Journal of Clinical Nursing* 2013;22(11-12):1639-46. doi: {10.1111/jocn.12112}
20. Moolaert VR, Verbunt JA, Bakx WG, et al. Stand still ... , and move on; a new early intervention service for cardiac arrest survivors and their caregivers: rationale and description of the intervention. *Clinical rehabilitation* 2011;25(10):867-79. doi: 10.1177/0269215511399937
21. van Wijnen HG, Rasquin SM, van Heugten CM, et al. The impact of cardiac arrest on the long-term wellbeing and caregiver burden of family caregivers: a prospective cohort study. *Clinical rehabilitation* 2017;31(9):1267-75. doi: 10.1177/0269215516686155
22. Holm MS, Norekval TM, Falun N, et al. Partners' ambivalence towards cardiac arrest and hypothermia treatment: a qualitative study. *Nurs Crit Care* 2012;17(5):231-8. doi: 10.1111/j.1478-5153.2012.00490.x [published Online First: 2012/08/18]
23. Haywood K, Dainty KN. Life after cardiac arrest: The importance of engaging with the 'forgotten patient'. *Resuscitation* 2018;128:A1-A2. doi: 10.1016/j.resuscitation.2018.04.034 [published Online First: 2018/05/05]
24. Van't Wout Hofland J, Moolaert V, van Heugten C, et al. Long-term quality of life of caregivers of cardiac arrest survivors and the impact of witnessing a cardiac event of a close relative. *Resuscitation* 2018;128:198-203. doi: 10.1016/j.resuscitation.2018.03.016 [published Online First: 2018/03/24]
25. Nolan JP, Soar J, Cariou A, et al. European Resuscitation Council and European Society of Intensive Care Medicine 2015 guidelines for post-resuscitation care. *Intensive care medicine* 2015;41(12):2039-56. doi: {10.1007/s00134-015-4051-3}
26. Tang LH, Joshi V, Egholm CL, et al. Are survivors of cardiac arrest provided with standard cardiac rehabilitation? - Results from a national survey of hospitals and municipalities in Denmark. *Eur J Cardiovasc Nurs* 2020;1474515120946313. doi: 10.1177/1474515120946313 [published Online First: 2020/08/05]
27. Boyce LW, Goossens PH, Moolaert VR, et al. Out-of-hospital cardiac arrest survivors need both cardiological and neurological rehabilitation! *Current opinion in critical care* 2019;25(3):240-43. doi: 10.1097/MCC.0000000000000609
28. Nolan JP, Lockett A, Perkins G, et al. Resuscitation Council (UK) Post resuscitation care guidelines 2015, 2016:1-21.
29. Tang LH, Zwisler A-D. Rehabilitation after cardiac arrest - we can surely do better! *Cardiologisk Forum* 2019;30(February):30-37.
30. Haywood K, Whitehead L, Nadkarni VM, et al. COSCA (Core Outcome Set for Cardiac Arrest) in Adults: An Advisory Statement From the International Liaison Committee on Resuscitation. *Resuscitation* 2018;127:147-63. doi: 10.1016/j.resuscitation.2018.03.022
31. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2011;20(10):1727-36. doi: 10.1007/s11136-011-9903-x
32. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 1983;67(6):361-70. doi: 10.1016/j.jad.2018.04.092
33. Christensen AV, Dixon JK, Juel K, et al. Psychometric properties of the Danish Hospital Anxiety and Depression Scale in patients with cardiac disease: results from the DenHeart survey. *Health Qual Life Outcomes* 2020;18(1):9. doi: 10.1186/s12955-019-1264-0 [published Online First: 2020/01/09]
34. Lilja G, Nielsen N, Friberg H, et al. Cognitive function after cardiac arrest and temperature management; rationale and description of a sub-study in the Target Temperature Management trial. *BMC Cardiovascular Disorders* 2013;13 doi: {10.1186/1471-2261-13-85}

35. Longstreth WT, Jr., Nichol G, Van Ottingham L, et al. Two simple questions to assess neurologic outcomes at 3 months after out-of-hospital cardiac arrest: experience from the public access defibrillation trial. *Resuscitation* 2010;81(5):530-3. doi: 10.1016/j.resuscitation.2010.01.011 [published Online First: 2010/02/23]
36. Schiehser DM, Delano-Wood L, Jak AJ, et al. Validation of the Modified Fatigue Impact Scale in mild to moderate traumatic brain injury. *J Head Trauma Rehabil* 2015;30(2):116-21. doi: 10.1097/HTR.000000000000019 [published Online First: 2014/01/15]
37. Amtmann D, Bamer AM, Noonan V, et al. Comparison of the psychometric properties of two fatigue scales in multiple sclerosis. *Rehabil Psychol* 2012;57(2):159-66. doi: 10.1037/a0027890 [published Online First: 2012/06/13]
38. Federici S, Bracalenti M, Meloni F, et al. World Health Organization disability assessment schedule 2.0: An international systematic review. *Disability and rehabilitation* 2017;39(23):2347-80. doi: 10.1080/09638288.2016.1223177 [published Online First: 2]
39. Garin O, Ayuso-Mateos JL, Almansa J, et al. Validation of the "World Health Organization Disability Assessment Schedule, WHODAS-2" in patients with chronic diseases. *Health and Quality of Life Outcomes* 2010;8:51. doi: 10.1186/1477-7525-8-51
40. Kuo CY, Liou TH, Chang KH, et al. Functioning and disability analysis of patients with traumatic brain injury and spinal cord injury by using the world health organization disability assessment schedule 2.0. *Int J Environ Res Public Health* 2015;12(4):4116-27. doi: 10.3390/ijerph120404116 [published Online First: 2015/04/16]
41. Danquah IH, Petersen CB, Skov SS, et al. Validation of the NPAQ-short - a brief questionnaire to monitor physical activity and compliance with the WHO recommendations. *BMC public health* 2018;18(1):601. doi: 10.1186/s12889-018-5538-y
42. The Danish Cancer Society. Kræftpatienters oplevelser med sundhedsvæsenet gennem udredning og behandling. The Experience of Cancer Patients during Diagnosis and Treatment. Copenhagen, 2011.
43. Veloso AG, Sperling C, Holm LV, et al. Unmet needs in cancer rehabilitation during the early cancer trajectory--a nationwide patient survey. *Acta Oncol* 2013;52(2):372-81. doi: 10.3109/0284186X.2012.745648 [published Online First: 2013/01/17]
44. Zinckernagel L, Schneekloth N, Zwisler AO, et al. How to measure experiences of healthcare quality in Denmark among patients with heart disease? The development and psychometric evaluation of a patient-reported instrument. *BMJ Open* 2017;7(10):e016234. doi: 10.1136/bmjopen-2017-016234 [published Online First: 2017/11/01]
45. Bech P, Olsen LR, Kjoller M, et al. Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five Well-Being Scale. *Int J Methods Psychiatr Res* 2003;12(2):85-91. doi: 10.1002/mpr.145
46. Topp CW, Ostergaard SD, Sondergaard S, et al. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom* 2015;84(3):167-76. doi: 10.1159/000376585 [published Online First: 2015/04/04]
47. Blennow Nordström E, Lilja G, Årestedt K, et al. Validity of the IQCODE-CA: An informant questionnaire on cognitive decline modified for a cardiac arrest population. *Resuscitation* 2017;118:8-14. doi: 10.1016/j.resuscitation.2017.06.012
48. Thornton M, Travis SS. Analysis of the Reliability of the Modified Caregiver Strain Index. *The Journals of Gerontology: Series B* 2003;58(2):S127-S32. doi: 10.1093/geronb/58.2.S127
49. Jensen HAR, Ekholm O, Davidsen M, et al. The Danish health and morbidity surveys: study design and participant characteristics. *BMC Med Res Methodol* 2019;19(1):91. doi: 10.1186/s12874-019-0733-9 [published Online First: 2019/05/06]
50. Jensen VM, Rasmussen AW. Danish Education Registers. *Scand J Public Health* 2011;39(7 Suppl):91-4. doi: 10.1177/1403494810394715 [published Online First: 2011/08/04]
51. Baadsgaard M, Quitzau J. Danish registers on personal income and transfer payments. *Scand J Public Health* 2011;39(7 Suppl):103-5. doi: 10.1177/1403494811405098 [published Online First: 2011/08/04]

- 1
2
3 52. Lynge E, Sandegaard JL, Rebolj M. The Danish National Patient Register. *Scand J Public Health*
4 2011;39(7 Suppl):30-3. doi: 10.1177/1403494811401482 [published Online First:
5 2011/08/04]
- 6 53. Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in
7 longitudinal studies: development and validation. *Journal of chronic diseases*
8 1987;40(5):373-83.
- 9 54. Hjollund NH, Larsen FB, Andersen JH. Register-based follow-up of social benefits and other
10 transfer payments: accuracy and degree of completeness in a Danish interdepartmental
11 administrative database compared with a population-based survey. *Scand J Public Health*
12 2007;35(5):497-502. doi: 10.1080/14034940701271882 [published Online First: 2007/09/14]
- 13 55. Kragholm K, Torp-Pedersen C. Cardiac arrest survivors: short residual risk of death, long life
14 expectancy. *Heart* 2017;103(14):1063-64. doi: 10.1136/heartjnl-2017-311259
- 15 56. Tolstrup Larsen R, Tang LH, Brochmann N, et al. Associations between fatigue, physical activity,
16 and QoL in patients with myeloproliferative neoplasms. *Eur J Haematol* 2018;100(6):550-59.
17 doi: 10.1111/ejh.13048 [published Online First: 2018/02/22]
- 18 57. Kildemoes HW, Sorensen HT, Hallas J. The Danish National Prescription Registry. *Scand J Public*
19 *Health* 2011;39(7 Suppl):38-41. doi: 10.1177/1403494810394717 [published Online First:
20 2011/08/04]
- 21 58. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies
22 in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *The*
23 *Lancet* 2007;370(9596):1453-57. doi: 10.1016/s0140-6736(07)61602-x
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

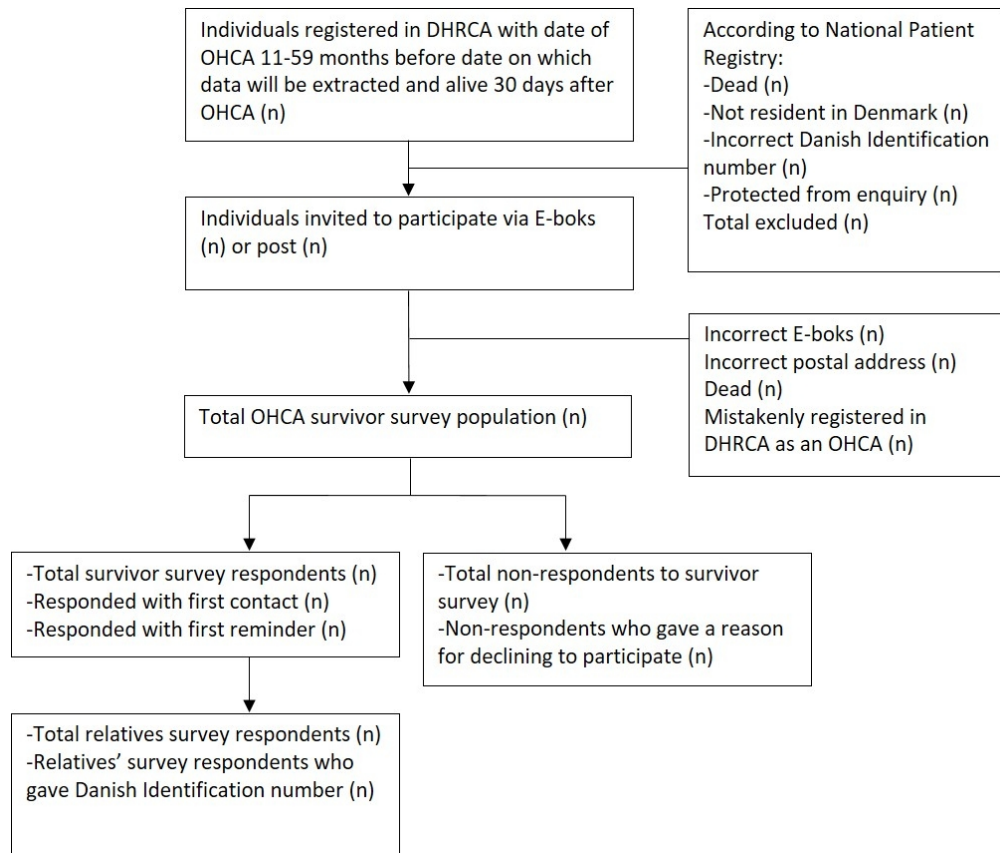


Figure 1. Flow chart of Survey Population

169x143mm (150 x 150 DPI)

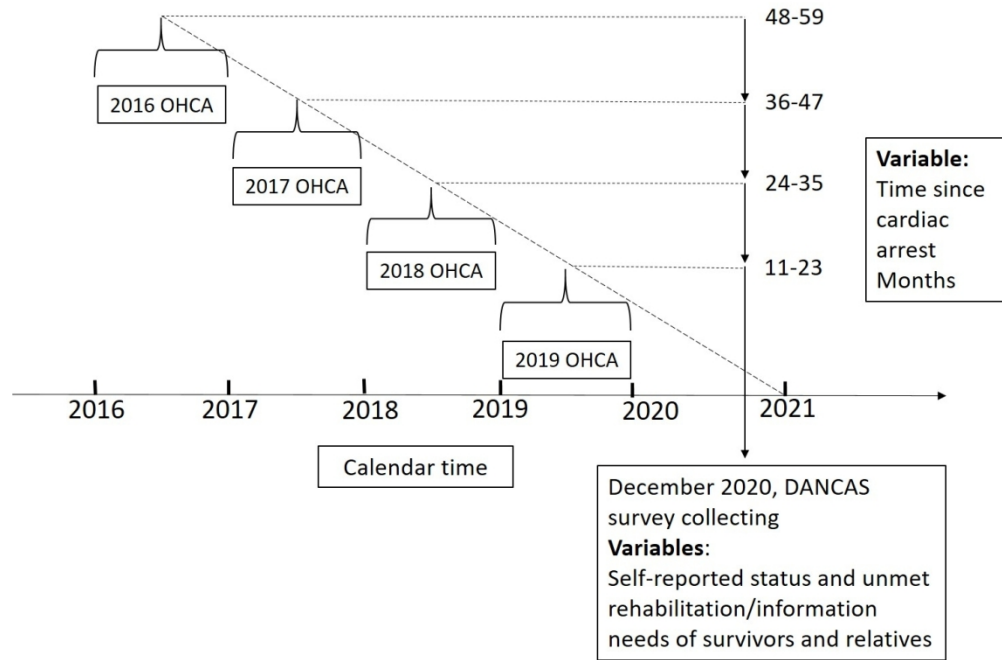


Figure 2. Design of DANCAS survey and grouping according to time since OHCA

250x169mm (150 x 150 DPI)

Supplementary data.

Table 1. Detailed content of DANCAS surveys

Outcome domain	Outcome measure	Items, scoring	Danish translation	Notes
Survivors				
Generic health	EQ-5D-5L	Five item health dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Divided into five levels: 1='No problems' to 5= 'Extreme problems', scores ≥ 2 signifies a problem. Sixth item: Self-rating of health. Visual Analogue Scale, 0-100. Higher scores signify better health status. ¹	Received from the EuroQoL group	
Anxiety and depression	HADS	Seven-item symptoms of anxiety subscale (HADS-A) Seven-item subscale symptoms of depression (HADS-D). Four responses: 0='No symptoms' to 3= 'maximum number of symptoms'. Total subscale scores range: 0-21. <8 = no psychological distress, 8-10 = mild psychological distress, >10 definite psychological distress. It has recently been shown to be a valid measure of anxiety and depression in a Danish cardiac disease population. ²	Received from DenHeart study group ³	Valid measure of anxiety and depression in Danish cardiac disease population ³

Mental recovery/dependency	TSQ	Yes to Q1a + Yes to Q1b signify new problems with dependency after cardiac arrest. No to Q2 indicates problems with mental recovery after cardiac arrest. ^{4 5}	Received from TTM2 study group ⁴	-
Fatigue impact on functional activities	MFIS	21 items in three sub-scales (physical, cognitive and psychosocial). Total scores range: 0-84. Total subscale scores: physical= 0 -36; cognitive=0=40; psychosocial= 0-8. ≥30 signify a fatigued individual (Antmann, 2012, Schiehser, 2015)	Translation received from the Provide, Map Research Trust.	Validated in people with multiple sclerosis. ⁶ and mild to moderate brain injury. ⁷
Function and disability	12-item WHO DAS 2.0	12-item assessing 6 domains of functioning: 1) Understanding and communication; 2) Self-care; 3) Mobility; 4) Interpersonal relationships; 5) Work and household roles; and 6) Community and civic roles. Scored from 0= 'no difficulty' to 4= 'extreme difficulty or cannot do'. Total scores range: 0-48. Higher score indicating greater difficulty with activity and participation.	Available from: https://www.etf.dk/ergoterapi-og-politik/hverders-rehabilitering	Used extensively to research neurological conditions including traumatic brain injury and spinal cord injury, ⁸ and rehabilitation and disability in a wide range of disease populations. ⁹ Validated in patients with chronic diseases. ¹⁰
Physical activity level	NPAQ	2-3 items depending on age: <65 years: 1) Physically active at a moderate-to-high intensity ≥ 30 minutes/day and 2) physically active at a high-level ≥ 20 minutes/day twice a week.	Available at: http://www.kans.kernessundhed.dk/Spoergeskema	Tool determines whether WHO recommendations on weekly exercise are met.

		>65 years of age: 1) Physically active \geq 30 minutes/day, and undertakes strength or balance training twice a week. Responses are Yes/No. ¹¹		Found to be sufficiently reliable and valid to monitor physical activity levels in a Danish population. ¹¹
Life satisfaction/rehabilitation need	REHPA scale	A linear analogue scale, participants indicate how close they are to living the life they desire after their OHCA. Scale ranges from 0= 'goal reached' to 9= 'infinitely far from'. Score of \leq 3 will be considered as signifying having rehabilitation needs.	By DANCAS study authors	
Unmet rehabilitation needs		6-items asking if rehabilitation needs were met in different domains, for example, emotional reactions. Scored on a 4-point Likert type scale from 'Yes to a high level' to 'No, not at all'. ¹²	Adapted by DANCAS authors from	Questions adapted from existing survey 'The Experience of Cancer Patients during Diagnosis and Treatment'. ^{12 13}
Unmet information needs	Adapted from Zinckernagel et al., 2017	7-items asking if information needs were met in different domains, for example, 'treatment of your heart condition' Scored on a 4-point Likert type scale from 'Yes to a high level' to 'No, not at all'. ¹⁴	Adapted by DANCAS authors for OHCA survivors from a Danish survey of patients with heart disease. ¹⁴	

Relatives				
Anxiety and depression	HADS	As above		
Mental well-being	WHO-5	Five items with 6 responses from 0='At no time' to 5='all of the time'. Scores are totaled and multiplied by 4 to give range 0-100. Score <50 signifies poor emotional well-being. ¹⁵	Developed in Denmark. ¹⁶	Valid in multiple patient populations. ¹⁷
Cognitive problems in daily life	IQCODE-CA	26-items scored on a five-point scale, 1= 'much improved' to 5= 'much worse'. Scores are totaled, divided by the number of questions to give a total, range 1-5. Score ≥ 3.04 signifies cognitive decline after cardiac arrest. ¹⁸	Received from TTM2 study group	Relatives or close friends compare current cognitive function with pre-cardiac arrest cognitive function. Has been shown to accurately identify cardiac arrest survivors with potential cognitive problems. ¹⁸
Carer strain	MCSI	13-items, scored: 2= 'Yes, On a Regular Basis', 1= 'Yes, sometimes', 0= 'No'. Range: 0-26, higher scores signify a higher level of carer strain. ¹⁹	Translated by DANCAS study authors ^a	Found to have high internal validity with a population of family caregivers. ¹⁹
Witness to OHCA	Questions designed for this survey	1-item on whether they witnessed the OHCA	Created by DANCAS study authors	
Labour market	Questions designed for this survey	7-items on educational level completed, current labour market status, status in pre-OHCA period and details of any sick leave in post-OHCA period.	Created by DANCAS study authors	These questions are asked of the relatives as their survey answers cannot be connected to Danish

				labour market registry data unless they provide their Danish personal identification number.
Social isolation	Question from Danish national health survey	One item: Does it ever happen that you are alone even though you would prefer to be with other people?" Answers: "yes, often" and "yes, sometimes" signify loneliness. Other possible responses are "yes, but rarely" and "no.	Available at: http://www.danskernesundhed.dk/Spoergeskema	
Support received post-OHCA	Questions designed for this survey	4-items on: whether relatives feel they have someone to talk to if they need support (yes, always/yes, mostly/yes, sometimes/no never or almost never); who have they received support from (multiple options); if they received the support they needed (Yes, No), and who would they have like to have received support from in the post-OHCA period (free text box).	Created by DANCAS study authors	
<p>Abbreviations: HADS= Hospital Anxiety and Depression Scale; TSQ=Two Simple Questions; TTM2= Targeted Hypothermia versus Targeted Normothermia after OHCA trial 2; MFIS: Modified Fatigue Impact Scale, WHO DAS 2.0= World Health Organisation disability assessment schedule 2.0 Short; NPAQ= Nordic Physical activity questionnaire; REHPA= Danish Knowledge Center for Rehabilitation and Palliative Care; OHCA=Out-of-hospital Cardiac Arrest; DANCAS=DANish Cardiac Arrest Survivorship; WHO-5= World Health Organisation-Five Well-Being index; IQCODE-CA: Informant Questionnaire on Cognitive Decline in the Elderly, Cardiac Arrest Version; MCSI= Modified Carer Strain Index.</p> <p>^aTranslation, cultural adaption and psychometric testing performed by study authors, results are planned to be available in a future publication.</p>				

6/bmjopen-2020-045668 on 2 April 2021 by guest. Protected by copyright.

1. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2011;20(10):1727-35. doi: 10.1007/s11136-011-9903-x
2. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 1983;67(6):367-70. doi: 10.1016/j.jad.2018.04.092
3. Christensen AV, Dixon JK, Juel K, et al. Psychometric properties of the Danish Hospital Anxiety and Depression Scale in patients with cardiac disease: results from the DenHeart survey. *Health Qual Life Outcomes* 2020;18(1):9. doi: 10.1186/s12955-019-12640-0 [published Online First: 2020/01/09]
4. Lilja G, Nielsen N, Friberg H, et al. Cognitive function after cardiac arrest and temperature management; rationale and description of a sub-study in the Target Temperature Management trial. *BMC Cardiovascular Disorders* 2013;13 doi: {10.1186/1471-2261-13-85}
5. Longstreth WT, Jr., Nichol G, Van Ottingham L, et al. Two simple questions to assess neurologic outcomes at 3 months after out-of-hospital cardiac arrest: experience from the public access defibrillation trial. *Resuscitation* 2010;81(5):530-3. doi: 10.1016/j.resuscitation.2010.01.011 [published Online First: 2010/02/23]
6. Amtmann D, Bamer AM, Noonan V, et al. Comparison of the psychometric properties of two fatigue scales in multiple sclerosis. *Rehabil Psychol* 2012;57(2):159-66. doi: 10.1037/a0027890 [published Online First: 2012/06/13]
7. Schiehser DM, Delano-Wood L, Jak AJ, et al. Validation of the Modified Fatigue Impact Scale in mild to moderate traumatic brain injury. *J Head Trauma Rehabil* 2015;30(2):116-21. doi: 10.1097/HTR.000000000000019 [published Online First: 2014/07/15]
8. Kuo CY, Liou TH, Chang KH, et al. Functioning and disability analysis of patients with traumatic brain injury and spinal cord injury by using the world health organization disability assessment schedule 2.0. *Int J Environ Res Public Health* 2015;12(4):4116-27. doi: 10.3390/ijerph120404116 [published Online First: 2015/04/16]
9. Federici S, Bracalenti M, Meloni F, et al. World Health Organization disability assessment schedule 2.0: An international systematic review. *Disability and rehabilitation* 2017;39(23):2347-80. doi: 10.1080/09638288.2016.1223177 [published Online First: 2]
10. Garin O, Ayuso-Mateos JL, Almansa J, et al. Validation of the "World Health Organization Disability Assessment Schedule, WHODAS-2" in patients with chronic diseases. *Health and Quality of Life Outcomes* 2010;8:51. doi: 10.1186/1477-7525-8-51
11. Danquah IH, Petersen CB, Skov SS, et al. Validation of the NPAQ-short - a brief questionnaire to monitor physical activity and compliance with the WHO recommendations. *BMC public health* 2018;18(1):601. doi: 10.1186/s12889-018-5538-y
12. The Danish Cancer Society. Kræftpatienters oplevelser med sundhedsvæsenet gennem udredning og behandling. The Experience of Cancer Patients during Diagnosis and Treatment. Copenhagen, 2011.
13. Veloso AG, Sperling C, Holm LV, et al. Unmet needs in cancer rehabilitation during the early cancer trajectory--a nationwide patient survey. *Acta Oncol* 2013;52(2):372-81. doi: 10.3109/0284186X.2012.745648 [published Online First: 2013/01/17]
14. Zinckernagel L, Schneekloth N, Zwisler AO, et al. How to measure experiences of healthcare quality in Denmark among patients with heart disease? The development and psychometric evaluation of a patient-reported instrument. *BMJ Open* 2017;7(10):e016234. doi: 10.1136/bmjopen-2017-016234 [published Online First: 2017/11/01]
15. Lowe B. Comparative validity of three screening questionnaires for DSM-IV depressive disorders and physician diagnoses. *Journal of Affective Disorders* 2004;78(2):131-40. doi: 10.1016/s0165-0327(02)00237-9

16. Bech P, Olsen LR, Kjoller M, et al. Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five Well-Being Scale. *Int J Methods Psychiatr Res* 2003;12(2):85-91. doi: 10.1002/pspr.145
17. Topp CW, Ostergaard SD, Sondergaard S, et al. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom* 2015;84(3):167-76. doi: 10.1159/000376585 [published Online First: 2015/04/04]
18. Blennow Nordström E, Lilja G, Årestedt K, et al. Validity of the IQCODE-CA: An informant questionnaire on cognitive decline modified for a cardiac arrest population. *Resuscitation* 2017;118:8-14. doi: 10.1016/j.resuscitation.2017.06.012
19. Thornton M, Travis SS. Analysis of the Reliability of the Modified Caregiver Strain Index. *The Journals of Gerontology: Series B* 2003;58(2):S127-S32. doi: 10.1093/geronb/58.2.S127

For peer review only

BMJ Open

Long-term physical and psychological outcomes after out-of-hospital cardiac arrest– Protocol for a national cross-sectional survey of survivors and their relatives (the DANCAS survey)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-045668.R1
Article Type:	Protocol
Date Submitted by the Author:	28-Jan-2021
Complete List of Authors:	Joshi, Vicky; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Tang, Lars; Slagelse Hospital, Department of Physiotherapy and Occupational Therapy; University of Southern Denmark, The Department of Regional Health Research Borregaard, Britt; Odense University Hospital, Department of Cardiology; University of Southern Denmark, Department of Clinical Research Zinckernagel, Line; University of Southern Denmark, National Institute of Public Health; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Mikkelsen, Tina; Odense University Hospital, REHPA, The Danish Knowledge Centre for Rehabilitation and Palliative Care Taylor, Rod; University of Glasgow, MRC/CSO Social and Public Health Sciences Unit & Robertson Centre for Biostatistics, Institute of Health and Well Being; University of Exeter, College of Medicine and Health Christiansen, Sofie; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Nielsen, Jørgen ; Regional Hospital Hammel Neurocenter; Aarhus University, Department of Clinical Medicine Zwisler, Ann Dorthe; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care; Odense University Hospital, Department of Cardiology
Primary Subject Heading:	Cardiovascular medicine
Secondary Subject Heading:	Rehabilitation medicine, Epidemiology
Keywords:	Adult cardiology < CARDIOLOGY, REHABILITATION MEDICINE, EPIDEMIOLOGY

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

BMJ Open: first published as 10.1136/bmjopen-2020-045668 on 2 April 2021. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3
4 **Long-term physical and psychological outcomes after out-of-hospital cardiac arrest–**
5 **Protocol for a national cross-sectional survey of survivors and their relatives (the DANCAS**
6 **survey)**
7
8

9 Vicky L Joshi, PhD student¹ (victoria.louise.joshi@rsyd.dk)

10 Lars H Tang, Assistant professor^{2,3} (larta@regionsjaelland.dk)

11 Britt Borregaard, Post doc^{4,5} (britt.Borregaard@rsyd.dk)

12 Line Zinckernagel, PhD student^{1,6} (lizi@niph.dk)

13 Tina Broby Mikkelsen, Data manager¹ (tina.Broby.mikkelsen@rsyd.dk)

14 Rod S Taylor, Professor^{7,8} (rod.taylor@gla.ac.uk)

15 Sofie Raahauge Christiansen, researcher¹ (sofie.Raahauge.Christiansen@rsyd.dk)

16 Jørgen Feldbæk Nielsen, Professor⁹ (joerniel@rm.dk)

17 Ann-Dorthe Zwisler, Professor^{1,4} (ann.dorthe.olsen.zwisler@rsyd.dk)

18
19
20
21
22
23
24
25
26 ¹REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care, University of Southern
27 Denmark, and Odense University Hospital, Denmark

28
29 ²Department of Physiotherapy and Occupational Therapy, Næstved-Slagelse-Ringsted Hospitals

30
31 ³The Department of Regional Health Research, University of Southern Denmark

32
33 ⁴Department of Cardiology, Odense University Hospital, Odense, Denmark

34
35 ⁵Department of Clinical Research, University of Southern Denmark, Odense, Denmark

36
37 ⁶The National Institute for Public Health, University of Southern Denmark, Copenhagen, Denmark

38
39 ⁷MRC/CSO Social and Public Health Sciences Unit & Robertson Centre for Biostatistics, Institute of
40 Health and Well Being, University of Glasgow, UK

41
42 ⁸College of Medicine and Health, University of Exeter, UK

43
44 ⁹Hammel Neuro Center, Hospitalsenhed Midt, Viborg, Denmark

45
46 Corresponding author: Vicky L Joshi, address: Studiestræde 6, 1455 Copenhagen. email:

47 victoria.louise.joshi@rsyd.dk. Tel: +4550229798.

48
49
50
51 Word count manuscript: 3837

52
53 Key words: Out-of-hospital cardiac arrest survivor, relatives of out-of-hospital cardiac arrest
54 survivors, cross-sectional survey, self-report.
55
56
57
58
59
60

ABSTRACT

Introduction

The number of out-of-hospital cardiac arrest (OHCA) survivors is increasing. However, there remains limited knowledge on the long-term physical and psychological problems suffered by survivors and their relatives. The aims of the DANCAS (DANish cardiac arrest survivorship) survey are to describe the prevalence of physical and psychological problems, identify predictors associated with suffering them and to determine unmet rehabilitation needs in order to make recommendations on the timing and content of future rehabilitation interventions.

Methods and analysis

The DANCAS survey has a cross-sectional design involving a survey of OHCA survivors and their relatives. OHCA survivors will be identified through the Danish Cardiac Arrest Registry as having suffered an OHCA between 1st January 2016 and 31st December 2019. Each survivor will be asked to identify their closest relative to complete the relatives' survey. Contents of survivor survey: EQ-5D-5L, Hospital Anxiety and Depression Scale, Two Simple Questions, Modified Fatigue Impact Scale, 12-item World Health Organisation Disability Assessment Scale 2.0, plus questions on unmet rehabilitation and information needs. Contents of relatives' survey: World Health Organisation-Five Well-Being Index, Hospital Anxiety and Depression Scale, Informant Questionnaire on Cognitive Decline in the Elderly – Cardiac Arrest and the Modified Caregiver Strain Index. Self-report outcome data collected through the surveys will be enriched by data from Danish national registries including: demographic characteristics, circumstances of cardiac arrest and co-morbidities. The survey will be completed either electronically or by post December 2020-February 2021.

Ethics and dissemination

The study will be conducted in accordance with the Declaration of Helsinki. Surveys and registry-based research studies do not normally require ethical approval in Denmark. This has been confirmed for this study by the Region of Southern Denmark ethics committee (20192000_19). Results of the study will be disseminated via several peer-reviewed publications and will be presented at national and international conferences.

Article Summary

Strengths and limitations of this study:

- Denmark has markedly improved the survival rate among OHCA survivors during the last five years.
- This will be one of the largest nationwide surveys of OHCA survivors to date with data collected from survivors and relatives up to five-years after cardiac arrest.

- 1
2
3 -Data will be derived from both self-report measures and national registries providing a
4 comprehensive picture of the problems experienced by OHCA survivors and the risk factors
5 associated with suffering them.
6
7 -The response rate from OHCA survivors suffering from cognitive problems and/or fatigue may be
8 lower due to difficulties completing the survey compared to those without these problems to
9 counter this the survey will be available both electronically and on paper.
10
11 -The change in physical and psychological problems over time may be influenced by a treatment
12 cohort effect and other unknown time-dependent modifying factors.
13
14
15
16
17
18

19 INTRODUCTION

20 The number of people surviving an out-of-hospital cardiac arrest (OHCA) is increasing every year due
21 to advances in pre-hospital and acute medical care.^{1,2} In Denmark, thirty-day survival after OHCA
22 improved from 4% to 16% between 2001 and 2018.³ This amounts to at least 800 new survivors
23 every year.³ Still, after the acute phase ends, the physical and psychological impact of OHCA may
24 continue.⁴ Most OHCA survivors will have a new or ongoing cardiac condition.^{5,6} They may suffer
25 from psychological trauma due to surviving a near-death experience.⁷ Further, reduced oxygen
26 levels to the brain during an OHCA can cause cognitive deficits in up to 50% of survivors.⁸⁻¹⁰ Due to
27 this combination of factors, OHCA survivors have been shown to suffer anxiety and depression,
28 fatigue and reduced participation in society.^{7,8,11,12} General health, return-to-work rates and quality
29 of life do, however, appear to improve over time¹³⁻¹⁵ but data regarding: health measures, return-to-
30 work patterns and unmet rehabilitation needs beyond 12-months after OHCA are limited.^{7,11,14,16,17}
31
32
33
34
35
36
37
38
39

40 As most OHCA occur in private homes, relatives are likely to witness the event.¹⁸ Combined with the
41 changes in both physical and psychological status of many OHCA survivors, quality of life and
42 psychological health among relatives might be influenced. It has previously been described how
43 relatives of OHCA survivors suffer from emotional problems including anxiety, depression and post-
44 traumatic stress, due to becoming a carer for their loved one or fear of the cardiac arrest
45 recurring.^{19,20} Likewise, lack of control, feelings of insecurity, mood and sleep disturbances have
46 been reported among relatives.^{21,22} Yet, very few research studies have investigated the
47 consequences of OHCA for relatives in the longer term,^{23,24} or how these are associated with
48 witnessing the event or with the physical, psychological problems suffered by the OCHA survivor.
49
50
51
52
53
54
55
56

57 Rehabilitation for OHCA survivors is recommended in international guidelines^{4,25} but the specific
58 content and timing of these interventions has not been established. Survivors will commonly be
59
60

1
2
3 offered cardiac rehabilitation related to their new or ongoing cardiac condition,^{4 26} but it has been
4 suggested that the psychological and neurological rehabilitation needs of OHCA are not met to the
5 same degree.²⁷ Hence, the aims of this national cross-sectional study are to 1) describe the long-
6 term prevalence of physical and psychological problems for OHCA survivors and their relatives and
7 how these change over time 2) identify predictors associated with increased risk of suffering these
8 problems and 3) determine unmet rehabilitation needs in order to make recommendations on the
9 timing and content of future rehabilitation interventions. Specific objectives for each aim will be
10 defined in future publications.
11
12
13
14
15
16
17
18

19 **METHODS AND ANALYSIS**

20 **Study design**

21 The DANCAS (DANish Cardiac Arrest Survivorship) survey aims will be achieved through a cross-
22 sectional study design.
23
24
25
26

27 **Setting and participants**

28 In Denmark, pre-hospital care, hospital care and all cardiac treatment and rehabilitation are funded
29 via the tax system and are free of charge for patients. The Danish Out-of-Hospital Cardiac Arrest
30 (DHRCA) registry will be used to identify the Danish personal identification numbers of people who
31 have suffered an OHCA from 1st January 2016 to 31st December 2019 and were alive 30-days after
32 their cardiac arrest (figure 1). All patients in Denmark who have suffered an OHCA, where
33 bystanders or paramedics attempted treatment are included in the DHRCA registry. Data is recorded
34 electronically immediately after the OHCA in the pre-hospital patient record by paramedics from one
35 of the five regional ambulance services and collected in the DHRCA.
36
37
38
39
40
41
42
43

44 The DHRCA started collecting data in 2001, however, before 2016, this was recorded by hand on
45 paper and hence significant gaps in the data exist³. In addition, pre-hospital and medical
46 management of OHCA has changed significantly in the period 2001-2015.²⁸ Consequently, the
47 proposed timeframe of 1-5 years since OHCA provides both a long-term perspective and ensures
48 data is relevant to the contemporary OHCA survivor population.
49
50
51
52
53

54 The extracted Danish personal identification numbers will be matched by the Danish National Health
55 Digital Board to names, and addresses in the Danish National Patient Registry retrieve.
56
57
58
59
60

1
2
3 The information letter received by the OHCA survivors will ask them to identify their closest relative
4 and ask them to complete the relatives' survey. This method of recruitment has been tested in the
5 development of the survey and is feasible. Closest relative is defined as a partner, spouse, sibling, or
6 parent that is closest to the survivor.
7
8
9

10 11 **Eligibility criteria**

12 OHCA survivor participants included in the survey will have a Danish personal identification number,
13 be alive at least 30-days post-cardiac arrest, resident in Denmark, over 18-years of age and able to
14 read and write in Danish and not protected from receiving inquiries during scientific surveys.
15
16
17

18
19 Relative participants must have a relative who has survived an OHCA, be over 18 years of age and be
20 able to read and write in Danish. The relatives do not need to have a Danish personal identification
21 number, as they will be invited to complete their survey via the information letter to the OHCA
22 survivor participants. However, they will be asked to provide their Danish personal identification
23 number to allow linkage with Danish national registries.
24
25
26
27

28 29 **Data collection**

30 All OHCA survivor participants that meet the eligibility criteria will receive an invitation to participate
31 in the survey via REDCap (Research Electronic Data Capture) software to their e-Boks (government
32 electronic mail account) or via post if they do not have an E-boks address. Based on the age profile
33 of OHCA survivors over the last 5-years and the age-profile of Danes with e-Boks addresses it is
34 estimated that 20% of participants will require a postal survey.
35
36
37
38
39
40

41 The link to complete the separate relatives' survey will be included in the invitation sent to the
42 OHCA survivors' eBoks. Invitations sent via post to the OHCA survivor will include a paper copy of
43 both surveys, two stamped addressed envelopes (for survivor and relative) and information on how
44 to complete the surveys online rather than by post if they wish. A participant information sheet will
45 be included with all invitations to participate in the survey. This will detail the purpose of the
46 research study, how data will be used and will explain that by returning the survey, they are
47 consenting to take part. The information sheet will include a telephone number to call a member of
48 the research team if participants have any questions. Participants who receive the E-boks survey will
49 have the option to request a paper survey by post. A reminder invitation will be sent via E-boks/post
50 after two-weeks.
51
52
53
54
55
56
57
58
59

60 Additional data from the DHRCA will provide information on circumstances of the OHCA (Table 1).

Table. 1 Data on circumstances of OHCA from DHRCA

Table. 1 Data on circumstances of OHCA from DHRCA

Location of cardiac arrest (Private/public)

First observed heart rhythm (shockable/not shockable)

Cardiopulmonary resuscitation was given before the arrival of the ambulance (Yes/No)

Defibrillated before the arrival of the ambulance (Yes/No)

Time to return of spontaneous circulation (minutes: second)

Development of the DANCAS surveys

The outcome domains for the two DANCAS surveys were developed from a public and patient involvement (PPI) event held in Denmark²⁹ (see PPI section below) and from the outcomes identified as important by participants in the COSCA (core outcome set for cardiac arrest) initiative.³⁰ For each of these outcome domains, appropriate existing self-report outcome measures were chosen. For domains where no outcome measure existed, questions from other patient groups were adapted for OHCA survivors or new questions were developed.

The PPI group participants tested individual outcome measures for acceptability and face validity where there was more than one outcome measure available (for example, in the domain 'function and disability'). The PPI group also gave feedback on draft versions of the whole DANCAS surveys, and the participant information sheet. Feedback was received from eight survivors, three relatives, and three clinicians with experience of treating OHCA survivors and relatives. Based on this feedback, we reduced the number of questions, removed any outcome measures where the item content overlapped and improved the clarity of the participation information sheet.

Self-report outcome measures in the DANCAS surveys

Full details on the self-report outcome measures, scoring, and Danish translations can be found in the Supplementary data.

The following self-report outcome measures will be completed by OHCA survivors:

EQ-5D-5L: This is a six-item standardised instrument for measuring current health status.³¹ The questionnaire covers five-dimensions of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is divided into five-levels: no problems, slight, moderate,

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

severe or extreme problems. The sixth-item, a Visual Analogue Scale, 0-100, allows the respondent to provide a self-rating of his or her health. A higher score signifies a better health status.

Hospital Anxiety and Depression Scale (HADS): The HADS consists of a seven-item subscale measuring symptoms of anxiety (HADS-A) and a seven-item subscale measuring symptoms of depression (HADS-D).³² Each item has a four-choice response, with scores ranging from 0 (no symptoms) to 3 (maximum number of symptoms). The total scores on each subscale range from 0 to 21. A score of less than 8 indicates no psychological distress, 8 to 10 mild psychological distress and over 10 definite psychological distress. It has recently been shown to be a valid measure of anxiety and depression in a Danish cardiac disease population.³³

Two Simple Questions (TSQ): Consists of three-items. Developed to assess the survivor's own perception of mental recovery and dependency in daily activities after cardiac arrest.^{34 35}

Modified Fatigue Impact Scale (MFIS): The MFIS assesses impact of fatigue on performance of functional activities and consists of 21-items in three-sub-scales (physical, cognitive and psychosocial). Total scores range from 0 to 84 with a score of 30 or more signifying a fatigued individual. It has been validated in people with multiple sclerosis and traumatic brain injury.^{36 37}

12-item World Health Organisation Disability Assessment Schedule 2.0 (12-item WHO DAS 2.0): This assesses disability and functioning in the prior month on six adult life tasks. There are twelve-items scored from 0=no difficulty to 4=extreme difficulty, total score 0 to 48 with higher scores indicating greater difficulty. Used extensively to research rehabilitation and disability in a wide range of disease populations³⁸ and validated in patients with chronic diseases³⁹ including traumatic brain injury.⁴⁰

REHPA scale: A linear analogue self-assessment scale, where participants indicate how close they are to living the life they desire after their OHCA, indicating rehabilitation need. The scale is rated between 0 (goal reached) to 9 (infinitely far from).

Questions on unmet rehabilitation needs have been adapted from the Danish Cancer Society questionnaire 'The experiences of cancer patients during diagnosis and treatment'.^{41 42} Participants are asked if they received the help they needed after their cardiac arrest in six areas: emotional reactions, cognitive problems, physical activity, peer-support and family (supplementary data). Questions on unmet information needs after cardiac arrest were adapted from a questionnaire evaluating experiences of healthcare quality in Denmark among patients with heart disease.⁴³

1
2
3 Participants are asked if they felt informed after their cardiac arrest on seven subjects: treatment of
4 heart condition, medication for heart condition, emotional reaction, cognitive problems, physical
5 activity, return-to-work and impact on family.
6
7

8
9 In addition to the HADS, the relatives' survey includes:

10
11 *World Health Organisation Five Well-Being Index:* The WHO-5 is a self-report measure of current
12 mental well-being⁴⁴ that has been shown to be a valid tool across a wide range of study fields.⁴⁵ The
13 tool consists of five statements with six responses on a scale from 'At no time' to 'All of the time'
14 scoring 0-5. Scores are totaled and multiplied by 4 with 0 representing the worst imaginable well-
15 being and 100 representing the best imaginable well-being. The WHO-5 was chosen as a generic
16 global measure of health for the survey, as opposed to using the EQ-5D-5L as in the OHCA survivor
17 survey. This choice was based on feedback from a PPI workshop asking relatives to fill-in and provide
18 feedback on individual questionnaires. The relatives felt the EQ-5D-5L was about medical problems
19 and was for their relative (who had suffered the OHCA) to complete and they were unsure how to
20 answer the questions. Conversely, they understood why the WHO-5 might be relevant to their life
21 situation and felt able to complete it.
22
23
24
25
26
27
28
29

30
31 *The Informant Questionnaire on Cognitive Decline in the Elderly – Cardiac Arrest (IQCODE-CA):* This is
32 a modified version of the observer-reported questionnaire designed to measure global cognitive
33 decline in the dementia population.⁴⁶ Informants, defined as relatives or close friends are requested
34 to compare current cognitive function of the survivor with pre-cardiac arrest cognitive function. The
35 tool contains 26-items scored on a five-point scale with higher scores indicating greater impairment.
36 It has been shown to identify cardiac arrest survivors with possible cognitive problems.⁴⁶
37
38
39
40
41

42
43 *Modified caregiver strain index (MCSI):* This is a self-reported questionnaire that screens for
44 caregiver strain in caregivers.⁴⁷ The tool has 13 questions scoring 2 points for 'yes', 1 point for
45 'sometimes' and 0 for 'no'. Scores range from 26-0 with higher scores indicating a higher level of
46 caregiver strain. The MCSI has been found to be easily administered and a reliable test of strain in an
47 informal caregiver population.⁴⁷
48
49
50
51

52
53 Further, one question derived from the Danish National Health Survey 2017⁴⁸ on loneliness and four
54 questions on support received in the post-cardiac arrest period (created for this survey,
55 supplementary data). Seven questions on educational level, labour market status and sick leave are
56 also asked in the relatives section as their survey answers can only be connected to Danish labour
57
58
59
60

1
2
3 market registry data if relatives choose to provide their Danish personal identification number in
4 their survey response.
5
6
7

8 **Data enrichment from registries**

9
10 Following data collection via the two surveys, data enrichment will occur via Danish national
11 registries for both survivors and relatives. The Danish Civil Registration System will provide gender,
12 age and marital status. The Danish Education Register:⁴⁹ education level and the Danish Register on
13 personal income⁵⁰: income.
14
15
16
17

18 The Danish National Patient Register,⁵¹ provides data on 19 selected somatic co-morbidities scored
19 on a 3-point scale. This data will be used to calculate the Charlson Comorbidity Index,⁵² based on the
20 10 years previous to the date of the surveys. The Charlson Comorbidity Index has three categories:
21 0, 1-2 and ≥ 3 . This registry will also provide data on hospital admissions and healthcare use for the
22 potential sub-study on societal costs after surviving OHCA.
23
24
25
26
27

28 Current and pre-OHCA employment status for the working-age population will be obtained from the
29 Danish Register for Evaluation of Marginalization.(DREAM)⁵³ Participants who are not on any social
30 benefits or participants who are on State Education Fund grants, maternity leave pay, or leave-of-
31 absence schemes will be classified as being part of the workforce.⁵⁴ Accordingly, patients receiving
32 unemployment benefits, being on paid sick leave, on early retirement payment or disability pension
33 will be defined as being on social benefits. Pre-OHCA employment status will be assessed in a 5-
34 week span before cardiac arrest to classify patients as either working or receiving social benefits.
35
36
37
38
39
40

41 Information from the DHRCA and other national registries will be collected for all eligible study
42 participants both responders and non-responders to the survey (figure 1).
43
44
45
46

47 **Data handling and record-keeping**

48 The study has been registered on the Region of Southern Denmark's record of data processing
49 activities (19/8559). A license agreement has been made with Odense Patient Data Explorative
50 Network (OPEN) (OP_843) to establish the REDCap system, secure data storage, data analysis and
51 data linkage with national registries. REDCap will be used to import Danish personal identification
52 numbers for survey distribution via E-boks. Postal surveys received will be scanned, and the data
53 imported into REDCap and destroyed.
54
55
56
57
58
59
60

Sample size considerations

Each year approximately 800 people are alive 30-days after surviving an OHCA in Denmark.³ Hence, we estimate the survey could be sent to approximately n=3200 survivors. Based on similar studies in heart diseases,^{17 55} we are assuming a 20% (n=640) loss due to a person having moved out of Denmark, being protected from inquiries or having died,¹⁶ and a response rate of 60%. Hence, the estimated total study population would be approximately n= 1540 OHCA survivors. The response rate to the relatives' survey is likely to be less as not all survivors will have a relative able to complete the survey. Hence, estimated 50% (1200) of relatives will respond and 50% (600) of responders will provide Danish personal identification numbers.

Planned analysis

Continuous data will be checked for normality and described as mean and standard deviation (SD) or median with 25th and 75th quartiles [IQR, interquartile range], as appropriate. Categorical variables will be described as numbers and percentages (n (%)). To investigate changes in physical and psychological outcomes over time, participants will be stratified into four groups: those suffering an OHCA in 2016, 2017, 2018 and 2019 (figure 2). Differences in the prevalence of self-report problems between the groups will be determined by Chi-squared test or Fisher's Exact test as appropriate and time-trend analyses will be performed. The OHCA survivor and relatives' surveys will be linked via a unique identifying number to discover if associations exist between each groups' self-report outcomes.

Predictors of physical and psychological problems will be identified from self-report outcomes, demographic characteristics, circumstances of OHCA and unmet rehabilitation/information needs using univariate binary logistic regression. All univariate predictors with $p < 0.10$ will be entered into a multivariate binary logistic regression, with description of odds ratios or β and 95% confidence intervals. In all regression analyses, both crude and adjusted models will be presented. Level of statistical significance will be set at $p < 0.05$.

A potential sub-study is planned to calculate the total societal costs (healthcare costs and absenteeism from work) of surviving OHCA using the EQ-5D-5L data and registry data (National Prescription Registry,⁵⁶ and DREAM database).

Ethics and dissemination

The study will be conducted in accordance with the Declaration of Helsinki. Surveys and registry-based research studies do not normally require ethical approval in Denmark. This has been

1
2 confirmed for this study by the Region of Southern Denmark ethics committee (20192000_19).
3
4 Participants will be informed about the study via the participant information sheet. Consent to
5
6 participate will be implied through the return of the completed survey.
7
8

9 Results of the study will be disseminated via several peer-reviewed publications and will be
10 presented at national and international conferences. The results of the proposed study will be
11 reported with reference to the international statement in the Strengthening the Reporting of
12 Observational studies in Epidemiology (STROBE) checklist for cross-sectional studies⁵⁷. Health
13 professionals will be informed of the study results through professional literature via new national
14 clinical guidelines on rehabilitation after OHCA. Finally, the survey is part of a larger project on
15 rehabilitation after surviving a cardiac arrest and all results, including the survey results, will be
16 presented at a project-closing event to which all participants, stakeholders and interested parties
17 will be invited.
18
19
20
21
22
23
24
25

26 **Patient and public involvement**

27 The themes for the survey were developed from a PPI event involving OHCA survivors, relatives and
28 clinicians.²⁹ A further group of survivors and relatives have helped to develop the survey by testing
29 individual questionnaires and by providing feedback on the whole survey. At the end of the study,
30 the research advisory group and PPI group will discuss and comment on the findings and contribute
31 to how the results will be disseminated and implemented in the next stage of the research.
32
33
34
35
36
37

38 **Discussion**

39 Recovery after OHCA can be complicated by a new or ongoing cardiac condition, mental trauma
40 from surviving a near-death experience or possible anoxic brain injury. Small scale, short term
41 studies suggest these complications can lead to an increased physical and psychological burden for
42 both survivors and their relatives. However, little is known about the long-term prevalence of
43 physical and psychological problems or who is at most risk of developing them. Rehabilitation has
44 been recommended to meet the secondary physical and psychological consequences of OHCA but
45 more knowledge is needed including establishing the perceived unmet rehabilitation and
46 information needs from OHCA survivors and their relatives themselves.
47
48
49
50
51
52
53

54 The results from this study will be used to identify the most prevalent problems suffered by OHCA
55 survivors and their families and those at most risk of suffering them. This will allow researchers and
56 managers within the Danish healthcare system to design assessment tools to ensure problems are
57 detected early after OHCA, and survivors and relatives are offered rehabilitation plans tailored to
58
59
60

1
2
3 their needs. Further, currently there are few high quality studies investigating the effectiveness of
4 rehabilitation interventions for OHCA survivors. Results from the DANCAS survey will provide
5 researchers with specific information to design the content and timing of new rehabilitation
6 interventions for OHCA survivors and their relatives.
7
8
9

10
11 Although this study will be one of the largest surveys involving OHCA survivors and one of the first to
12 survey both survivors and relatives, with the ability to link between the two, there are several
13 potential limitations. The majority of the self-report questionnaires have undergone some validation
14 testing. However, not all these tools have been validated in Danish or in the OHCA survivor
15 population and some questions have been written specifically for this survey (see supplementary
16 data).
17
18
19
20
21

22
23 The survey uses questionnaires based on self-report. However, approximately 50% of OHCA
24 survivors suffer from cognitive deficits and/or fatigue, leading to difficulties completing the survey
25 and hence potentially a lower response rate from survivors with these problems. To counter this,
26 the survey will be available both electronically and on paper, survivors will be allowed to have help to
27 complete the survey and asked to state if they had help. In addition, the relatives' section of the
28 survey will include an observer-reported cognitive questionnaire and relatives will be asked to
29 complete this even if the survivor questionnaire is not completed. However, it remains possible that
30 those with cognitive deficits and/or fatigue will be underrepresented in the survey response group
31 and this has to be accepted as a limitation of the self-report method chosen to gain data from as
32 many OHCA survivors as possible. Surveys will only be received by OHCA survivors able to access e-
33 Boks or living at home, so we are very unlikely to receive responses from any survivor living in long-
34 term residential care. Further, the DHRCA only records OHCA and therefore people who have
35 suffered an in-hospital cardiac arrest will not be included in this study. To ensure the characteristics
36 of the survey population are clear, baseline characteristics of non-responders will also be presented.
37
38
39
40
41
42
43
44
45
46
47

48 One aim of the survey is to describe how the prevalence of physical and psychological problems
49 suffered by survivors and their relatives changes over time since OHCA. Ideally, this would be
50 investigated using a prospective longitudinal study with data from the same population at multiple
51 follow-up points. The disadvantage of this design is the results would not be available for five-years,
52 and participants are asked to complete multiple surveys. The design of our survey groups
53 participants dependent on time since OHCA to describe changes over time. However, as these are
54 not the same participants in each time interval group, there is a risk of an unknown time-dependent
55 confounding factor effecting one of the groups more than another. Further, the cross-sectional
56
57
58
59
60

1
2
3 design, by definition, does not allow the formation of solid conclusions but the generation of
4 hypotheses based on associations between variables.
5
6
7
8

9 **Acknowledgements**

10 We would like to thank the member of the DANCAS network for their support in designing this
11 study: (Anette Marianne Fedder, Anette Rasmussen, Bo Gregers Winkel, Camilla Kofoed Dichman,
12 Charlotte Brun Thorup, Christian Hassager, Christina Marr Andersen, Elin Petersen, Frank Humle,
13 Hanne Balle, Hanne Kruise Rasmusen, Hanne Skovgaard Petersen, Helle Westberg, Irene Hallas,
14 Jens-Jakob Eifer Møller, Jette Nørr Møllebjerg, Jørgen Feldbeck Nielsen, Klaus Nikolaisen, Lars
15 Thrysoe, Lene Mønsted Nielsen, Lisa Gregersen Østergaard, Lone Andersen, Malene Hollingdal,
16 Malene Missel, Mette Stougaard, Mette Wagner, Mogens Hørder, Morten Jensen, Nina Rottmann,
17 Rikke Mols, Rikke Tornfeldt Martens, Steen Pehrson, Susanne Budin Holst, Susanne S Pedersen, Tina
18 L.B. Andersen, Dorte Qvistgaard).

19 LHT is currently funded by a grant from the Danish Regions and The Danish Health Confederation
20 through the Development and Research Fund for financial support (project nr. 2703) and a grant
21 from Region Zealand, Denmark (Exercise First).
22
23
24
25

26 **Author contributions** VJ, LHT and ADZ conceived the study; VJ and LHT designed the study with ADZ,
27 BB, LZ, TMB, RS, SRC and JFN. VJ led the writing of the manuscript, which was revised by all authors.
28 The final manuscript was approved by all authors.
29
30
31
32

33 **Funding** This project will be supported by infrastructure provided by REHPA, Danish Knowledge
34 Centre for Rehabilitation and Palliative Care, Odense University Hospital which receives funding
35 from the Danish Government. This project is part of a PhD partially funded by a PhD Faculty
36 scholarship (no grant number) from the University of Southern Denmark and a stipendium from the
37 Region of Southern Denmark (19/15041).
38
39
40
41
42
43
44
45
46
47
48

49 **Competing interests** None declared
50
51

52 **Patient consent** Not required
53
54

55 **Data statement:** Within the boundaries of Danish legislation, the anonymised data from the study
56 will be available for other researchers upon reasonable request when the results have been
57 published.
58
59
60

1
2
3
4 **Figure legends:**
5
6

7 Figure 1. Flow chart of Survey Population
8
9

10 Figure 2. Design of DANCAS survey and grouping according to time since OHCA
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

REFERENCES

1. Wissenberg M, Lippert FK, Folke F, et al. Association of national initiatives to improve cardiac arrest management with rates of bystander intervention and patient survival after out-of-hospital cardiac arrest. *JAMA* 2013;310(13):1377-84. doi: 10.1001/jama.2013.278483
2. Berdowski J, Berg RA, Tijssen JGP, et al. Global incidences of out-of-hospital cardiac arrest and survival rates: Systematic review of 67 prospective studies. *Resuscitation* 2010;81(11):1479-87. doi: 10.1016/j.resuscitation.2010.08.006
3. Ringgren KB, Christensen HC, Schønau L, et al. Out of hospital cardiac arrest in Denmark 2018. *Danish Cardiac Arrest Registry*
4. Sawyer KN, Camp-Rogers TR, Kotini-Shah P, et al. Sudden Cardiac Arrest Survivorship: A Scientific Statement From the American Heart Association. *Circulation* 2020;141(12):e654-e85. doi: 10.1161/CIR.0000000000000747 [published Online First: 2020/02/23]
5. Andrew E, Nehme Z, Wolfe R, et al. Long-term survival following out-of-hospital cardiac arrest. *Heart* 2017;103(14):1104-10. doi: 10.1136/heartjnl-2016-310485
6. Hawkes C, Booth S, Ji C, et al. Epidemiology and outcomes from out-of-hospital cardiac arrests in England. *Resuscitation* 2017;110:133-40. doi: 10.1016/j.resuscitation.2016.10.030
7. Schaaf KPW, Artman LK, Peberdy MA, et al. Anxiety, depression, and PTSD following cardiac arrest: A systematic review of the literature. *Resuscitation* 2013;84(7):873-77. doi: 10.1016/j.resuscitation.2012.11.021
8. Lilja G. Follow-Up of Cardiac Arrest Survivors: Why, How, and When? A Practical Approach. *Seminars in Neurology* 2017;37(1):88-93. doi: {10.1055/5-0036-1593859}
9. Maciel CB, Barden MM, Greer DM. Neurologic Recovery After Cardiac Arrest: a Multifaceted Puzzle Requiring Comprehensive Coordinated Care. *Current treatment options in cardiovascular medicine* 2017;19(7):52. doi: 10.1007/s11936-017-0548-0
10. Cronberg T, Greer DM, Lilja G, et al. Brain injury after cardiac arrest: from prognostication of comatose patients to rehabilitation. *The Lancet Neurology* 2020;19(7):611-22. doi: 10.1016/s1474-4422(20)30117-4
11. Lilja G, Nielsen N, Bro-Jeppesen J, et al. Return to Work and Participation in Society After Out-of-Hospital Cardiac Arrest. *Circulation: Cardiovascular Quality and Outcomes* 2018;11(1) doi: {10.1161/CIRCOUTCOMES.117.003566}
12. Kim YJ, Rogers JC, Raina KD, et al. An intervention for cardiac arrest survivors with chronic fatigue: A feasibility study with preliminary outcomes. *Resuscitation* 2016;105:109-15. doi: 10.1016/j.resuscitation.2016.05.020
13. Elliott VJ, Rodgers DL, Brett SJ. Systematic review of quality of life and other patient-centred outcomes after cardiac arrest survival. *Resuscitation* 2011;82(3):247-56. doi: 10.1016/j.resuscitation.2010.10.030
14. Kragholm K, Wissenberg M, Mortensen RN, et al. Return to Work in Out-of-Hospital Cardiac Arrest Survivors: A Nationwide Register-Based Follow-Up Study. *Circulation* 2015;131(19):1682-90. doi: 10.1161/CIRCULATIONAHA.114.011366
15. Viktorisson A, Sunnerhagen KS, Johansson D, et al. One-year longitudinal study of psychological distress and self-assessed health in survivors of out-of-hospital cardiac

- 1
2
3 arrest. *BMJ Open* 2019;9(7):e029756. doi: 10.1136/bmjopen-2019-029756
4 [published Online First: 2019/07/06]
- 5 16. Caro-Codon J, Rey JR, Lopez-de-Sa E, et al. Long-term neurological outcomes in out-of-
6 hospital cardiac arrest patients treated with targeted-temperature management.
7 *Resuscitation* 2018;133:33-39. doi: 10.1016/j.resuscitation.2018.09.015 [published
8 Online First: 2018/09/27]
- 9 17. Viktorisson A, Sunnerhagen KS, Pöder U, et al. Well-being among survivors of out-of-
10 hospital cardiac arrest: a cross-sectional retrospective study in Sweden. *BMJ Open*
11 2018;8(6):e021729. doi: 10.1136/bmjopen-2018-021729
- 12 18. Ann-Britt T, Ella D, Johan H, et al. Spouses' experiences of a cardiac arrest at home: an
13 interview study. *Eur J Cardiovasc Nurs* 2010;9(3):161-7. doi:
14 10.1016/j.ejcnurse.2009.12.005 [published Online First: 2010/01/15]
- 15 19. Wallin E, Larsson I-M, Rubertsson S, et al. Relatives' experiences of everyday life
16 six months after hypothermia treatment of a significant others cardiac arrest.
17 *Journal of Clinical Nursing* 2013;22(11-12):1639-46. doi: {10.1111/jocn.12112}
- 18 20. Moolaert VR, Verbunt JA, Bakx WG, et al. Stand still ... , and move on; a new early
19 intervention service for cardiac arrest survivors and their caregivers: rationale and
20 description of the intervention. *Clinical rehabilitation* 2011;25(10):867-79. doi:
21 10.1177/0269215511399937
- 22 21. van Wijnen HG, Rasquin SM, van Heugten CM, et al. The impact of cardiac arrest on the
23 long-term wellbeing and caregiver burden of family caregivers: a prospective cohort
24 study. *Clinical rehabilitation* 2017;31(9):1267-75. doi: 10.1177/0269215516686155
- 25 22. Holm MS, Norekval TM, Falun N, et al. Partners' ambivalence towards cardiac arrest and
26 hypothermia treatment: a qualitative study. *Nurs Crit Care* 2012;17(5):231-8. doi:
27 10.1111/j.1478-5153.2012.00490.x [published Online First: 2012/08/18]
- 28 23. Haywood K, Dainty KN. Life after cardiac arrest: The importance of engaging with the
29 'forgotten patient'. *Resuscitation* 2018;128:A1-A2. doi:
30 10.1016/j.resuscitation.2018.04.034 [published Online First: 2018/05/05]
- 31 24. Van't Wout Hofland J, Moolaert V, van Heugten C, et al. Long-term quality of life of
32 caregivers of cardiac arrest survivors and the impact of witnessing a cardiac event of
33 a close relative. *Resuscitation* 2018;128:198-203. doi:
34 10.1016/j.resuscitation.2018.03.016 [published Online First: 2018/03/24]
- 35 25. Nolan JP, Soar J, Cariou A, et al. European Resuscitation Council and European Society of
36 Intensive Care Medicine 2015 guidelines for post-resuscitation care. *Intensive care
37 medicine* 2015;41(12):2039-56. doi: {10.1007/s00134-015-4051-3}
- 38 26. Tang LH, Joshi V, Egholm CL, et al. Are survivors of cardiac arrest provided with standard
39 cardiac rehabilitation? - Results from a national survey of hospitals and
40 municipalities in Denmark. *Eur J Cardiovasc Nurs* 2020;1474515120946313. doi:
41 10.1177/1474515120946313 [published Online First: 2020/08/05]
- 42 27. Boyce LW, Goossens PH, Moolaert VR, et al. Out-of-hospital cardiac arrest survivors
43 need both cardiological and neurological rehabilitation! *Current opinion in critical
44 care* 2019;25(3):240-43. doi: 10.1097/MCC.0000000000000609
- 45 28. Nolan JP, Lockey A, Perkins G, et al. Resuscitation Council (UK) Post resuscitation care
46 guidelines 2015, 2016:1-21.
- 47 29. Tang LH, Zwisler A-D. Rehabilitation after cardiac arrest - we can surely do better!
48 *Cardiologisk Forum* 2019;30(February):30-37.
- 49 30. Haywood K, Whitehead L, Nadkarni VM, et al. COSCA (Core Outcome Set for Cardiac
50 Arrest) in Adults: An Advisory Statement From the International Liaison Committee
51
52
53
54
55
56
57
58
59
60

- 1
2
3 on Resuscitation. *Resuscitation* 2018;127:147-63. doi:
4 10.1016/j.resuscitation.2018.03.022
- 5 31. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new
6 five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international*
7 *journal of quality of life aspects of treatment, care and rehabilitation*
8 2011;20(10):1727-36. doi: 10.1007/s11136-011-9903-x
- 9 32. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica*
10 *Scandinavica* 1983;67(6):361-70. doi: 10.1016/j.jad.2018.04.092
- 11 33. Christensen AV, Dixon JK, Juel K, et al. Psychometric properties of the Danish Hospital
12 Anxiety and Depression Scale in patients with cardiac disease: results from the
13 DenHeart survey. *Health Qual Life Outcomes* 2020;18(1):9. doi: 10.1186/s12955-019-
14 1264-0 [published Online First: 2020/01/09]
- 15 34. Lilja G, Nielsen N, Friberg H, et al. Cognitive function after cardiac arrest and
16 temperature management; rationale and description of a sub-study in the Target
17 Temperature Management trial. *BMC Cardiovascular Disorders* 2013;{13} doi:
18 {10.1186/1471-2261-13-85}
- 19 35. Longstreth WT, Jr., Nichol G, Van Ottingham L, et al. Two simple questions to assess
20 neurologic outcomes at 3 months after out-of-hospital cardiac arrest: experience
21 from the public access defibrillation trial. *Resuscitation* 2010;81(5):530-3. doi:
22 10.1016/j.resuscitation.2010.01.011 [published Online First: 2010/02/23]
- 23 36. Schiehser DM, Delano-Wood L, Jak AJ, et al. Validation of the Modified Fatigue Impact
24 Scale in mild to moderate traumatic brain injury. *J Head Trauma Rehabil*
25 2015;30(2):116-21. doi: 10.1097/HTR.000000000000019 [published Online First:
26 2014/01/15]
- 27 37. Amtmann D, Bamer AM, Noonan V, et al. Comparison of the psychometric properties of
28 two fatigue scales in multiple sclerosis. *Rehabil Psychol* 2012;57(2):159-66. doi:
29 10.1037/a0027890 [published Online First: 2012/06/13]
- 30 38. Federici S, Bracalenti M, Meloni F, et al. World Health Organization disability assessment
31 schedule 2.0: An international systematic review. *Disability and rehabilitation*
32 2017;39(23):2347-80. doi: 10.1080/09638288.2016.1223177 [published Online First:
33 2]
- 34 39. Garin O, Ayuso-Mateos JL, Almansa J, et al. Validation of the "World Health Organization
35 Disability Assessment Schedule, WHODAS-2" in patients with chronic diseases.
36 *Health and Quality of Life Outcomes* 2010;8:51. doi: 10.1186/1477-7525-8-51
- 37 40. Kuo CY, Liou TH, Chang KH, et al. Functioning and disability analysis of patients with
38 traumatic brain injury and spinal cord injury by using the world health organization
39 disability assessment schedule 2.0. *Int J Environ Res Public Health* 2015;12(4):4116-
40 27. doi: 10.3390/ijerph120404116 [published Online First: 2015/04/16]
- 41 41. The Danish Cancer Society. Kræftpatienters oplevelser med sundhedsvæsenet gennem
42 udredning og behandling. The Experience of Cancer Patients during Diagnosis and
43 Treatment. Copenhagen, 2011.
- 44 42. Veloso AG, Sperling C, Holm LV, et al. Unmet needs in cancer rehabilitation during the
45 early cancer trajectory--a nationwide patient survey. *Acta Oncol* 2013;52(2):372-81.
46 doi: 10.3109/0284186X.2012.745648 [published Online First: 2013/01/17]
- 47 43. Zinckernagel L, Schneekloth N, Zwisler AO, et al. How to measure experiences of
48 healthcare quality in Denmark among patients with heart disease? The development
49 and psychometric evaluation of a patient-reported instrument. *BMJ Open*
50
51
52
53
54
55
56
57
58
59
60

- 2017;7(10):e016234. doi: 10.1136/bmjopen-2017-016234 [published Online First: 2017/11/01]
44. Bech P, Olsen LR, Kjoller M, et al. Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five Well-Being Scale. *Int J Methods Psychiatr Res* 2003;12(2):85-91. doi: 10.1002/mpr.145
45. Topp CW, Ostergaard SD, Sondergaard S, et al. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom* 2015;84(3):167-76. doi: 10.1159/000376585 [published Online First: 2015/04/04]
46. Blenow Nordström E, Lilja G, Årestedt K, et al. Validity of the IQCODE-CA: An informant questionnaire on cognitive decline modified for a cardiac arrest population. *Resuscitation* 2017;118:8-14. doi: 10.1016/j.resuscitation.2017.06.012
47. Thornton M, Travis SS. Analysis of the Reliability of the Modified Caregiver Strain Index. *The Journals of Gerontology: Series B* 2003;58(2):S127-S32. doi: 10.1093/geronb/58.2.S127
48. Jensen HAR, Ekholm O, Davidsen M, et al. The Danish health and morbidity surveys: study design and participant characteristics. *BMC Med Res Methodol* 2019;19(1):91. doi: 10.1186/s12874-019-0733-9 [published Online First: 2019/05/06]
49. Jensen VM, Rasmussen AW. Danish Education Registers. *Scand J Public Health* 2011;39(7 Suppl):91-4. doi: 10.1177/1403494810394715 [published Online First: 2011/08/04]
50. Baadsgaard M, Quitzau J. Danish registers on personal income and transfer payments. *Scand J Public Health* 2011;39(7 Suppl):103-5. doi: 10.1177/1403494811405098 [published Online First: 2011/08/04]
51. Lyng E, Sandegaard JL, Rebolj M. The Danish National Patient Register. *Scand J Public Health* 2011;39(7 Suppl):30-3. doi: 10.1177/1403494811401482 [published Online First: 2011/08/04]
52. Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *Journal of chronic diseases* 1987;40(5):373-83.
53. Hjollund NH, Larsen FB, Andersen JH. Register-based follow-up of social benefits and other transfer payments: accuracy and degree of completeness in a Danish interdepartmental administrative database compared with a population-based survey. *Scand J Public Health* 2007;35(5):497-502. doi: 10.1080/14034940701271882 [published Online First: 2007/09/14]
54. Kragholm K, Torp-Pedersen C. Cardiac arrest survivors: short residual risk of death, long life expectancy. *Heart* 2017;103(14):1063-64. doi: 10.1136/heartjnl-2017-311259
55. Tolstrup Larsen R, Tang LH, Brochmann N, et al. Associations between fatigue, physical activity, and QoL in patients with myeloproliferative neoplasms. *Eur J Haematol* 2018;100(6):550-59. doi: 10.1111/ejh.13048 [published Online First: 2018/02/22]
56. Kildemoes HW, Sorensen HT, Hallas J. The Danish National Prescription Registry. *Scand J Public Health* 2011;39(7 Suppl):38-41. doi: 10.1177/1403494810394717 [published Online First: 2011/08/04]
57. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *The Lancet* 2007;370(9596):1453-57. doi: 10.1016/s0140-6736(07)61602-x

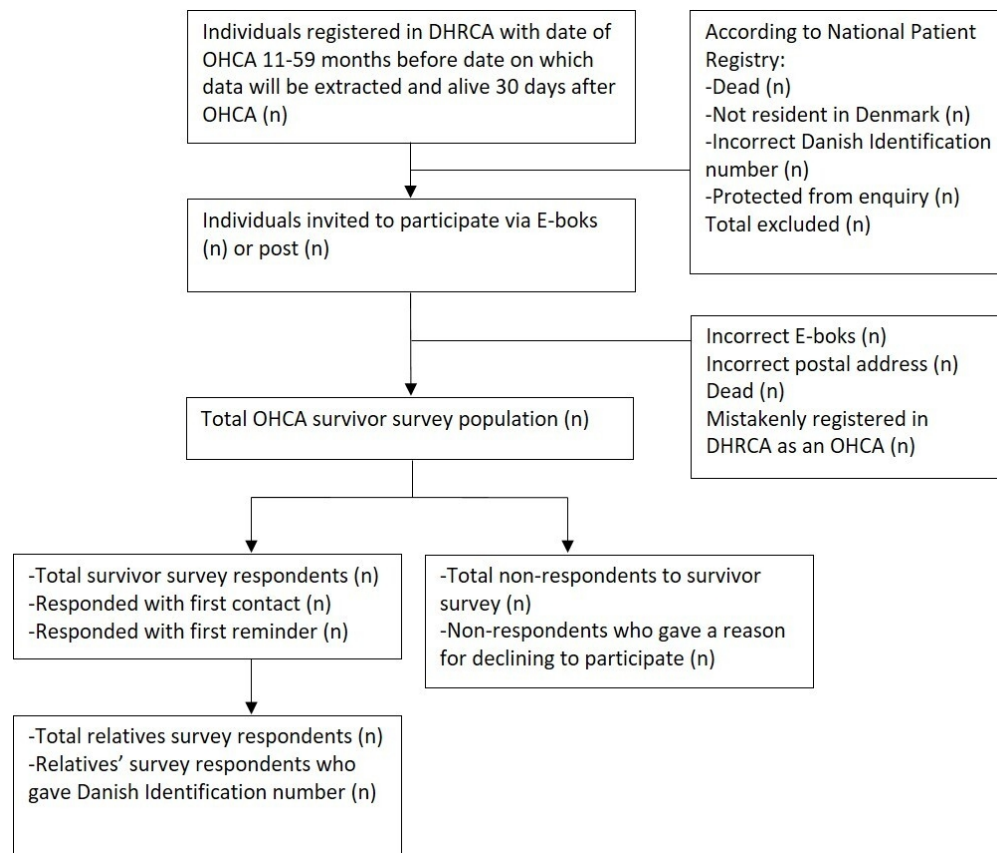


Figure 1. Flow chart of Survey Population

84x71mm (300 x 300 DPI)

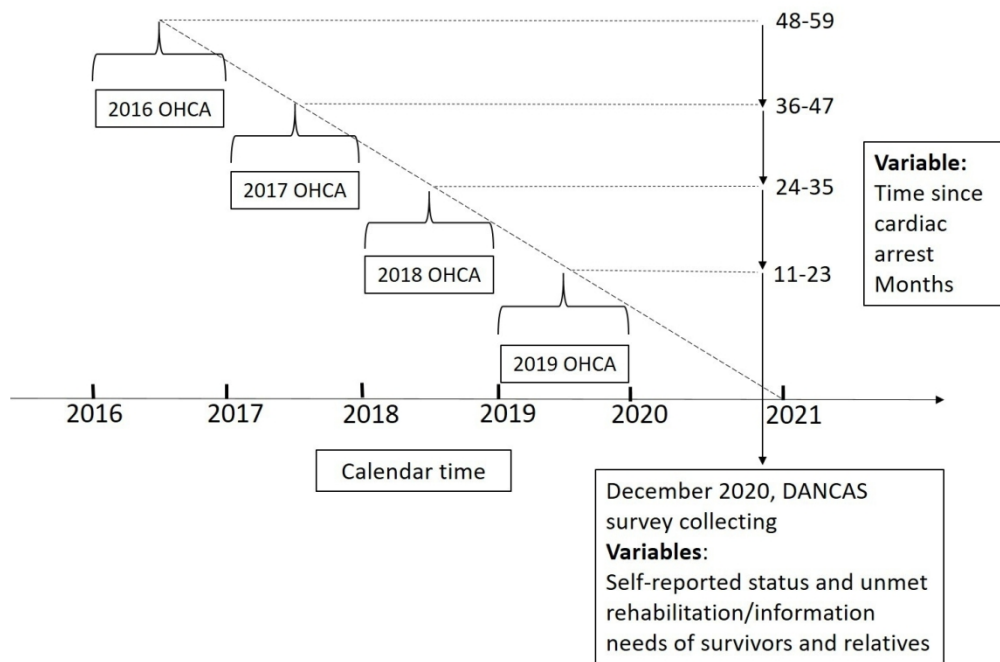


Figure 2. Design of DANCAS survey and grouping according to time since OHCA

125x84mm (300 x 300 DPI)

Supplementary data.

Table 1. Detailed content of DANCAS surveys

Outcome domain	Outcome measure	Items, scoring	Danish translation	Notes
Survivors				
Generic health	EQ-5D-5L	Five item health dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Divided into five levels: 1='No problems' to 5= 'Extreme problems', scores ≥ 2 signifies a problem. Sixth item: Self-rating of health. Visual Analogue Scale, 0-100. Higher scores signify better health status. ¹	Received from the EuroQoL group	
Anxiety and depression	HADS	Seven-item symptoms of anxiety subscale (HADS-A) Seven-item subscale symptoms of depression (HADS-D). Four responses: 0='No symptoms' to 3= 'maximum number of symptoms'. Total subscale scores range: 0-21. <8 = no psychological distress, 8-10 = mild psychological distress, >10 definite psychological distress. It has recently been shown to be a valid measure of anxiety and depression in a Danish cardiac disease population. ²	Received from DenHeart study group ³	Valid measure of anxiety and depression in Danish cardiac disease population ³

Mental recovery/dependency	TSQ	Yes to Q1a + Yes to Q1b signify new problems with dependency after cardiac arrest. No to Q2 indicates problems with mental recovery after cardiac arrest. ^{4,5}	Received from TTM2 study group ⁴	-
Fatigue impact on functional activities	MFIS	21 items in three sub-scales (physical, cognitive and psychosocial). Total scores range: 0-84. Total subscale scores: physical= 0 -36; cognitive=0=40; psychosocial= 0-8. ≥30 signify a fatigued individual (Antmann, 2012, Schiehser, 2015)	Translation received from the Provide, Map Research Trust.	Validated in people with multiple sclerosis. ⁶ and mild to moderate brain injury. ⁷
Function and disability	12-item WHO DAS 2.0	12-item assessing 6 domains of functioning: 1) Understanding and communication; 2) Self-care; 3) Mobility; 4) Interpersonal relationships; 5) Work and household roles; and 6) Community and civic roles. Scored from 0= 'no difficulty' to 4= 'extreme difficulty or cannot do'. Total scores range: 0-48. Higher score indicating greater difficulty with activity and participation.	Available from: https://www.etf.dk/ergoterapi-og-politik/hverdagsrehabilitering	Used extensively to research neurological conditions including traumatic brain injury and spinal cord injury, ⁸ and rehabilitation and disability in a wide range of disease populations. ⁹ Validated in patients with chronic diseases. ¹⁰
Life satisfaction/rehabilitation need	REHPA scale	A linear analogue scale, participants indicate how close they are to living the life they desire after their OHCA. Scale ranges from 0= 'goal reached' to 9= 'infinitely far from'.	By DANCAS study authors	

		Score of ≤ 3 will be considered as signifying having rehabilitation needs.		
Unmet rehabilitation needs		6-items asking if rehabilitation needs were met in different domains, for example, emotional reactions. Scored on a 4-point Likert type scale from 'Yes to a high level' to 'No, not at all'. ¹²	Adapted by DANCAS authors	Questions adapted from existing survey 'The Experience of Cancer Patients during Diagnosis and Treatment'. ^{12 13}
Unmet information needs	Adapted from Zinckernagel et al., 2017	7-items asking if information needs were met in different domains, for example, 'treatment of your heart condition' Scored on a 4-point Likert type scale from 'Yes to a high level' to 'No, not at all'. ¹⁴	Adapted by DANCAS authors for OHCA survivors from a Danish survey of patients with heart disease. ¹⁴	
Relatives				
Anxiety and depression	HADS	As above		
Mental well-being	WHO-5	Five items with 6 responses from 0='At no time' to 5='all of the time'. Scores are totaled and multiplied by 4 to give range 0-100. Score <50 signifies poor emotional well-being. ¹⁵	Developed in Denmark. ¹⁶	Valid in multiple patient populations. ¹⁷

<p>Cognitive problems in daily life</p>	<p>IQCODE-CA</p>	<p>26-items scored on a five-point scale, 1= 'much improved' to 5= 'much worse'. Scores are totaled, divided by the number of questions to give a total, range 1-5. Score ≥ 3.04 signifies cognitive decline after cardiac arrest.¹⁸</p>	<p>Received from TTM2 study group</p>	<p>Relatives or close friends compare current cognitive function with pre-cardiac arrest cognitive function. Has been shown to accurately identify cardiac arrest survivors with potential cognitive problems.¹⁸</p>
<p>Caregiver strain</p>	<p>MCSI</p>	<p>13-items, scored: 2= 'Yes, On a Regular Basis', 1= 'Yes, sometimes', 0= 'No'. Range: 0-26, higher scores signify a higher level of carer strain.¹⁹</p>	<p>Translated by DANCAS study authors^a</p>	<p>Found to have high internal validity with a population of family caregivers.¹⁹</p>
<p>Witness to OHCA</p>	<p>Questions designed for this survey</p>	<p>1-item on whether they witnessed the OHCA</p>	<p>Created by DANCAS study authors</p>	
<p>Labour market</p>	<p>Questions designed for this survey</p>	<p>7-items on educational level completed, current labour market status, status in pre-OHCA period and details of any sick leave in post-OHCA period.</p>	<p>Created by DANCAS study authors</p>	<p>These questions are asked of the relatives as their survey answers cannot be connected to Danish labour market registry data unless they provide their Danish personal identification number.</p>
<p>Social isolation</p>	<p>Question from Danish national health survey</p>	<p>One item: Does it ever happen that you are alone even though you would prefer to be with other people?"</p>	<p>Available at: http://www.danskernesundhed.dk/Spoergeskema</p>	

6/bmjopen-2022-045668 on 2 April 2021. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

		Answers: “yes, often” and “yes, sometimes” signify loneliness. Other possible responses are “yes, but rarely” and “no.		
Support received post-OHCA	Questions designed for this survey	4-items on: whether relatives feel they have someone to talk to if they need support (yes, always/yes, mostly/yes, sometimes/no never or almost never); who have they received support from (multiple options); if they received the support they needed (Yes, No), and who would they like to have received support from in the post-OHCA period (free text box).	Created by DANCAS study authors	
<p>Abbreviations: HADS= Hospital Anxiety and Depression Scale; TSQ=Two Simple Questions; TTM2= Targeted Hypothermia versus Targeted Normothermia after OHCA trial 2; MFIS: Modified Fatigue Impact Scale, WHO DAS 2.0= World Health Organisation disability assessment schedule 2.0 Short; REHPA= Danish Knowledge Center for Rehabilitation and Palliative Care; OHCA=Out-of-hospital Cardiac Arrest; DANCAS=Danish Cardiac Arrest Survivorship; WHO-5= World Health Organisation-Five Well-Being index; IQCODE-CA: Informant Questionnaire on Cognitive Decline in the Elderly, Cardiac Arrest Version; MCSI= Modified Carer Strain Index.</p> <p>^aTranslation, cultural adaption and psychometric testing performed by study authors, results are planned to be available in a future publication.</p>				

1. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2011;20(10):1727-35. doi: 10.1007/s11136-011-9903-x
2. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 1983;67(6):366-70. doi: 10.1016/j.jad.2018.04.092
3. Christensen AV, Dixon JK, Juel K, et al. Psychometric properties of the Danish Hospital Anxiety and Depression Scale in patients with cardiac disease: results from the DenHeart survey. *Health Qual Life Outcomes* 2020;18(1):9. doi: 10.1186/s12955-019-1264-0 [published Online First: 2020/01/09]

4. Lilja G, Nielsen N, Friberg H, et al. Cognitive function after cardiac arrest and temperature management; rationale and description of a sub-study in the Target Temperature Management trial. *BMC Cardiovascular Disorders* 2013;13 doi: {10.1186/1471-2261-13-85}
5. Longstreth WT, Jr., Nichol G, Van Ottingham L, et al. Two simple questions to assess neurologic outcomes at 3 months after out-of-hospital cardiac arrest: experience from the public access defibrillation trial. *Resuscitation* 2010;81(5):530-3. doi: 10.1016/j.resuscitation.2010.01.011 [published Online First: 2010/02/23]
6. Amtmann D, Bamer AM, Noonan V, et al. Comparison of the psychometric properties of two fatigue scales in multiple sclerosis. *Rehabil Psychol* 2012;57(2):159-66. doi: 10.1037/a0027890 [published Online First: 2012/06/13]
7. Schiehser DM, Delano-Wood L, Jak AJ, et al. Validation of the Modified Fatigue Impact Scale in mild to moderate traumatic brain injury. *J Head Trauma Rehabil* 2015;30(2):116-21. doi: 10.1097/HTR.000000000000019 [published Online First: 2014/07/15]
8. Kuo CY, Liou TH, Chang KH, et al. Functioning and disability analysis of patients with traumatic brain injury and spinal cord injury by using the world health organization disability assessment schedule 2.0. *Int J Environ Res Public Health* 2015;12(4):4116-27. doi: 10.3390/ijerph120404116 [published Online First: 2015/04/16]
9. Federici S, Bracalenti M, Meloni F, et al. World Health Organization disability assessment schedule 2.0: An international systematic review. *Disability and rehabilitation* 2017;39(23):2347-80. doi: 10.1080/09638288.2016.1223177 [published Online First: 2]
10. Garin O, Ayuso-Mateos JL, Almansa J, et al. Validation of the "World Health Organization Disability Assessment Schedule, WHODAS-2" in patients with chronic diseases. *Health and Quality of Life Outcomes* 2010;8:51. doi: 10.1186/1477-7525-8-51
11. Danquah IH, Petersen CB, Skov SS, et al. Validation of the NPAQ-short - a brief questionnaire to monitor physical activity and compliance with the WHO recommendations. *BMC public health* 2018;18(1):601. doi: 10.1186/s12889-018-5538-y
12. The Danish Cancer Society. Kræftpatienters oplevelser med sundhedsvæsenet gennem udredning og behandling. The Experience of Cancer Patients during Diagnosis and Treatment. Copenhagen, 2011.
13. Veloso AG, Sperling C, Holm LV, et al. Unmet needs in cancer rehabilitation during the early cancer trajectory--a nationwide patient survey. *Acta Oncol* 2013;52(2):372-81. doi: 10.3109/0284186X.2012.745648 [published Online First: 2013/01/17]
14. Zinckernagel L, Schneekloth N, Zwisler AO, et al. How to measure experiences of healthcare quality in Denmark among patients with heart disease? The development and psychometric evaluation of a patient-reported instrument. *BMJ Open* 2017;7(10):e016234. doi: 10.1136/bmjopen-2017-016234 [published Online First: 2017/11/01]
15. Lowe B. Comparative validity of three screening questionnaires for DSM-IV depressive disorders and physicians' diagnoses. *Journal of Affective Disorders* 2004;78(2):131-40. doi: 10.1016/s0165-0327(02)00237-9
16. Bech P, Olsen LR, Kjoller M, et al. Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five Well-Being Scale. *Int J Methods Psychiatr Res* 2003;12(2):85-91. doi: 10.1002/mpr.145
17. Topp CW, Ostergaard SD, Sondergaard S, et al. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom* 2015;84(3):167-76. doi: 10.1159/000376585 [published Online First: 2015/04/04]
18. Blenow Nordström E, Lilja G, Årestedt K, et al. Validity of the IQCODE-CA: An informant questionnaire on cognitive decline modified for a cardiac arrest population. *Resuscitation* 2017;118:8-14. doi: 10.1016/j.resuscitation.2017.06.012
19. Thornton M, Travis SS. Analysis of the Reliability of the Modified Caregiver Strain Index. *The Journals of Gerontology: Series B* 2003;58(2):S127-S32. doi: 10.1093/geronb/58.2.S127

BMJ Open

Long-term physical and psychological outcomes after out-of-hospital cardiac arrest– Protocol for a national cross-sectional survey of survivors and their relatives (the DANCAS survey)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-045668.R2
Article Type:	Protocol
Date Submitted by the Author:	23-Feb-2021
Complete List of Authors:	Joshi, Vicky; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Tang, Lars; Slagelse Hospital, Department of Physiotherapy and Occupational Therapy; University of Southern Denmark, The Department of Regional Health Research Borregaard, Britt; Odense University Hospital, Department of Cardiology; University of Southern Denmark, Department of Clinical Research Zinckernagel, Line; University of Southern Denmark, National Institute of Public Health; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Mikkelsen, Tina; Odense University Hospital, REHPA, The Danish Knowledge Centre for Rehabilitation and Palliative Care Taylor, Rod; University of Glasgow, MRC/CSO Social and Public Health Sciences Unit & Robertson Centre for Biostatistics, Institute of Health and Well Being; University of Exeter, College of Medicine and Health Christiansen, Sofie; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care Nielsen, Jørgen ; Regional Hospital Hammel Neurocenter; Aarhus University, Department of Clinical Medicine Zwisler, Ann Dorthe; Odense University Hospital, REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care; Odense University Hospital, Department of Cardiology
Primary Subject Heading:	Cardiovascular medicine
Secondary Subject Heading:	Rehabilitation medicine, Epidemiology
Keywords:	Adult cardiology < CARDIOLOGY, REHABILITATION MEDICINE, EPIDEMIOLOGY

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

BMJ Open: first published as 10.1136/bmjopen-2020-045668 on 2 April 2021. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3
4 **Long-term physical and psychological outcomes after out-of-hospital cardiac arrest–**
5 **Protocol for a national cross-sectional survey of survivors and their relatives (the DANCAS**
6 **survey)**
7
8

9 Vicky L Joshi, PhD student¹ (victoria.louise.joshi@rsyd.dk)

10 Lars H Tang, Assistant professor^{2,3} (larta@regionsjaelland.dk)

11 Britt Borregaard, Post doc^{4,5} (britt.borregaard@rsyd.dk)

12 Line Zinckernagel, PhD student^{1,6} (lizi@niph.dk)

13 Tina Broby Mikkelsen, Data manager¹ (tina.broby.mikkelsen@rsyd.dk)

14 Rod S Taylor, Professor^{7,8} (rod.taylor@gla.ac.uk)

15 Sofie Raahauge Christiansen, researcher¹ (sofie.raahauge.christiansen@rsyd.dk)

16 Jørgen Feldbæk Nielsen, Professor⁹ (joerniel@rm.dk)

17 Ann-Dorthe Zwisler, Professor^{1,4} (ann.dorthe.olsen.zwisler@rsyd.dk)

18
19
20
21
22
23
24
25
26 ¹REHPA, Danish Knowledge Centre for Rehabilitation and Palliative Care, University of Southern
27 Denmark, and Odense University Hospital, Denmark

28
29 ²Department of Physiotherapy and Occupational Therapy, Næstved-Slagelse-Ringsted Hospitals

30
31 ³The Department of Regional Health Research, University of Southern Denmark

32
33 ⁴Department of Cardiology, Odense University Hospital, Odense, Denmark

34
35 ⁵Department of Clinical Research, University of Southern Denmark, Odense, Denmark

36
37 ⁶The National Institute for Public Health, University of Southern Denmark, Copenhagen, Denmark

38
39 ⁷MRC/CSO Social and Public Health Sciences Unit & Robertson Centre for Biostatistics, Institute of
40 Health and Well Being, University of Glasgow, UK

41
42 ⁸College of Medicine and Health, University of Exeter, UK

43
44 ⁹Hammel Neuro Center, Hospitalsenhed Midt, Viborg, Denmark

45
46 Corresponding author: Vicky L Joshi, address: Studiestræde 6, 1455 Copenhagen. email:

47 victoria.louise.joshi@rsyd.dk. Tel: +4550229798.

48
49
50
51 Word count manuscript: 3908

52
53 Key words: Out-of-hospital cardiac arrest survivor, relatives of out-of-hospital cardiac arrest
54 survivors, cross-sectional survey, self-report.
55
56
57
58
59
60

ABSTRACT

Introduction

The number of out-of-hospital cardiac arrest (OHCA) survivors is increasing. However, there remains limited knowledge on the long-term physical and psychological problems suffered by survivors and their relatives. The aims of the DANCAS (DANish cardiac arrest survivorship) survey are to describe the prevalence of physical and psychological problems, identify predictors associated with suffering them and to determine unmet rehabilitation needs in order to make recommendations on the timing and content of future rehabilitation interventions.

Methods and analysis

The DANCAS survey has a cross-sectional design involving a survey of OHCA survivors and their relatives. OHCA survivors will be identified through the Danish Cardiac Arrest Registry as having suffered an OHCA between 1st January 2016 and 31st December 2019. Each survivor will be asked to identify their closest relative to complete the relatives' survey. Contents of survivor survey: EQ-5D-5L, Hospital Anxiety and Depression Scale, Two Simple Questions, Modified Fatigue Impact Scale, 12-item World Health Organisation Disability Assessment Scale 2.0, plus questions on unmet rehabilitation and information needs. Contents of relatives' survey: World Health Organisation-Five Well-Being Index, Hospital Anxiety and Depression Scale, Informant Questionnaire on Cognitive Decline in the Elderly – Cardiac Arrest and the Modified Caregiver Strain Index. Self-report outcome data collected through the surveys will be enriched by data from Danish national registries including: demographic characteristics, circumstances of cardiac arrest and co-morbidities. The survey will be completed either electronically or by post December 2020-February 2021.

Ethics and dissemination

The study will be conducted in accordance with the Declaration of Helsinki. Surveys and registry-based research studies do not normally require ethical approval in Denmark. This has been confirmed for this study by the Region of Southern Denmark ethics committee (20192000_19). Results of the study will be disseminated via several peer-reviewed publications and will be presented at national and international conferences.

Article Summary

Strengths and limitations of this study:

- Denmark has markedly improved the survival rate among OHCA survivors during the last five years.
- This will be one of the largest nationwide surveys of OHCA survivors to date with data collected from survivors and relatives up to five-years after cardiac arrest.

- 1
2
3 -Data will be derived from both self-report measures and national registries providing a
4 comprehensive picture of the problems experienced by OHCA survivors and the risk factors
5 associated with suffering them.
6
7 -The response rate from OHCA survivors suffering from cognitive problems and/or fatigue may be
8 lower due to difficulties completing the survey compared to those without these problems to
9 counter this the survey will be available both electronically and on paper.
10
11 -The change in physical and psychological problems over time may be influenced by a treatment
12 cohort effect and other unknown time-dependent modifying factors.
13
14
15
16
17
18

19 INTRODUCTION

20 The number of people surviving an out-of-hospital cardiac arrest (OHCA) is increasing every year due
21 to advances in pre-hospital and acute medical care.^{1,2} In Denmark, thirty-day survival after OHCA
22 improved from 4% to 16% between 2001 and 2018.³ This amounts to at least 800 new survivors
23 every year.³ Still, after the acute phase ends, the physical and psychological impact of OHCA may
24 continue.⁴ Most OHCA survivors will have a new or ongoing cardiac condition.^{5,6} They may suffer
25 from psychological trauma due to surviving a near-death experience.⁷ Further, reduced oxygen
26 levels to the brain during an OHCA can cause cognitive deficits in up to 50% of survivors.⁸⁻¹⁰ Due to
27 this combination of factors, OHCA survivors have been shown to suffer anxiety and depression,
28 fatigue and reduced participation in society.^{7,8,11,12} General health, return-to-work rates and quality
29 of life do, however, appear to improve over time¹³⁻¹⁵ but data regarding: health measures, return-to-
30 work patterns and unmet rehabilitation needs beyond 12-months after OHCA are limited.^{7,11,14,16,17}
31
32
33
34
35
36
37
38
39

40 As most OHCA occur in private homes, relatives are likely to witness the event.¹⁸ Combined with the
41 changes in both physical and psychological status of many OHCA survivors, quality of life and
42 psychological health among relatives might be influenced. It has previously been described how
43 relatives of OHCA survivors suffer from emotional problems including anxiety, depression and post-
44 traumatic stress, due to becoming a carer for their loved one or fear of the cardiac arrest
45 recurring.^{19,20} Likewise, lack of control, feelings of insecurity, mood and sleep disturbances have
46 been reported among relatives.^{21,22} Yet, very few research studies have investigated the
47 consequences of OHCA for relatives in the longer term,^{23,24} or how these are associated with
48 witnessing the event or with the physical, psychological problems suffered by the OCHA survivor.
49
50
51
52
53
54
55
56

57 Rehabilitation for OHCA survivors is recommended in international guidelines^{4,25} but the specific
58 content and timing of these interventions has not been established. Survivors will commonly be
59
60

1
2
3 offered cardiac rehabilitation related to their new or ongoing cardiac condition,^{4 26} but it has been
4 suggested that the psychological and neurological rehabilitation needs of OHCA are not met to the
5 same degree.²⁷ Hence, the aims of this national cross-sectional study are to 1) describe the long-
6 term prevalence of physical and psychological problems for OHCA survivors and their relatives and
7 how these change over time 2) identify predictors associated with increased risk of suffering these
8 problems and 3) determine unmet rehabilitation needs in order to make recommendations on the
9 timing and content of future rehabilitation interventions. Specific objectives for each aim will be
10 defined in future publications.
11
12
13
14
15
16
17
18

19 **METHODS AND ANALYSIS**

20 **Study design**

21 The DANCAS (DANish Cardiac Arrest Survivorship) survey aims will be achieved through a cross-
22 sectional study design.
23
24
25
26

27 **Setting and participants**

28 In Denmark, pre-hospital care, hospital care and all cardiac treatment and rehabilitation are funded
29 via the tax system and are free of charge for patients. The Danish Out-of-Hospital Cardiac Arrest
30 (DHRCA) registry will be used to identify the Danish personal identification numbers of people who
31 have suffered an OHCA from 1st January 2016 to 31st December 2019 and were alive 30-days after
32 their cardiac arrest (figure 1). All patients in Denmark who have suffered an OHCA, where
33 bystanders or paramedics attempted treatment are included in the DHRCA registry. Data is recorded
34 electronically immediately after the OHCA in the pre-hospital patient record by paramedics from one
35 of the five regional ambulance services and collected in the DHRCA. The DHRCA collects data on
36 OHCA in Denmark for the purposes of quality improvement. The pre-hospital managers of the five
37 Danish regions are responsible for collecting the data, have ownership of their own data, and give
38 approval for data access on behalf of OHCA survivors. Access to DHRCA data is granted via approval
39 of a research protocol by the DHRCA steering group.
40
41
42
43
44
45
46
47
48
49

50 The DHRCA started collecting data in 2001, however, before 2016, this was recorded by hand on
51 paper and hence significant gaps in the data exist³. In addition, pre-hospital and medical
52 management of OHCA has changed significantly in the period 2001-2015.²⁸ Consequently, the
53 proposed timeframe of 1-5 years since OHCA provides both a long-term perspective and ensures
54 data is relevant to the contemporary OHCA survivor population.
55
56
57
58
59
60

1
2
3 The extracted Danish personal identification numbers will be matched by the Danish National Health
4 Digital Board to names, and addresses in the Danish National Patient Registry retrieve.
5
6

7
8 The information letter received by the OHCA survivors will ask them to identify their closest relative
9 and ask them to complete the relatives' survey. This method of recruitment has been tested in the
10 development of the survey and is feasible. Closest relative is defined as a partner, spouse, sibling, or
11 parent that is closest to the survivor.
12
13
14

15 16 **Eligibility criteria**

17
18 OHCA survivor participants included in the survey will have a Danish personal identification number,
19 be alive at least 30-days post-cardiac arrest, resident in Denmark, over 18-years of age and able to
20 read and write in Danish and not protected from receiving inquiries during scientific surveys.
21
22
23

24
25 Relative participants must have a relative who has survived an OHCA, be over 18 years of age and be
26 able to read and write in Danish. The relatives do not need to have a Danish personal identification
27 number, as they will be invited to complete their survey via the information letter to the OHCA
28 survivor participants. However, they will be asked to provide their Danish personal identification
29 number to allow linkage with Danish national registries.
30
31
32

33 34 **Data collection**

35
36 All OHCA survivor participants that meet the eligibility criteria will receive an invitation to participate
37 in the survey via REDCap (Research Electronic Data Capture) software to their e-Boks (government
38 electronic mail account) or via post if they do not have an E-boks address. Based on the age profile
39 of OHCA survivors over the last 5-years and the age-profile of Danes with e-Boks addresses it is
40 estimated that 20% of participants will require a postal survey.
41
42
43
44
45

46
47 The link to complete the separate relatives' survey will be included in the invitation sent to the
48 OHCA survivors' eBoks. Invitations sent via post to the OHCA survivor will include a paper copy of
49 both surveys, two stamped addressed envelopes (for survivor and relative) and information on how
50 to complete the surveys online rather than by post if they wish. A participant information sheet will
51 be included with all invitations to participate in the survey. This will detail the purpose of the
52 research study, how data will be used and will explain that by returning the survey, they are
53 consenting to take part. The information sheet will include a telephone number to call a member of
54 the research team if participants have any questions. Participants who receive the E-boks survey will
55
56
57
58
59
60

1
2
3 have the option to request a paper survey by post. A reminder invitation will be sent via E-boks/post
4 after two-weeks.
5
6

7 Additional data from the DHRCA will provide information on circumstances of the OHCA (Table 1).

8
9 Table. 1 Data on circumstances of OHCA from DHRCA
10

11 **Table. 1 Data on circumstances of OHCA from DHRCA**

12 Location of cardiac arrest (Private/public)

13 First observed heart rhythm (shockable/not shockable)

14 Cardiopulmonary resuscitation was given before the arrival of the ambulance (Yes/No)

15 Defibrillated before the arrival of the ambulance (Yes/No)

16 Time to return of spontaneous circulation (minutes: second)
17
18
19
20
21
22
23
24

25 **Development of the DANCAS surveys**

26 The outcome domains for the two DANCAS surveys were developed from a public and patient
27 involvement (PPI) event held in Denmark²⁹ (see PPI section below) and from the outcomes identified
28 as important by participants in the COSCA (core outcome set for cardiac arrest) initiative.³⁰ For each
29 of these outcome domains, appropriate existing self-report outcome measures were chosen. For
30 domains where no outcome measure existed, questions from other patient groups were adapted for
31 OHCA survivors or new questions were developed.
32
33
34
35
36
37

38 The PPI group participants tested individual outcome measures for acceptability and face validity
39 where there was more than one outcome measure available (for example, in the domain 'function
40 and disability'). The PPI group also gave feedback on draft versions of the whole DANCAS surveys,
41 and the participant information sheet. Feedback was received from eight survivors, three relatives,
42 and three clinicians with experience of treating OHCA survivors and relatives. Based on this
43 feedback, we reduced the number of questions, removed any outcome measures where the item
44 content overlapped and improved the clarity of the participation information sheet.
45
46
47
48
49
50

51 **Self-report outcome measures in the DANCAS surveys**

52 Full details on the self-report outcome measures, scoring, and Danish translations can be found in
53 the Supplementary data.
54
55
56
57
58

59 The following self-report outcome measures will be completed by OHCA survivors:
60

1
2
3 *EQ-5D-5L*: This is a six-item standardised instrument for measuring current health status.³¹ The
4 questionnaire covers five-dimensions of health: mobility, self-care, usual activities, pain/discomfort
5 and anxiety/depression. Each dimension is divided into five-levels: no problems, slight, moderate,
6 severe or extreme problems. The sixth-item, a Visual Analogue Scale, 0-100, allows the respondent
7 to provide a self-rating of his or her health. A higher score signifies a better health status.
8
9

10
11
12 *Hospital Anxiety and Depression Scale (HADS)*: The HADS consists of a seven-item subscale
13 measuring symptoms of anxiety (HADS-A) and a seven-item subscale measuring symptoms of
14 depression (HADS-D).³² Each item has a four-choice response, with scores ranging from 0 (no
15 symptoms) to 3 (maximum number of symptoms). The total scores on each subscale range from 0 to
16 21. A score of less than 8 indicates no psychological distress, 8 to 10 mild psychological distress and
17 over 10 definite psychological distress. It has recently been shown to be a valid measure of anxiety
18 and depression in a Danish cardiac disease population.³³
19
20
21
22
23

24
25
26 *Two Simple Questions (TSQ)*: Consists of three-items. Developed to assess the survivor's own
27 perception of mental recovery and dependency in daily activities after cardiac arrest.^{34 35}
28
29

30
31 *Modified Fatigue Impact Scale (MFIS)*: The MFIS assesses impact of fatigue on performance of
32 functional activities and consists of 21-items in three-sub-scales (physical, cognitive and
33 psychosocial). Total scores range from 0 to 84 with a score of 30 or more signifying a fatigued
34 individual. It has been validated in people with multiple sclerosis and traumatic brain injury.^{36 37}
35
36
37
38

39
40 *12-item World Health Organisation Disability Assessment Schedule 2.0 (12-item WHO DAS 2.0)*: This
41 assesses disability and functioning in the prior month on six adult life tasks. There are twelve-items
42 scored from 0=no difficulty to 4=extreme difficulty, total score 0 to 48 with higher scores indicating
43 greater difficulty. Used extensively to research rehabilitation and disability in a wide range of disease
44 populations³⁸ and validated in patients with chronic diseases³⁹ including traumatic brain injury.⁴⁰
45
46
47
48

49 *REHPA scale*: A linear analogue self-assessment scale, where participants indicate how close they are
50 to living the life they desire after their OHCA, indicating rehabilitation need. The scale is rated
51 between 0 (goal reached) to 9 (infinitely far from).
52
53
54

55
56 Questions on unmet rehabilitation needs have been adapted from the Danish Cancer Society
57 questionnaire 'The experiences of cancer patients during diagnosis and treatment'.^{41 42} Participants
58 are asked if they received the help they needed after their cardiac arrest in six areas: emotional
59
60

1
2 reactions, cognitive problems, physical activity, peer-support and family (supplementary data).
3
4 Questions on unmet information needs after cardiac arrest were adapted from a questionnaire
5 evaluating experiences of healthcare quality in Denmark among patients with heart disease.⁴³
6
7 Participants are asked if they felt informed after their cardiac arrest on seven subjects: treatment of
8 heart condition, medication for heart condition, emotional reaction, cognitive problems, physical
9 activity, return-to-work and impact on family.
10
11
12
13

14 In addition to the HADS, the relatives' survey includes:

15
16 *World Health Organisation Five Well-Being Index:* The WHO-5 is a self-report measure of current
17 mental well-being⁴⁴ that has been shown to be a valid tool across a wide range of study fields.⁴⁵ The
18 tool consists of five statements with six responses on a scale from 'At no time' to 'All of the time'
19 scoring 0-5. Scores are totaled and multiplied by 4 with 0 representing the worst imaginable well-
20 being and 100 representing the best imaginable well-being. The WHO-5 was chosen as a generic
21 global measure of health for the survey, as opposed to using the EQ-5D-5L as in the OHCA survivor
22 survey. This choice was based on feedback from a PPI workshop asking relatives to fill-in and provide
23 feedback on individual questionnaires. The relatives felt the EQ-5D-5L was about medical problems
24 and was for their relative (who had suffered the OHCA) to complete and they were unsure how to
25 answer the questions. Conversely, they understood why the WHO-5 might be relevant to their life
26 situation and felt able to complete it.
27
28
29
30
31
32
33
34
35

36 *The Informant Questionnaire on Cognitive Decline in the Elderly – Cardiac Arrest (IQCODE-CA):* This is
37 a modified version of the observer-reported questionnaire designed to measure global cognitive
38 decline in the dementia population.⁴⁶ Informants, defined as relatives or close friends are requested
39 to compare current cognitive function of the survivor with pre-cardiac arrest cognitive function. The
40 tool contains 26-items scored on a five-point scale with higher scores indicating greater impairment.
41 It has been shown to identify cardiac arrest survivors with possible cognitive problems.⁴⁶
42
43
44
45
46
47

48 *Modified caregiver strain index (MCSI):* This is a self-reported questionnaire that screens for
49 caregiver strain in caregivers.⁴⁷ The tool has 13 questions scoring 2 points for 'yes', 1 point for
50 'sometimes' and 0 for 'no'. Scores range from 26-0 with higher scores indicating a higher level of
51 caregiver strain. The MCSI has been found to be easily administered and a reliable test of strain in an
52 informal caregiver population.⁴⁷
53
54
55
56
57

58 Further, one question derived from the Danish National Health Survey 2017⁴⁸ on loneliness and four
59 questions on support received in the post-cardiac arrest period (created for this survey,
60

1
2
3 supplementary data). Seven questions on educational level, labour market status and sick leave are
4 also asked in the relatives section as their survey answers can only be connected to Danish labour
5 market registry data if relatives choose to provide their Danish personal identification number in
6 their survey response. One question will ask if they witnessed the OHCA.
7
8
9

10 11 **Data enrichment from registries**

12
13 Following data collection via the two surveys, data enrichment will occur via Danish national
14 registries for both survivors and relatives. The Danish Civil Registration System will provide gender,
15 age and marital status. The Danish Education Register:⁴⁹ education level and the Danish Register on
16 personal income⁵⁰: income.
17
18
19

20
21 The Danish National Patient Register,⁵¹ provides data on 19 selected somatic co-morbidities scored
22 on a 3-point scale. This data will be used to calculate the Charlson Comorbidity Index,⁵² based on the
23 10 years previous to the date of the surveys. The Charlson Comorbidity Index has three categories:
24 0, 1-2 and ≥ 3 . This registry will also provide data on hospital admissions and healthcare use for the
25 potential sub-study on societal costs after surviving OHCA.
26
27
28
29

30
31 Current and pre-OHCA employment status for the working-age population will be obtained from the
32 Danish Register for Evaluation of Marginalization.(DREAM)⁵³ Participants who are not on any social
33 benefits or participants who are on State Education Fund grants, maternity leave pay, or leave-of-
34 absence schemes will be classified as being part of the workforce.⁵⁴ Accordingly, patients receiving
35 unemployment benefits, being on paid sick leave, on early retirement payment or disability pension
36 will be defined as being on social benefits. Pre-OHCA employment status will be assessed in a 5-
37 week span before cardiac arrest to classify patients as either working or receiving social benefits.
38
39
40
41
42
43
44

45 Information from the DHRCA and other national registries will be collected for all eligible study
46 participants both responders and non-responders to the survey (figure 1).
47
48
49

50 51 **Data handling and record-keeping**

52 The study has been registered on the Region of Southern Denmark's record of data processing
53 activities (19/8559). A license agreement has been made with Odense Patient Data Explorative
54 Network (OPEN) (OP_843) to establish the REDCap system, secure data storage, data analysis and
55 data linkage with national registries. REDCap will be used to import Danish personal identification
56
57
58
59
60

1
2 numbers for survey distribution via E-boks. Postal surveys received will be scanned, and the data
3 imported into REDCap and destroyed.
4
5
6
7

8 **Sample size considerations**

9 Each year approximately 800 people are alive 30-days after surviving an OHCA in Denmark.³ Hence,
10 we estimate the survey could be sent to approximately n=3200 survivors. Based on similar studies in
11 heart diseases,^{17 55} we are assuming a 20% (n=640) loss due to a person having moved out of
12 Denmark, being protected from inquiries or having died,¹⁶ and a response rate of 60%. Hence, the
13 estimated total study population would be approximately n= 1540 OHCA survivors. The response
14 rate to the relatives' survey is likely to be less as not all survivors will have a relative able to
15 complete the survey. Hence, estimated 50% (770) of relatives will respond and 50% (380) of
16 responders will provide Danish personal identification numbers.
17
18
19
20
21
22
23
24

25 **Planned analysis**

26 Continuous data will be checked for normality and described as mean and standard deviation (SD) or
27 median with 25th and 75th quartiles [IQR, interquartile range], as appropriate. Categorical variables
28 will be described as numbers and percentages (n (%)). To investigate changes in physical and
29 psychological outcomes over time, participants will be stratified into four groups: those suffering an
30 OHCA in 2016, 2017, 2018 and 2019 (figure 2). Differences in the prevalence of self-report problems
31 between the groups will be determined by Chi-squared test or Fisher's Exact test as appropriate and
32 time-trend analyses will be performed. The OHCA survivor and relatives' surveys will be linked via a
33 unique identifying number to discover if associations exist between each groups' self-report
34 outcomes.
35
36
37
38
39
40
41
42

43 Predictors of physical and psychological problems will be identified from self-report outcomes,
44 demographic characteristics, circumstances of OHCA and unmet rehabilitation/information needs
45 using univariate binary logistic regression. All univariate predictors with p<0.10 will be entered into a
46 multivariate binary logistic regression, with description of odds ratios or β and 95% confidence
47 intervals. In all regression analyses, both crude and adjusted models will be presented. Level of
48 statistical significance will be set at p<0.05.
49
50
51
52
53
54

55 A potential sub-study is planned to calculate the total societal costs (healthcare costs and
56 absenteeism from work) of surviving OHCA using the EQ-5D-5L data and registry data (National
57 Prescription Registry,⁵⁶ and DREAM database).
58
59
60

Ethics and dissemination

The study will be conducted in accordance with the Declaration of Helsinki. Surveys and registry-based research studies do not normally require ethical approval in Denmark. This has been confirmed for this study by the Region of Southern Denmark ethics committee (20192000_19). Participants will be informed about the study via the participant information sheet. Consent to participate will be implied through the return of the completed survey.

Results of the study will be disseminated via several peer-reviewed publications and will be presented at national and international conferences. The results of the proposed study will be reported with reference to the international statement in the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) checklist for cross-sectional studies⁵⁷. Health professionals will be informed of the study results through professional literature via new national clinical guidelines on rehabilitation after OHCA. Finally, the survey is part of a larger project on rehabilitation after surviving a cardiac arrest and all results, including the survey results, will be presented at a project-closing event to which all participants, stakeholders and interested parties will be invited.

Patient and public involvement

The themes for the survey were developed from a PPI event involving OHCA survivors, relatives and clinicians.²⁹ A further group of survivors and relatives have helped to develop the survey by testing individual questionnaires and by providing feedback on the whole survey. At the end of the study, the research advisory group and PPI group will discuss and comment on the findings and contribute to how the results will be disseminated and implemented in the next stage of the research.

Discussion

Recovery after OHCA can be complicated by a new or ongoing cardiac condition, mental trauma from surviving a near-death experience or possible anoxic brain injury. Small scale, short term studies suggest these complications can lead to an increased physical and psychological burden for both survivors and their relatives. However, little is known about the long-term prevalence of physical and psychological problems or who is at most risk of developing them. Rehabilitation has been recommended to meet the secondary physical and psychological consequences of OHCA but more knowledge is needed including establishing the perceived unmet rehabilitation and information needs from OHCA survivors and their relatives themselves.

1
2
3 The results from this study will be used to identify the most prevalent problems suffered by OHCA
4 survivors and their families and those at most risk of suffering them. This will allow researchers and
5 managers within the Danish healthcare system to design assessment tools to ensure problems are
6 detected early after OHCA, and survivors and relatives are offered rehabilitation plans tailored to
7 their needs. Further, currently there are few high quality studies investigating the effectiveness of
8 rehabilitation interventions for OHCA survivors. Results from the DANCAS survey will provide
9 researchers with specific information to design the content and timing of new rehabilitation
10 interventions for OHCA survivors and their relatives.
11
12
13
14
15
16

17
18 Although this study will be one of the largest surveys involving OHCA survivors and one of the first to
19 survey both survivors and relatives, with the ability to link between the two, there are several
20 potential limitations. The majority of the self-report questionnaires have undergone some validation
21 testing. However, not all these tools have been validated in Danish or in the OHCA survivor
22 population and some questions have been written specifically for this survey (see supplementary
23 data).
24
25
26
27
28

29
30 The survey uses questionnaires based on self-report. However, approximately 50% of OHCA
31 survivors suffer from cognitive deficits and/or fatigue, leading to difficulties completing the survey
32 and hence potentially a lower response rate from survivors with these problems. To counter this,
33 the survey will be available both electronically and on paper, survivors will be allowed to have help to
34 complete the survey and asked to state if they had help. In addition, the relatives' section of the
35 survey will include an observer-reported cognitive questionnaire and relatives will be asked to
36 complete this even if the survivor questionnaire is not completed. However, it remains possible that
37 those with cognitive deficits and/or fatigue will be underrepresented in the survey response group
38 and this has to be accepted as a limitation of the self-report method chosen to gain data from as
39 many OHCA survivors as possible. Surveys will only be received by OHCA survivors able to access e-
40 Boks or living at home, so we are very unlikely to receive responses from any survivor living in long-
41 term residential care. Further, the DHRCA only records OHCA and therefore people who have
42 suffered an in-hospital cardiac arrest will not be included in this study. To ensure the characteristics
43 of the survey population are clear, baseline characteristics of non-responders will also be presented.
44
45
46
47
48
49
50
51
52
53

54
55 One aim of the survey is to describe how the prevalence of physical and psychological problems
56 suffered by survivors and their relatives changes over time since OHCA. Ideally, this would be
57 investigated using a prospective longitudinal study with data from the same population at multiple
58 follow-up points. The disadvantage of this design is the results would not be available for five-years,
59
60

1
2 and participants are asked to complete multiple surveys. The design of our survey groups
3 participants dependent on time since OHCA to describe changes over time. However, as these are
4 not the same participants in each time interval group, there is a risk of an unknown time-dependent
5 confounding factor effecting one of the groups more than another. Further, the cross-sectional
6 design, by definition, does not allow the formation of solid conclusions but the generation of
7 hypotheses based on associations between variables.
8
9
10
11
12
13
14
15

16 **Acknowledgements**

17 We would like to thank the member of the DANCAS network for their support in designing this
18 study: (Anette Marianne Fedder, Anette Rasmussen, Bo Gregers Winkel, Camilla Kofoed Dichman,
19 Charlotte Brun Thorup, Christian Hassager, Christina Marr Andersen, Elin Petersen, Frank Humle,
20 Hanne Balle, Hanne Kruise Rasmussen, Hanne Skovgaard Petersen, Helle Westberg, Irene Hallas,
21 Jens-Jakob Eifer Møller, Jette Nørr Møllebjerg, Jørgen Feldbeck Nielsen, Klaus Nikolaisen, Lars
22 Thrysoe, Lene Mønsted Nielsen, Lisa Gregersen Østergaard, Lone Andersen, Malene Hollingdal,
23 Malene Missel, Mette Stougaard, Mette Wagner, Mogens Hørder, Morten Jensen, Nina Rottmann,
24 Rikke Mols, Rikke Tornfeldt Martens, Steen Pehrson, Susanne Budin Holst, Susanne S Pedersen, Tina
25 L.B. Andersen, Dorte Qvistgaard).

26 LHT is currently funded by a grant from the Danish Regions and The Danish Health Confederation
27 through the Development and Research Fund for financial support (project nr. 2703) and a grant
28 from Region Zealand, Denmark (Exercise First).
29
30
31
32
33
34
35
36
37
38

39 **Author contributions** VLJ, LHT and ADZ conceived the study; VLJ and LHT designed the study with
40 ADZ, BB, LZ, TMB, RST, SRC and JFN. VLJ led the writing of the manuscript, which was revised by all
41 authors. The final manuscript was approved by all authors.
42
43
44
45

46 **Funding** This project will be supported by infrastructure provided by REHPA, Danish Knowledge
47 Centre for Rehabilitation and Palliative Care, Odense University Hospital which receives funding
48 from the Danish Government. This project is part of a PhD partially funded by a PhD Faculty
49 scholarship (no grant number) from the University of Southern Denmark and a stipendium from the
50 Region of Southern Denmark (19/15041).
51
52
53
54
55

56 **Competing interests** None declared
57
58
59

60 **Patient consent** Not required

1
2
3
4 **Data statement:** Within the boundaries of Danish legislation, the anonymised data from the study
5 will be available for other researchers upon reasonable request when the results have been
6 published.
7
8
9

10
11 **Figure legends:**
12

13
14 Figure 1. Flow chart of Survey Population
15

16
17 Figure 2. Design of DANCAS survey and grouping according to time since OHCA
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

REFERENCES

1. Wissenberg M, Lippert FK, Folke F, et al. Association of national initiatives to improve cardiac arrest management with rates of bystander intervention and patient survival after out-of-hospital cardiac arrest. *JAMA* 2013;310(13):1377-84. doi: 10.1001/jama.2013.278483
2. Berdowski J, Berg RA, Tijssen JGP, et al. Global incidences of out-of-hospital cardiac arrest and survival rates: Systematic review of 67 prospective studies. *Resuscitation* 2010;81(11):1479-87. doi: 10.1016/j.resuscitation.2010.08.006
3. Ringgren KB, Christensen HC, Schønau L, et al. Out of hospital cardiac arrest in Denmark 2018. *Danish Cardiac Arrest Registry*
4. Sawyer KN, Camp-Rogers TR, Kotini-Shah P, et al. Sudden Cardiac Arrest Survivorship: A Scientific Statement From the American Heart Association. *Circulation* 2020;141(12):e654-e85. doi: 10.1161/CIR.0000000000000747 [published Online First: 2020/02/23]
5. Andrew E, Nehme Z, Wolfe R, et al. Long-term survival following out-of-hospital cardiac arrest. *Heart* 2017;103(14):1104-10. doi: 10.1136/heartjnl-2016-310485
6. Hawkes C, Booth S, Ji C, et al. Epidemiology and outcomes from out-of-hospital cardiac arrests in England. *Resuscitation* 2017;110:133-40. doi: 10.1016/j.resuscitation.2016.10.030
7. Schaaf KPW, Artman LK, Peberdy MA, et al. Anxiety, depression, and PTSD following cardiac arrest: A systematic review of the literature. *Resuscitation* 2013;84(7):873-77. doi: 10.1016/j.resuscitation.2012.11.021
8. Lilja G. Follow-Up of Cardiac Arrest Survivors: Why, How, and When? A Practical Approach. *Seminars in Neurology* 2017;37(1):88-93. doi: {10.1055/5-0036-1593859}
9. Maciel CB, Barden MM, Greer DM. Neurologic Recovery After Cardiac Arrest: a Multifaceted Puzzle Requiring Comprehensive Coordinated Care. *Current treatment options in cardiovascular medicine* 2017;19(7):52. doi: 10.1007/s11936-017-0548-0
10. Cronberg T, Greer DM, Lilja G, et al. Brain injury after cardiac arrest: from prognostication of comatose patients to rehabilitation. *The Lancet Neurology* 2020;19(7):611-22. doi: 10.1016/s1474-4422(20)30117-4
11. Lilja G, Nielsen N, Bro-Jeppesen J, et al. Return to Work and Participation in Society After Out-of-Hospital Cardiac Arrest. *Circulation: Cardiovascular Quality and Outcomes* 2018;11(1) doi: {10.1161/CIRCOUTCOMES.117.003566}
12. Kim YJ, Rogers JC, Raina KD, et al. An intervention for cardiac arrest survivors with chronic fatigue: A feasibility study with preliminary outcomes. *Resuscitation* 2016;105:109-15. doi: 10.1016/j.resuscitation.2016.05.020
13. Elliott VJ, Rodgers DL, Brett SJ. Systematic review of quality of life and other patient-centred outcomes after cardiac arrest survival. *Resuscitation* 2011;82(3):247-56. doi: 10.1016/j.resuscitation.2010.10.030
14. Kragholm K, Wissenberg M, Mortensen RN, et al. Return to Work in Out-of-Hospital Cardiac Arrest Survivors: A Nationwide Register-Based Follow-Up Study. *Circulation* 2015;131(19):1682-90. doi: 10.1161/CIRCULATIONAHA.114.011366
15. Viktorisson A, Sunnerhagen KS, Johansson D, et al. One-year longitudinal study of psychological distress and self-assessed health in survivors of out-of-hospital cardiac

- 1
2
3 arrest. *BMJ Open* 2019;9(7):e029756. doi: 10.1136/bmjopen-2019-029756
4 [published Online First: 2019/07/06]
- 5 16. Caro-Codon J, Rey JR, Lopez-de-Sa E, et al. Long-term neurological outcomes in out-of-
6 hospital cardiac arrest patients treated with targeted-temperature management.
7 *Resuscitation* 2018;133:33-39. doi: 10.1016/j.resuscitation.2018.09.015 [published
8 Online First: 2018/09/27]
- 9 17. Viktorisson A, Sunnerhagen KS, Pöder U, et al. Well-being among survivors of out-of-
10 hospital cardiac arrest: a cross-sectional retrospective study in Sweden. *BMJ Open*
11 2018;8(6):e021729. doi: 10.1136/bmjopen-2018-021729
- 12 18. Ann-Britt T, Ella D, Johan H, et al. Spouses' experiences of a cardiac arrest at home: an
13 interview study. *Eur J Cardiovasc Nurs* 2010;9(3):161-7. doi:
14 10.1016/j.ejcnurse.2009.12.005 [published Online First: 2010/01/15]
- 15 19. Wallin E, Larsson I-M, Rubertsson S, et al. Relatives' experiences of everyday life
16 six months after hypothermia treatment of a significant others cardiac arrest.
17 *Journal of Clinical Nursing* 2013;22(11-12):1639-46. doi: {10.1111/jocn.12112}
- 18 20. Moulaert VR, Verbunt JA, Bakx WG, et al. Stand still ... , and move on; a new early
19 intervention service for cardiac arrest survivors and their caregivers: rationale and
20 description of the intervention. *Clinical rehabilitation* 2011;25(10):867-79. doi:
21 10.1177/0269215511399937
- 22 21. van Wijnen HG, Rasquin SM, van Heugten CM, et al. The impact of cardiac arrest on the
23 long-term wellbeing and caregiver burden of family caregivers: a prospective cohort
24 study. *Clinical rehabilitation* 2017;31(9):1267-75. doi: 10.1177/0269215516686155
- 25 22. Holm MS, Norekval TM, Falun N, et al. Partners' ambivalence towards cardiac arrest and
26 hypothermia treatment: a qualitative study. *Nurs Crit Care* 2012;17(5):231-8. doi:
27 10.1111/j.1478-5153.2012.00490.x [published Online First: 2012/08/18]
- 28 23. Haywood K, Dainty KN. Life after cardiac arrest: The importance of engaging with the
29 'forgotten patient'. *Resuscitation* 2018;128:A1-A2. doi:
30 10.1016/j.resuscitation.2018.04.034 [published Online First: 2018/05/05]
- 31 24. Van't Wout Hofland J, Moulaert V, van Heugten C, et al. Long-term quality of life of
32 caregivers of cardiac arrest survivors and the impact of witnessing a cardiac event of
33 a close relative. *Resuscitation* 2018;128:198-203. doi:
34 10.1016/j.resuscitation.2018.03.016 [published Online First: 2018/03/24]
- 35 25. Nolan JP, Soar J, Cariou A, et al. European Resuscitation Council and European Society of
36 Intensive Care Medicine 2015 guidelines for post-resuscitation care. *Intensive care
37 medicine* 2015;41(12):2039-56. doi: {10.1007/s00134-015-4051-3}
- 38 26. Tang LH, Joshi V, Egholm CL, et al. Are survivors of cardiac arrest provided with standard
39 cardiac rehabilitation? - Results from a national survey of hospitals and
40 municipalities in Denmark. *Eur J Cardiovasc Nurs* 2020;1474515120946313. doi:
41 10.1177/1474515120946313 [published Online First: 2020/08/05]
- 42 27. Boyce LW, Goossens PH, Moulaert VR, et al. Out-of-hospital cardiac arrest survivors
43 need both cardiological and neurological rehabilitation! *Current opinion in critical
44 care* 2019;25(3):240-43. doi: 10.1097/MCC.0000000000000609
- 45 28. Nolan JP, Lockey A, Perkins G, et al. Resuscitation Council (UK) Post resuscitation care
46 guidelines 2015, 2016:1-21.
- 47 29. Tang LH, Zwisler A-D. Rehabilitation after cardiac arrest - we can surely do better!
48 *Cardiologisk Forum* 2019;30(February):30-37.
- 49 30. Haywood K, Whitehead L, Nadkarni VM, et al. COSCA (Core Outcome Set for Cardiac
50 Arrest) in Adults: An Advisory Statement From the International Liaison Committee
51
52
53
54
55
56
57
58
59
60

- on Resuscitation. *Resuscitation* 2018;127:147-63. doi: 10.1016/j.resuscitation.2018.03.022
31. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2011;20(10):1727-36. doi: 10.1007/s11136-011-9903-x
32. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 1983;67(6):361-70. doi: 10.1016/j.jad.2018.04.092
33. Christensen AV, Dixon JK, Juel K, et al. Psychometric properties of the Danish Hospital Anxiety and Depression Scale in patients with cardiac disease: results from the DenHeart survey. *Health Qual Life Outcomes* 2020;18(1):9. doi: 10.1186/s12955-019-1264-0 [published Online First: 2020/01/09]
34. Lilja G, Nielsen N, Friberg H, et al. Cognitive function after cardiac arrest and temperature management; rationale and description of a sub-study in the Target Temperature Management trial. *BMC Cardiovascular Disorders* 2013;{13} doi: {10.1186/1471-2261-13-85}
35. Longstreth WT, Jr., Nichol G, Van Ottingham L, et al. Two simple questions to assess neurologic outcomes at 3 months after out-of-hospital cardiac arrest: experience from the public access defibrillation trial. *Resuscitation* 2010;81(5):530-3. doi: 10.1016/j.resuscitation.2010.01.011 [published Online First: 2010/02/23]
36. Schiehser DM, Delano-Wood L, Jak AJ, et al. Validation of the Modified Fatigue Impact Scale in mild to moderate traumatic brain injury. *J Head Trauma Rehabil* 2015;30(2):116-21. doi: 10.1097/HTR.000000000000019 [published Online First: 2014/01/15]
37. Amtmann D, Bamer AM, Noonan V, et al. Comparison of the psychometric properties of two fatigue scales in multiple sclerosis. *Rehabil Psychol* 2012;57(2):159-66. doi: 10.1037/a0027890 [published Online First: 2012/06/13]
38. Federici S, Bracalenti M, Meloni F, et al. World Health Organization disability assessment schedule 2.0: An international systematic review. *Disability and rehabilitation* 2017;39(23):2347-80. doi: 10.1080/09638288.2016.1223177 [published Online First: 2]
39. Garin O, Ayuso-Mateos JL, Almansa J, et al. Validation of the "World Health Organization Disability Assessment Schedule, WHODAS-2" in patients with chronic diseases. *Health and Quality of Life Outcomes* 2010;8:51. doi: 10.1186/1477-7525-8-51
40. Kuo CY, Liou TH, Chang KH, et al. Functioning and disability analysis of patients with traumatic brain injury and spinal cord injury by using the world health organization disability assessment schedule 2.0. *Int J Environ Res Public Health* 2015;12(4):4116-27. doi: 10.3390/ijerph120404116 [published Online First: 2015/04/16]
41. The Danish Cancer Society. Kræftpatienters oplevelser med sundhedsvæsenet gennem udredning og behandling. The Experience of Cancer Patients during Diagnosis and Treatment. Copenhagen, 2011.
42. Veloso AG, Sperling C, Holm LV, et al. Unmet needs in cancer rehabilitation during the early cancer trajectory--a nationwide patient survey. *Acta Oncol* 2013;52(2):372-81. doi: 10.3109/0284186X.2012.745648 [published Online First: 2013/01/17]
43. Zinckernagel L, Schneekloth N, Zwisler AO, et al. How to measure experiences of healthcare quality in Denmark among patients with heart disease? The development and psychometric evaluation of a patient-reported instrument. *BMJ Open*

- 2017;7(10):e016234. doi: 10.1136/bmjopen-2017-016234 [published Online First: 2017/11/01]
44. Bech P, Olsen LR, Kjoller M, et al. Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five Well-Being Scale. *Int J Methods Psychiatr Res* 2003;12(2):85-91. doi: 10.1002/mpr.145
45. Topp CW, Ostergaard SD, Sondergaard S, et al. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom* 2015;84(3):167-76. doi: 10.1159/000376585 [published Online First: 2015/04/04]
46. Blenow Nordström E, Lilja G, Årestedt K, et al. Validity of the IQCODE-CA: An informant questionnaire on cognitive decline modified for a cardiac arrest population. *Resuscitation* 2017;118:8-14. doi: 10.1016/j.resuscitation.2017.06.012
47. Thornton M, Travis SS. Analysis of the Reliability of the Modified Caregiver Strain Index. *The Journals of Gerontology: Series B* 2003;58(2):S127-S32. doi: 10.1093/geronb/58.2.S127
48. Jensen HAR, Ekholm O, Davidsen M, et al. The Danish health and morbidity surveys: study design and participant characteristics. *BMC Med Res Methodol* 2019;19(1):91. doi: 10.1186/s12874-019-0733-9 [published Online First: 2019/05/06]
49. Jensen VM, Rasmussen AW. Danish Education Registers. *Scand J Public Health* 2011;39(7 Suppl):91-4. doi: 10.1177/1403494810394715 [published Online First: 2011/08/04]
50. Baadsgaard M, Quitzau J. Danish registers on personal income and transfer payments. *Scand J Public Health* 2011;39(7 Suppl):103-5. doi: 10.1177/1403494811405098 [published Online First: 2011/08/04]
51. Lyng E, Sandegaard JL, Rebolj M. The Danish National Patient Register. *Scand J Public Health* 2011;39(7 Suppl):30-3. doi: 10.1177/1403494811401482 [published Online First: 2011/08/04]
52. Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *Journal of chronic diseases* 1987;40(5):373-83.
53. Hjollund NH, Larsen FB, Andersen JH. Register-based follow-up of social benefits and other transfer payments: accuracy and degree of completeness in a Danish interdepartmental administrative database compared with a population-based survey. *Scand J Public Health* 2007;35(5):497-502. doi: 10.1080/14034940701271882 [published Online First: 2007/09/14]
54. Kragholm K, Torp-Pedersen C. Cardiac arrest survivors: short residual risk of death, long life expectancy. *Heart* 2017;103(14):1063-64. doi: 10.1136/heartjnl-2017-311259
55. Tolstrup Larsen R, Tang LH, Brochmann N, et al. Associations between fatigue, physical activity, and QoL in patients with myeloproliferative neoplasms. *Eur J Haematol* 2018;100(6):550-59. doi: 10.1111/ejh.13048 [published Online First: 2018/02/22]
56. Kildemoes HW, Sorensen HT, Hallas J. The Danish National Prescription Registry. *Scand J Public Health* 2011;39(7 Suppl):38-41. doi: 10.1177/1403494810394717 [published Online First: 2011/08/04]
57. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *The Lancet* 2007;370(9596):1453-57. doi: 10.1016/s0140-6736(07)61602-x

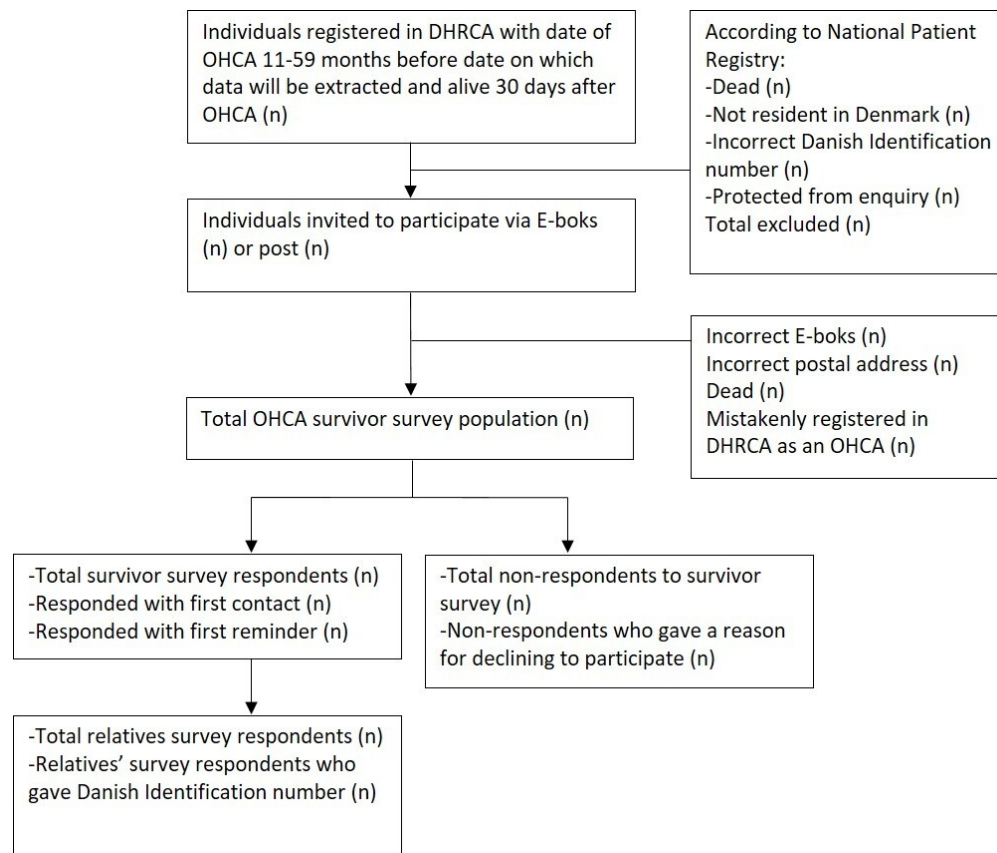


Figure 1. Flow chart of Survey Population

84x71mm (300 x 300 DPI)

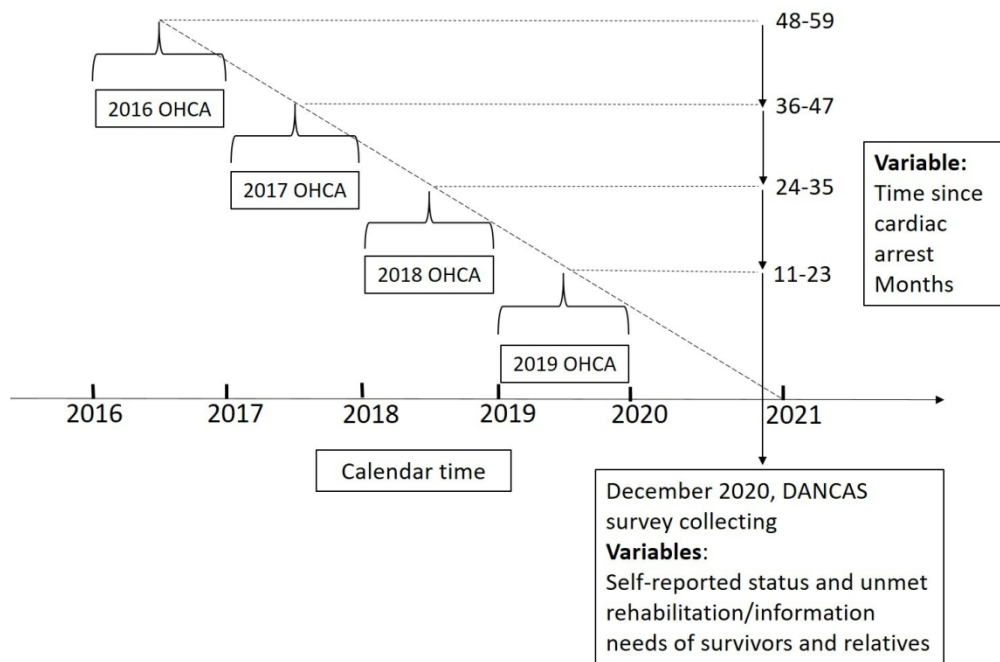


Figure 2. Design of DANCAS survey and grouping according to time since OHCA

125x84mm (300 x 300 DPI)

Supplementary data.

Table 1. Detailed content of DANCAS surveys

Outcome domain	Outcome measure	Items, scoring	Danish translation	Notes
Survivors				
Generic health	EQ-5D-5L	Five item health dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Divided into five levels: 1='No problems' to 5= 'Extreme problems', scores ≥ 2 signifies a problem. Sixth item: Self-rating of health. Visual Analogue Scale, 0-100. Higher scores signify better health status. ¹	Received from the EuroQoL group	
Anxiety and depression	HADS	Seven-item symptoms of anxiety subscale (HADS-A) Seven-item subscale symptoms of depression (HADS-D). Four responses: 0='No symptoms' to 3= 'maximum number of symptoms'. Total subscale scores range: 0-21. <8 = no psychological distress, 8-10 = mild psychological distress, >10 definite psychological distress. It has recently been shown to be a valid measure of anxiety and depression in a Danish cardiac disease population. ²	Received from DenHeart study group ³	Valid measure of anxiety and depression in Danish cardiac disease population ³

Mental recovery/dependency	TSQ	Yes to Q1a + Yes to Q1b signify new problems with dependency after cardiac arrest. No to Q2 indicates problems with mental recovery after cardiac arrest. ^{4,5}	Received from TTM2 study group ⁴	-
Fatigue impact on functional activities	MFIS	21 items in three sub-scales (physical, cognitive and psychosocial). Total scores range: 0-84. Total subscale scores: physical= 0 -36; cognitive=0=40; psychosocial= 0-8. ≥30 signify a fatigued individual (Antmann, 2012, Schiehser, 2015)	Translation received from the Provide, Map Research Trust.	Validated in people with multiple sclerosis. ⁶ and mild to moderate brain injury. ⁷
Function and disability	12-item WHO DAS 2.0	12-item assessing 6 domains of functioning: 1) Understanding and communication; 2) Self-care; 3) Mobility; 4) Interpersonal relationships; 5) Work and household roles; and 6) Community and civic roles. Scored from 0= 'no difficulty' to 4= 'extreme difficulty or cannot do'. Total scores range: 0-48. Higher score indicating greater difficulty with activity and participation.	Available from: https://www.etf.dk/ergoterapi-og-politik/hverdagsrehabilitering	Used extensively to research neurological conditions including traumatic brain injury and spinal cord injury, ⁸ and rehabilitation and disability in a wide range of disease populations. ⁹ Validated in patients with chronic diseases. ¹⁰
Life satisfaction/rehabilitation need	REHPA scale	A linear analogue scale, participants indicate how close they are to living the life they desire after their OHCA. Scale ranges from 0= 'goal reached' to 9= 'infinitely far from'.	By DANCAS study authors	

		Score of ≤ 3 will be considered as signifying having rehabilitation needs.		
Unmet rehabilitation needs		6-items asking if rehabilitation needs were met in different domains, for example, emotional reactions. Scored on a 4-point Likert type scale from 'Yes to a high level' to 'No, not at all'. ¹²	Adapted by DANCAS authors	Questions adapted from existing survey 'The Experience of Cancer Patients during Diagnosis and Treatment'. ^{12 13}
Unmet information needs	Adapted from Zinckernagel et al., 2017	7-items asking if information needs were met in different domains, for example, 'treatment of your heart condition' Scored on a 4-point Likert type scale from 'Yes to a high level' to 'No, not at all'. ¹⁴	Adapted by DANCAS authors for OHCA survivors from a Danish survey of patients with heart disease. ¹⁴	
Relatives				
Anxiety and depression	HADS	As above		
Mental well-being	WHO-5	Five items with 6 responses from 0='At no time' to 5='all of the time'. Scores are totaled and multiplied by 4 to give range 0-100. Score <50 signifies poor emotional well-being. ¹⁵	Developed in Denmark. ¹⁶	Valid in multiple patient populations. ¹⁷

<p>Cognitive problems in daily life</p>	<p>IQCODE-CA</p>	<p>26-items scored on a five-point scale, 1= 'much improved' to 5= 'much worse'. Scores are totaled, divided by the number of questions to give a total, range 1-5. Score ≥ 3.04 signifies cognitive decline after cardiac arrest.¹⁸</p>	<p>Received from TTM2 study group</p>	<p>Relatives or close friends compare current cognitive function with pre-cardiac arrest cognitive function. Has been shown to accurately identify cardiac arrest survivors with potential cognitive problems.¹⁸</p>
<p>Caregiver strain</p>	<p>MCSI</p>	<p>13-items, scored: 2= 'Yes, On a Regular Basis', 1= 'Yes, sometimes', 0= 'No'. Range: 0-26, higher scores signify a higher level of carer strain.¹⁹</p>	<p>Translated by DANCAS study authors^a</p>	<p>Found to have high internal validity with a population of family caregivers.¹⁹</p>
<p>Witness to OHCA</p>	<p>Questions designed for this survey</p>	<p>1-item on whether they witnessed the OHCA</p>	<p>Created by DANCAS study authors</p>	
<p>Labour market</p>	<p>Questions designed for this survey</p>	<p>7-items on educational level completed, current labour market status, status in pre-OHCA period and details of any sick leave in post-OHCA period.</p>	<p>Created by DANCAS study authors</p>	<p>These questions are asked of the relatives as their survey answers cannot be connected to Danish labour market registry data unless they provide their Danish personal identification number.</p>
<p>Social isolation</p>	<p>Question from Danish national health survey</p>	<p>One item: Does it ever happen that you are alone even though you would prefer to be with other people?"</p>	<p>Available at: http://www.danskernesundhed.dk/Spoergeskema</p>	

6/bmjopen-2022-045668 on 2 April 2021. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

		Answers: “yes, often” and “yes, sometimes” signify loneliness. Other possible responses are “yes, but rarely” and “no.		
Support received post-OHCA	Questions designed for this survey	4-items on: whether relatives feel they have someone to talk to if they need support (yes, always/yes, mostly/yes, sometimes/no never or almost never); who have they received support from (multiple options); if they received the support they needed (Yes, No), and who would they like to have received support from in the post-OHCA period (free text box).	Created by DANCAS study authors	
<p>Abbreviations: HADS= Hospital Anxiety and Depression Scale; TSQ=Two Simple Questions; TTM2= Targeted Hypothermia versus Targeted Normothermia after OHCA trial 2; MFIS: Modified Fatigue Impact Scale, WHO DAS 2.0= World Health Organisation disability assessment schedule 2.0 Short; REHPA= Danish Knowledge Center for Rehabilitation and Palliative Care; OHCA=Out-of-hospital Cardiac Arrest; DANCAS=Danish Cardiac Arrest Survivorship; WHO-5= World Health Organisation-Five Well-Being index; IQCODE-CA: Informant Questionnaire on Cognitive Decline in the Elderly, Cardiac Arrest Version; MCSI= Modified Carer Strain Index.</p> <p>^aTranslation, cultural adaption and psychometric testing performed by study authors, results are planned to be available in a future publication.</p>				

1. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2011;20(10):1727-35. doi: 10.1007/s11136-011-9903-x
2. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 1983;67(6):366-70. doi: 10.1016/j.jad.2018.04.092
3. Christensen AV, Dixon JK, Juel K, et al. Psychometric properties of the Danish Hospital Anxiety and Depression Scale in patients with cardiac disease: results from the DenHeart survey. *Health Qual Life Outcomes* 2020;18(1):9. doi: 10.1186/s12955-019-1264-0 [published Online First: 2020/01/09]

4. Lilja G, Nielsen N, Friberg H, et al. Cognitive function after cardiac arrest and temperature management; rationale and description of a sub-study in the Target Temperature Management trial. *BMC Cardiovascular Disorders* 2013;13 doi: {10.1186/1471-2261-13-85}
5. Longstreth WT, Jr., Nichol G, Van Ottingham L, et al. Two simple questions to assess neurologic outcomes at 3 months after out-of-hospital cardiac arrest: experience from the public access defibrillation trial. *Resuscitation* 2010;81(5):530-3. doi: 10.1016/j.resuscitation.2010.01.011 [published Online First: 2010/02/23]
6. Amtmann D, Bamer AM, Noonan V, et al. Comparison of the psychometric properties of two fatigue scales in multiple sclerosis. *Rehabil Psychol* 2012;57(2):159-66. doi: 10.1037/a0027890 [published Online First: 2012/06/13]
7. Schiehser DM, Delano-Wood L, Jak AJ, et al. Validation of the Modified Fatigue Impact Scale in mild to moderate traumatic brain injury. *J Head Trauma Rehabil* 2015;30(2):116-21. doi: 10.1097/HTR.000000000000019 [published Online First: 2014/07/15]
8. Kuo CY, Liou TH, Chang KH, et al. Functioning and disability analysis of patients with traumatic brain injury and spinal cord injury by using the world health organization disability assessment schedule 2.0. *Int J Environ Res Public Health* 2015;12(4):4116-27. doi: 10.3390/ijerph120404116 [published Online First: 2015/04/16]
9. Federici S, Bracalenti M, Meloni F, et al. World Health Organization disability assessment schedule 2.0: An international systematic review. *Disability and rehabilitation* 2017;39(23):2347-80. doi: 10.1080/09638288.2016.1223177 [published Online First: 2]
10. Garin O, Ayuso-Mateos JL, Almansa J, et al. Validation of the "World Health Organization Disability Assessment Schedule, WHODAS-2" in patients with chronic diseases. *Health and Quality of Life Outcomes* 2010;8:51. doi: 10.1186/1477-7525-8-51
11. Danquah IH, Petersen CB, Skov SS, et al. Validation of the NPAQ-short - a brief questionnaire to monitor physical activity and compliance with the WHO recommendations. *BMC public health* 2018;18(1):601. doi: 10.1186/s12889-018-5538-y
12. The Danish Cancer Society. Kræftpatienters oplevelser med sundhedsvæsenet gennem udredning og behandling. The Experience of Cancer Patients during Diagnosis and Treatment. Copenhagen, 2011.
13. Veloso AG, Sperling C, Holm LV, et al. Unmet needs in cancer rehabilitation during the early cancer trajectory--a nationwide patient survey. *Acta Oncol* 2013;52(2):372-81. doi: 10.3109/0284186X.2012.745648 [published Online First: 2013/01/17]
14. Zinckernagel L, Schneekloth N, Zwisler AO, et al. How to measure experiences of healthcare quality in Denmark among patients with heart disease? The development and psychometric evaluation of a patient-reported instrument. *BMJ Open* 2017;7(10):e016234. doi: 10.1136/bmjopen-2017-016234 [published Online First: 2017/11/01]
15. Lowe B. Comparative validity of three screening questionnaires for DSM-IV depressive disorders and physicians' diagnoses. *Journal of Affective Disorders* 2004;78(2):131-40. doi: 10.1016/s0165-0327(02)00237-9
16. Bech P, Olsen LR, Kjoller M, et al. Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five Well-Being Scale. *Int J Methods Psychiatr Res* 2003;12(2):85-91. doi: 10.1002/mpr.145
17. Topp CW, Ostergaard SD, Sondergaard S, et al. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom* 2015;84(3):167-76. doi: 10.1159/000376585 [published Online First: 2015/04/04]
18. Blennow Nordström E, Lilja G, Årestedt K, et al. Validity of the IQCODE-CA: An informant questionnaire on cognitive decline modified for a cardiac arrest population. *Resuscitation* 2017;118:8-14. doi: 10.1016/j.resuscitation.2017.06.012
19. Thornton M, Travis SS. Analysis of the Reliability of the Modified Caregiver Strain Index. *The Journals of Gerontology: Series B* 2003;58(2):S127-S32. doi: 10.1093/geronb/58.2.S127