CoreNAVI II

Feasibility of a patient-oriented navigation programme for patients with lung cancer or stroke in Germany

(two separate RCTs, and two cohort studies in patients with stroke and lung cancer)

(DRKS-ID: DRKS00025476)

Statistical Analysis Plan

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1 Background

1.1 Trial objective

Patient Navigation (PN) programs were first developed in the United States [1–3] and gained interest recently in Germany. Since the German health care system is fragmented (e.g. in inpatient and outpatient care, no centering of ambulatory care around general practitioners) and therefore continuity of care in often not ensured as coordination is mostly left to patients and/ or their caregivers. Navigation programs aim to decrease barriers to care for patients with complex care path and are therefore a conceivable way to address these shortcomings. Therefore, the aim of this study is to investigate the feasibility of a patient-oriented navigation program in the German healthcare context. We chose to test this in two patient groups: persons with stroke and persons with lung cancer. We further aim to provide estimates for the efficacy regarding selected patient reported outcomes and healthcare utilization costs.

1.2 Hypotheses

The primary hypotheses for each of the two RCTs are twofold:

1. The patient navigation program is feasible in stroke / lung cancer patients. Feasibility is demonstrated if the attendance rate in at least one initial face-to-face navigation session is at least 70% and the dropout rate is less than 40% at the end of the study period.

If the feasibility criteria is met the second primary hypothesis is:

2. The patient navigation program is efficient in stroke / lung cancer patients. Efficacy is assessed by overall satisfaction with care at 12 months after start of the intervention in the intervention group compared to the control group.

Secondary efficacy hypotheses will be analyzed over the intervention period and for each of the two RCTs separately. These are:

1. The patient navigation program yields a lower load of participants' individual support needs compared to control participants.
2. The patient navigation program yields a lower load of participants' individual information needs compared to controls.
3. The patient navigation program yields a higher participants' satisfaction with medical care of the respective disease compared to controls at 3 and 6 months.
4. The patient navigation program yields a higher participants' trust in medical care compared to controls.

Additionally several explorative hypotheses will be analyzed within the RCTs (see section 4.3), that evaluate differences between intervention and control group regarding the following parameters at the different time points:

- Processual outcomes regarding the screening and inclusion process (% of target population (potentially eligible patients) approached and informed about study at recruitment centers before discharge, % eligible patients interested to receive the navigator intervention, % consenting to the RCTs, % interested but unwilling to be randomized, % patients randomized and starting the intervention) procedural outcomes regarding the patient navigation program (Number of navigator contacts, % patient-navigator appointments carried out as planned, Delivery Mode of the navigator interaction (in-person, phone, email), % of individual patient goals achieved) and patient reported outcomes.)
- Patient reported outcomes include demand (support need, information need)
- Patient centered measures (health related quality of life, mental health, Barthel Index, distress, sleep, self-efficacy)
- Health care utilization (utilization of medical care, utilization of inpatient care, utilization of emergency department, utilization of therapy/counseling, utilization of rehabilitation, delayed care, and forgone care, medical adherence)
- Satisfaction (satisfaction with care, trust in medical care),
- Health literacy
- Social support (social relationships, people who support)
- Lifestyle (smoking, daily activity, use of computers)
- comorbidities (chronic disease, impairment, care level)

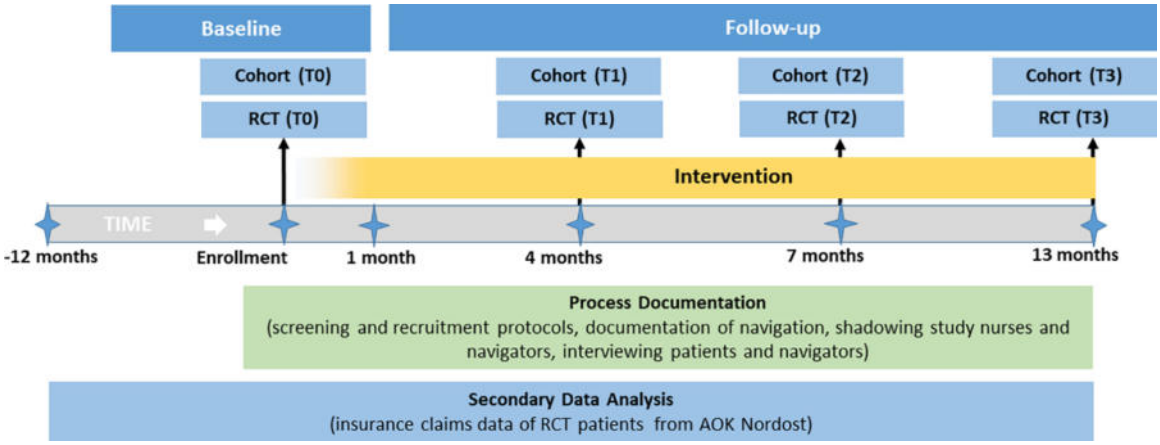
The accompanied analysis of the cohort studies will be used to analyze the situation of patients that didn't want to take part in the intervention study at study inclusion and changes over time in stroke and lung cancer patients with regard to the health status, the living situation, social support, demands, utilization of health care, satisfaction with health care and several other outcomes (see table 2 and 3).

1.3 Trial design

We evaluate the PN program via an open-labelled study with separate two-arm randomized controlled trials (RCTs) aligned with observational cohorts for stroke and lung cancer (one for each index disease). The study design of each arm is visually depicted in Figure 1. Patient-reported outcomes are assessed at multiple time points during the follow-up. Along the RCTs, a process evaluation is performed, including detailed documentation of screening, recruitment, and intervention process, a qualitative

study including participant's observation and personnel and participant interviews[1], a refuser questionnaire, as well as an economic evaluation of the program within a subgroup of patients in the RCT insured with a large German health insurance.

Figure 1: Study Design



1.4 Sample Size

Sample size calculation was done for the two RCTs separately. For the Cohort study and for the Claims data analysis no separate formal sample size calculation was done, but sample size is based on feasibility of recruitment. Biometric calculations were based on the two primary outcomes for determining feasibility. These are as follows:

The intervention is feasible if:

(1) At least 70% of patients/relatives in the intervention arm participated in at least one initial face-to-face navigation session.

(2) The dropout rate of the intervention arm of the RCT is less than 40% (here, dropouts are defined as participants/relatives who drop out of the intervention for reasons other than those that physically prevent patients/relatives from participating. E.g. move out of catchment area, deterioration in general health, long-term hospitalization, move to nursing home or hospice.)

Stroke

For the recruitment period, we expect a population of about 1850 stroke patients at the three planned recruitment sites (1100 patients at Charité – Universitätsmedizin Berlin Stroke Units at the sites Mitte and Virchow Klinikum, 750 patients at Oberhavel Klinik Henningsdorf) based on data from previous years. We assume that 70% of these patients can be approached by study personnel for participation in the study. Furthermore, of the patients approached, we expect a recruitment rate (depending on

[1] In this document we will not refer to the qualitative part of the study.

the site) of 30-50%. Therefore, based on these preliminary assumptions, we expect 460 stroke patients (and their relatives) to participate.

Relative to the feasibility criteria defined above, the statistical planning is as follows:

If 460 stroke patients are included in the study, and 230 (50%) of the patients are randomized to the intervention arm, we assume that at least 95% (n=219) will still have survived to receive patient navigation at four weeks. Therefore, if 166 (75.8%) or more of these 219 patients receive the initial navigation session, the first feasibility criterion will be met, as the 95% confidence interval of this proportion will not be less than 70% (95%CI: 70.1%-81.5%). We additionally assume that of these 230 patients (intervention arm), 85% (n=196) survived after one year. If of these 196 patients, 65 (33.2%) or fewer are lost-to-follow-up, the second feasibility criterion will be met, as the 95% confidence interval of this proportion will be less than 40% (95% CI: 26.6%-39.8%). The feasibility of the study is considered successful if both criteria are achieved.

Cohort Study

We expect a rate of 30% of the approached patients who refused to participate in the RCT to participate in the cohort study. This results in 225 stroke patients in the cohort study.

Insurance Claims Analysis

Based on the assumed 460 patients included in the RCT and the average proportion of AOK-insured patients of approximately 36% (as of 2018) in the total population of Germany, we expect a case number of 165 for the secondary data analysis of health insurance data.

Lung Cancer

For the recruitment period, we expect a population of approximately 550 lung cancer patients at the two planned recruitment sites (Charité – Universitätsmedizin Lung Cancer Center at the Virchow Klinikum site, 50 patients at the Brandenburg Municipal Hospital) based on data from previous years. We assume that 70% of these patients can be approached by the study staff for participation in the study. Furthermore, of the patients approached, we expect a recruitment rate (depending on the site) of 30-50%. Therefore, based on these preliminary assumptions, we expect 120 lung cancer patients (and their relatives) to participate.

Relative to the feasibility criteria defined above, the statistical planning is as follows:

If 120 lung cancer patients are included in the study, and 60 (50%) of the patients are randomized to the intervention arm, we assume that at least 95% (n=57) will still have survived to receive patient navigation at four weeks. Therefore, if 46 (80%) or more of these 57 patients receive the initial navigation session, the first feasibility criterion is met, as the 95% confidence interval of this proportion will not be less than 70% (95%CI: 70.5%-90.9%). We additionally assume that of these 57 patients (intervention arm), 75% (n=43) survived after one year. If of these 43 patients, 11 (25.6%) or fewer are

lost-to-follow-up, the second feasibility criterion will be met, as the 95% confidence interval of this proportion will be less than 40% (95% CI: 12.5%-38.6%). The feasibility of the study is considered successful if both criteria are achieved.

Cohort Study

We expect a rate of 30% of the approached patients who refused to participate in the RCT to participate in the cohort study. This results in a number of 75 lung cancer patients in the cohort study.

Insurance Claims Analysis

Based on the assumed 120 patients included in the RCT and the average proportion of AOK-insured patients of approximately 36% (as of 2018) in the total population of Germany, we expect a case number of 43 for the secondary data analysis of health insurance data.

2 Analysis sets

2.1 Definitions

The **full analysis sets for the RCTs stroke and lung cancer** will consist of all participants (patients or their caregiving relatives) who were screened successfully for eligibility according to the inclusion criteria and gave informed consent to the RCTs. In case participants withdraw informed consent after baseline assessment and before randomization, they will not be included in the full analysis set for the RCTs. The **per protocol analysis sets for the RCTs Stroke and Lung Cancer** comprises all subjects who received the full intervention or control intervention and completed all four questionnaires. For the RCTs data will contain the baseline questionnaire and three follow up questionnaires, and recruitment and navigation documentation.

The **analysis set for the cohort study** will consist of all participants (patients or their caregiving relatives) who were screened successfully did not give informed consent for the RCTs, but accepted the offer of participation in the parallel cohort study. In case participants withdraw informed consent after baseline assessment, they will not be included in the analysis set for the cohort study.

The **analysis set for the claims data analysis** will consist of all AOK Nordost-insured participants of the RCTs which gave informed consent to the additional claims data analysis. In case participants withdraw their informed consent for the RCTs or the claims data analysis after baseline assessment, they will be considered as screening failures and therefore not be included in the full analysis set of the claims data analysis set. Claims data will be matched with survey data.

The **refuser dataset** will consist of all subjects who refused to participate in either RCTs or cohort study, but gave answer to a brief questionnaire.

2.2 Application

The **primary outcome analysis** (feasibility and efficacy) will be done using the intervention arm of the full analysis sets for the RCT stroke and lung cancer. Analysis of feasibility will rely on the recruitment

and intervention documentation. Analysis of the efficacy will rely on the last follow up questionnaire and will include patients in intervention and control groups.

The **secondary outcome analysis** will rely on the four questionnaires, recruitment and navigation documentation as well as claims data (for a detailed description of the use of the datasets see Table)

3 Trial centres

The study was conducted in two coordinating centers: in the Charité Universitätsmedizin Berlin and in the Medizinische Hochschule Brandenburg.

3.1 Recruitment

Active recruitment sites of patients are inpatient or specialized outpatient clinics in Berlin and Brandenburg, Germany. Here, NAVICARE Study Nurses actively approached eligible patient that were reported by the participating hospitals for verbal and written study information. In case of willingness to participate, patients gave informed consent and study nurses conducted the baseline assessment at time of enrollment. In addition, a range of rehabilitation clinics in the Berlin and Brandenburg region have been selected for passive recruitment. These sites received study materials such as flyers to be distributed to patients and posters which advertise the study.

Inclusion Criteria are:

- Patients with confirmed diagnosis of stroke/TIA (ICD-10 codes: G45.x, I60.x, I61.x, I63.x, I64.x, H34.x (since 01.08.2021), H47.0 (since 01.05.2022) or confirmed diagnosis of lung cancer (ICD-10 codes: C34.1, C34.2, C34.3, C34.8, C34.9, C97)
- Caregiver of a patient (only for RCT) with any of the above diagnoses (with the patient's consent or existing legal representation).
- Age: ≥18 years
- Residence in Berlin or Brandenburg
- Insurance status with the AOK Nordost (for claims data analysis within RCT only)

Exclusion Criteria are:

- Nursing home residence at time of study enrolment
- Patients who are not capable of informed consent and have no existing legal care
- Dementia (inclusion of caregivers is possible for the RCT)
- Language barrier (inclusion of caregivers is possible for the RCT)

4 Analysis variables

Analysis variables include information listed in table 2 and 3. In short there are measures of feasibility like acceptance of the intervention, measures on patient's demands, patient reported outcomes such as quality of life, and every day functionality (Barthel Index), parameters on health care utilization,

health literacy, social support, lifestyle, comorbidities, and satisfaction and trust. Additionally claims data about health care utilization, costs and clinical outcomes (re-hospitalization, mortality, recurrent stroke) are considered.

4.1 Demography and baseline characteristics

Assessment of patient's characteristics will be conducted after inclusion. Among other information the following will be documented: a) demographic information including age and education; (b) information on living situation, marital status and social support; (c) body height and body weight, medical information and comorbidities; and (d) needs regarding the current health status and living situation.

4.2 Primary outcome variables

There are two primary outcomes: Feasibility and efficacy. For the feasibility the attendance of at least one in-person navigation session, and drop-out rates are assessed through the procedural documentation of the patient navigation program. To control for lost to follow up through death we will gather data from the residents' registration offices. The efficacy (satisfaction with care) will be measured in a single item 'Overall, how satisfied are you with the general medical care?' with 5-point Likert response scale at the final follow-up. Primary outcome variables are also described in Table .

4.3 Secondary outcome variables

For the secondary efficacy outcomes there are the participant's support needs, the participant's information needs, the participant's satisfaction with the medical care and the participants' trust in the medical care assessed at several time points.

Further there are exploratory outcomes: the processual outcomes regarding the screening and inclusion process (% of target population (potentially eligible patients) approached and informed about study at recruitment centers before discharge, % eligible patients interested to receive the navigator intervention, % consenting to the RCTs, % interested but unwilling to be randomized, % patients randomized and starting the intervention) procedural outcomes regarding the patient navigation program (Number of navigator contacts, % patient-navigator appointments carried out as planned, Delivery Mode of the navigator interaction (in-person, phone, email), % of individual patient goals achieved) and patient reported outcomes. Patient reported outcomes include demand (support need, information need), patient centered measures (health related quality of life, mental health, Barthel Index, distress, sleep, self-efficacy), health care utilization (utilization of medical care, utilization of inpatient care, utilization of emergency department, utilization of therapy/counseling, utilization of rehabilitation, delayed care, and forgone care, medical adherence), satisfaction (satisfaction with care, trust in medical care), health literacy, social support (social relationships, people who support), lifestyle (smoking, daily activity, use of computers), and comorbidities (chronic disease, impairment, care level. For a detailed description see Table . Most of the variables are measured at inclusion, 4 months, 7

months and 13 months after inclusion. Measures developed elsewhere will be analyzed in accordance with the methodology outlined in the primary source, whenever feasible.

5 Handling of missing values and outliers

5.1 Missing values

Only in the RCTs we will impute missing values. This will be done under the assumption of missing at random (MAR) or missing completely at random (MCAR) as missing data mechanism, data will be estimated using multiple imputation methods (multiple imputation using chained equations: MICE) with 30 imputed data sets. If the assumption of MAR or MCAR holds, will be checked using the refuser questionnaire. If missings values or not MAR or MCAR we will use other methods for imputation such as worst case imputation or similar. To estimate values in a realistic range and with values similar as in complete cases, we will use predictive mean matching.

6 Statistical analyses

For all analyses appropriate descriptive statistics (mean, standard deviation, median, interquartile range, absolute and relative frequencies) depending on the scale and distribution of the outcome variable will be presented.

6.1 Primary analysis

The feasibility criteria is met (1) as the 95% confidence interval of the proportion of patients within the intervention arm receiving at least one in-person navigator session exceeds 70%, and (2) the 95% confidence interval of the proportion of participants within the intervention arm dropping out lies below 40% within one year. Both analysis exclude patients who died during the respective time frame regarding the particular feasibility criteria (1: 1 month; 2: 13 month).

Efficacy will only be analyzed as primary outcome if feasibility is already demonstrated.

Efficacy will be analyzed using an ordinal regression analysis adjusted for baseline satisfaction score and for center, and if the information came from a patient or the respective caregiver. The proportional odds assumption will be tested in advance. If the assumption is not met, a partial proportional odds ordinal regression model will be used. Efficacy is met when the 95% confidence interval of the odds ratio of the satisfaction score with the general medical care at 13 months after inclusion between the intervention and control group lies above 1.

6.2 Secondary analyses

For the secondary analyses, we distinguish between efficacy outcomes and exploratory outcomes. For the validation of the three hypotheses regarding efficacy outcomes — the effects of PN on reducing support needs, increasing participant overall satisfaction with medical care, enhancing participants' trust — we examine the 95% confidence intervals associated with each respective outcome measure between control and intervention group. For the outcome support needs each domain[4] will be

analyzed separately using mixed linear model adjusted for baseline support needs score, the center, and if the information came from a patient or the respective caregiver. Further the model will include a random intercept for patients and an interaction term for the measurement time point and study group (intervention/control). For satisfaction with medical care and trust in medical care ordinal regression analysis adjusted for baseline measures, center, and if the information came from a patient or the respective caregiver will be used. These models will also include random intercepts for the patients and an interaction term for the measurement time point and the group (intervention/control). Exploratory outcome analyses will be done descriptively accompanied with standardized mean differences (SMD) and generalizations of the SMD for binary, categorical and ordinal outcomes without any adjustment. Exploratory outcome analyses will be done in the dataset without imputed values for missings.

6.3 Planned subgroup analyses

Preplanned subgroup analyses within the RCTs evaluate differential treatment effects for different age groups and for males and females. For each of the primary efficacy and the secondary efficacy outcome analyses we incorporate interaction effects for group (intervention / control) x subgroup (e.g. age group, sex) and calculate model based intervention effects at different time points for each of the subgroup. We will report the p-values for the interaction effects as well as model based subgroup specific intervention effect estimates with 95%CI. To account for intersectional stratification, we apply Multilevel Analysis of Individual Heterogeneity and Discriminatory Accuracy (MAIHDA), Measuring Variance Partition Coefficient (VPC) and Proportional Change in Variance (PCV). We will use social determinants to create unique intersectional strata (combinations of the categories of gender, age, education, social support).

6.4 Analysis of the cohort study

The analysis of the outcomes on satisfaction with care, trust and support needs will similarly as in the RCTs analyzed using mixed models over the study period (random intercept models with random intercepts for patients) additionally including covariates for age, sex, Barthel Index. All other outcome measures will be analyzed descriptively for each time point within the cohort study.

6.5 Analysis of claims data

For claims data we will report descriptive measures as well as incidence rates in total and by group, and incidence rate ratios with 95%CI, and for mortality a hazard ratio for group comparison and 95%CI. Mortality will be analyzed using Kaplan Meier and Cox regression models, adjusting for centre, age and sex. Incidence rates and incidence rate ratios will be calculated using Poisson regression models or negative binomial regression models depending on the distribution of the outcome measures adjusted for age, sex and center. Regression models will only be used if the sample size is feasible for these analyses.

6.6 Health economic evaluation

Over the intervention period (and 12 months prior to baseline as a potential adjustment variable in case of relevant group differences), the total costs of treatment will be collected and analysed using health insurance data of participating patients of AOK Nordost. All inpatient and outpatient billing data collected during the survey period will be taken into account. This includes costs of hospital services, rehabilitation services, services in terms of prescriptions for medicines, remedies, medical aids, travel costs, home nursing care, home help, but also services provided by contract doctors, hospice and palliative care services as well as social long-term care insurance services in accordance with SGB XI. In order to take into account the naturally skewed distribution of cost data, generalised linear models with gamma distribution and log link function will be performed for the statistical analysis to compare group costs differences. Additional cost-effectiveness analyses will be conducted if the intervention proves to be superior in terms of "quality adjusted life years (QALYs)". A QALY takes into account both lifetime and quality of life during the study duration. QALYs are calculated on the basis of quality of life questionnaires (EQ-5D), which are completed at baseline and the three subsequent time points during the project period. The self-reported data on quality of life will be transformed into health state utilities for each of the measurements using the EQ-5D index calculator with a German reference population. The theoretical concept of QALYs assumes that a patient can achieve a utility value between 1 (perfect quality of life) and 0 (state of death) for each quality of life measurement. In case of deceased patients, a utility value of 0 is assumed. Further a linear temporal change in utilities will be assumed between the measurement points. Individual QALYs will result from the calculation of the arising area under the curve. If the intervention leads to QALYs gained compared to the control group at lower costs, it will be considered as cost-effective and dominant compared to the standard of care. If additional costs in the intervention group come alongside with additional effect in terms of QALYs, the incremental cost-effectiveness ratio (ICER) will be calculated by estimating the mean additional costs for an additional QALY (group cost differences / group QALY differences). A threshold of €50,000 per extra QALY is often used in studies as a cut-off value for the cost-effectiveness of an intervention. If the ICER is below this limit, the intervention will be considered cost-effective. If the actual number of participating patients with available health insurance data is lower than 50% of the initially assumed numbers, only descriptive measures will be reported.

7 Software

Analysis will be performed with the R software (https://www.r-project.org/) and SPSS Statistics (https://www.ibm.com/de-de/spss).

8 References

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9 Appendices

Table 1: Sample Description

Characteristics	Lung Cancer				Stroke			
	Intervention n =	**Control n =**	**Total n =**	**Cohort n =**	**Intervention n =**	**Control n =**	**Total n =**	**Cohort n =**
Age (years)								
Gender (n, % female)								
Education								
Nationality and migration status								
Marital Status								
Social Support								
People who support								
Present Situation								
Loneliness								
Pet								
Height/Weight								
Bedarfe								
Bartel								
Komorbiditäten								
Claims data analysis								

Table 2: Claims data analysis

Outcomes	Stroke					Lung Cancer				
	Intervention n = / IR	**Control n = / IR**	**Total n = / IR**	**IRR (95%CI)**	**Cohort n = / IR**	**Intervention n = / IR**	**Control n = / IR**	**Total n = / IR**	**IRR (95%CI)**	**Cohort n = / IR**
Mortality										
Frequency of (re-)hospitalization										
Frequency of use of hospice- and palliative care										
Frequency of use of inpatient rehabilitation										
Care dependency level										
Duration until the determination of first care dependency level										
Frequency of utilization of home health care										
Duration until the utilization of home health care										
Frequency of utilization of physiotherapy and speech therapy										
Frequency of utilization of funds for remedies and aids										
Frequency of utilization of patient transfer										

: Incidence per people month; IR: Incidence rate ratio comparing intervention and control group.

Figure 2: CoreNAVI II CONSORT Flowchart

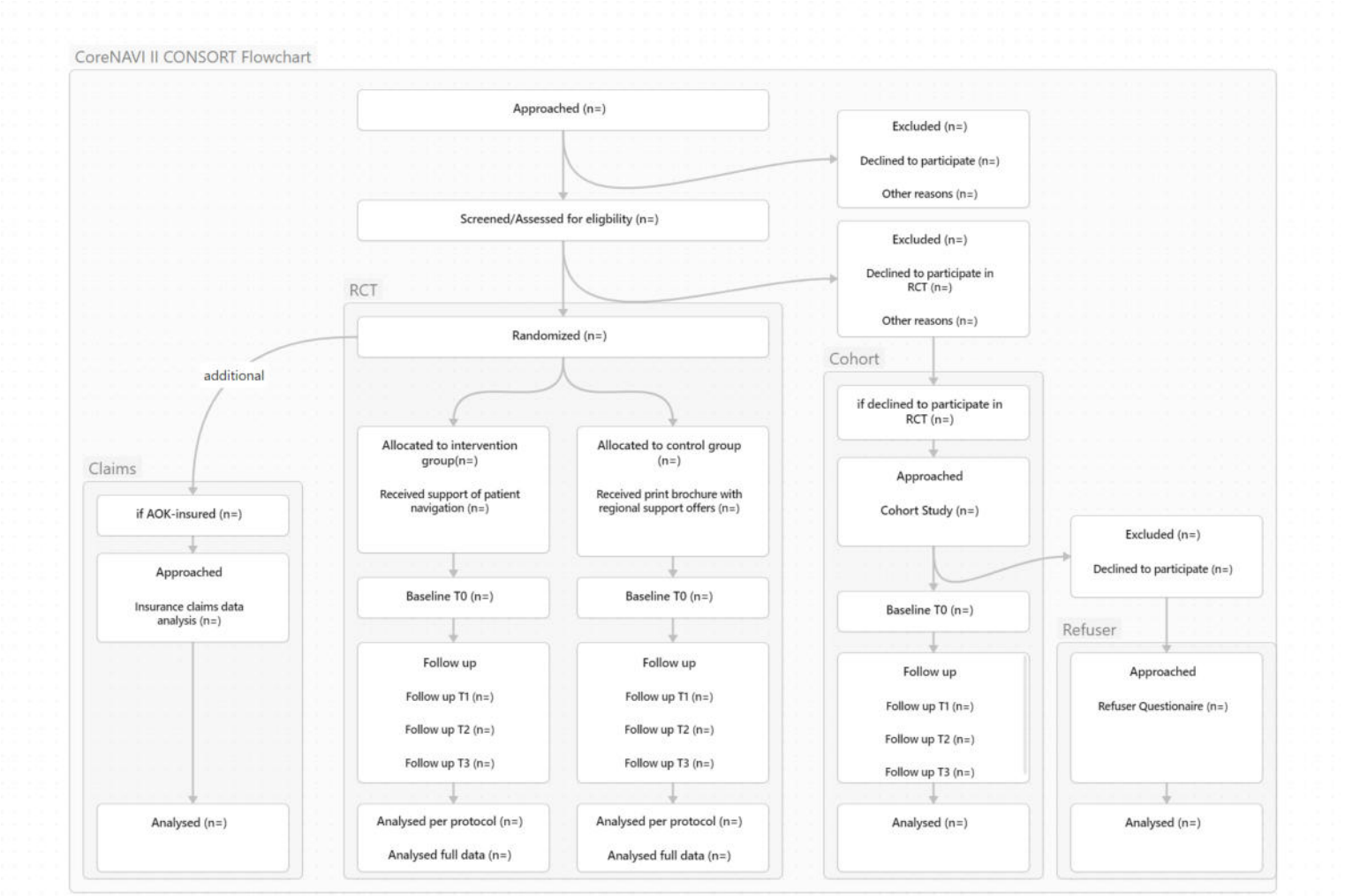

Table 3: Primary and Secondary Outcomes

Outcome name	Number of items	Stroke						Notes	Lung cancer						Notes	Reference
		B	T1	T2	T3	D	C		B	T1	T2	T3	D	C		
Primary Outcomes																
Feasibility																
Receiving in-person navigator session						X							X			
Drop out						X							X			
Efficacy																
Satisfaction with general medical care	1	X	X	X	X				X	X	X	X				
Secondary Outcomes																
Acceptance																
% eligible patients interested to receive the navigator intervention						X							X			
% consenting to the RCTs						X							X			
% interested but unwilling to be randomized						X							X			
% patients randomized and starting the intervention						X							X			
% patients adhering to the appointments with navigator						X		only in navigation group					X		only in navigation group	
% patients and % navigators, 'very satisfied' or 'satisfied' with the intervention	13		X	X*	X**			only in navigation group *new wording, +2 items, -1 item, -open questions **+1 item		X	X*	X**			only in navigation group *new wording, +2 items, -1 item, -open questions **+1 item	Adapted from [5] and self-developed
Demand																
Support needs	15	X	X*	X**	X**			* 19 items ** 23 items	X*	X**	X***	X***			*16 items **20 items *** 23 items	[4]and self-developed items
Information needs	4	X	X						X	X						[6]
Number of navigator contacts						X							X			
Delivery Mode of the navigator interaction (in-person, phone, email)						X							X			
Implementation and practicality																
% of target population (potentially eligible patients) approached and informed about study at recruitment centers before discharge						X							X			
% patient-navigator appointments carried out as planned						X							X			
% of individual patient goals achieved						X							X			
Patient and caregiver reported outcomes																
Health-related quality of life (generic), EQ-5DL	5	X	X	X	X				X	X	X	X				[7–10]
Health-related quality of life (generic, scale)	1	X	X	X	X				X	X	X	X				[7–10]
Health-related quality of life (specific, symptoms), EORTC QLQ-LC13	14								X	X	X	X			Specific for lung cancer	[11]
Mental health	4	X	X	X	X				X	X	X	X				[12]

Barthel-Index	10	X*	X	X	X			Specific for stroke *medical charts								[13]
Distress (scale)	1	X		X	X				X		X	X				[14]
Sleep	2		X	X	X					X	X	X				[15]
Self-efficacy	7			X	X				X	X	X	X				[16]
Utilization																
Utilization of medical care	1	X	X	X	X				X	X	X	X				Adapted from [15]
Utilization of inpatient care	1	X	X*	X*	X*			* +period of time +clinic/infirmary	X	X	X	X			* +period of time +clinic/infirmary	Adapted from [15]
Utilization of emergency department	2	X	X	X	X				X	X	X	X				[17]
Utilization of therapy/counseling	1		X	X	X				X	X	X	X				Adapted from [15]
Utilization of rehabilitation																Adapted from [15]
Delayed care	2	X	X	X	X				X	X	X	X				[17]
Foregone care (renunciation)	2		X						X	X	X					[18]
Medication adherence	1				X							X				Translated from [19]
Satisfaction																
Satisfaction with care	2	X	X	X	X				X	X	X	X				Self-developed
Trust in medical care	1	X	X	X	X				X	X	X	X				[18]
Health literacy																
Health literacy	4		X		X				X	X		X				[20]
Health literacy	3	X	X		X				X	X		X				[5]
Social support																
Social relationships	9		X	X						X	X	X				[21]
People who support	1	X	X	X	X			* + category “emotional support	X	X	X	X			* + category “emotional support	
Lifestyle																
Smoking	1		X	X	X					X	X	X				[17]
Daily activity	2		X	X	X					X	X	X				[15]
Use of computers	2			X							X					
Comorbidities																
Chronic disease	1			X	X						X	X				Adapted from [17]
Impairment/disability	2		X	X*	X*			* only disability		X*	X*	X*			* only disability	[17]
Care level	3	X	X	X	X				X	X	X	X				Adapted from [15]
Secondary data																
Health care utilization (outpatient and inpatient medical care, rehabilitation, remedies (e.g. physiotherapy), medication, nursing care)							X						X			
Health care costs (quality-adjusted life years (QALYs))						X	X					X	X			
Clinical outcomes (rehospitalization, 1 year mortality/survival, recurrent stroke event)							X						X			

B: Baseline questionnaire; T1: Questionnaire four month after enrollment; T2: Questionnaire 7 month after enrollment; T3: Questionnaire 13 Month after enrollment; D: Recruitment and navigation documentation; C: Claims data