Statistical Analysis Plan for the Patient Safety Checklist (PASC) Stepped Wedge Cluster Randomized Controlled Trial.

The original protocol version, including description of the statistical analysis, was approved by the Regional Ethical Committee of Western Norway (REK west) on the 21st of September 2016. The statistical analysis plan was drafted by Professor Arvid Steinar Haugen (head of project) and Professor in biostatistician Roy Miodini Nilsen, who also performed sample size calculations for the trial (expected n = 4200 in original protocol version 1.0). The approval was signed by the committee chair, Professor Ansgar Berg (reference 2016/1102/REK vest). The English title was "Effects on patient outcome in surgery: Development and Implementation of Patient Safety Checklists (PASC) before, during and after in-hospital surgery – a cluster RCT" with reference number 2016-1102.

The 1.0 protocol version was updated to version 2.0 on 30th of June 2021, and to version 2.1 on 10th of August 2022. The updates were approved by REC west, and they were signed by the committee chair, Professor Nina Langeland and by senior consultant Jessica Svärd (references 20569). The sample size calculation was updated in version 2.0 (30th of June 2021) prior to start of PASC data collection (1st of November 2021). The calculation was performed by Professor in biostatistics, Roy Miodini Nilsen and yielded then a required sample size at 5320 (protocol version 2.0). This update was based on empirical data from the development and validation of the PASC the intervention (Harris et al, 2022).

The main goals of the study are to investigate the impact of a patient safety checklist on patients having surgery within different surgical specialties, in three Norwegian hospitals (rural, central, and university hospital). The study has several work packages and hypothesis: a) The PASC checklist is hypothesized to have effect on surgical patients' complications, reoperations, readmissions, length of stay and mortality. Of these variables, complications are the primary outcome. Further, patients' experiences are hypothesized to be positively impacted by using PASC. Primary outcome for this part is the Patient Safety Checklist Experience Questionnaire. b) One part of the PASC checklist project include patients' self-screening on their risk of malnutrition, prior to surgery. Main hypothesis is that the PASC have impact on nutritional outcomes. Nutritional complications are a primary outcome for this part of the study, and secondary outcome are comparison of patients and healthcare staffs' risk assessments by comparing use of the Malnutrition Screening Tool. c) Investigate how implementation of the PASC checklist, a patient safety intervention, may be optimally used by the patients. Primary outcome is feasibility and compliance to using the checklist. Further, patients experiences are hypothesized to be positive towards the implementation. Primary outcome of this part is the PASC implementation survey. d) PASC is hypothesized to have an impact on cost-benefit of patients and the healthcare services. For this part of the study, the primary outcome is cost-effectiveness of the implementation across a-c. Secondary outcomes are the patient costs attributed associated with their surgical treatment. e) The PASC checklist is hypothesized to have impact on patients' health literacy. Primary outcome is the nine dimensions of the Health Literacy Questionnaire. f) PASC is hypothesized to have impact on patients' Quality of Life. Primary outcome is the EuroQual-5D-3L questionnaire.

Explanations of the statistical analysis techniques used for analyzing the data in the trial are detailed in the pages below.

Reference

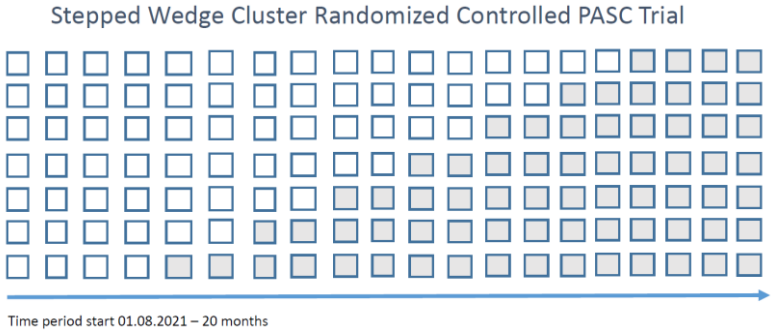
Harris et al. Development and validation of patients' surgical safety checklist. BMC Health Services Research. 2022; 22:259.

Statistical analysis plan a) for the PASC Stepped Wedge Cluster Randomized Controlled Trial

Hypothesis
The primary hypothesis is that PASC reduce complications up to 30 days after surgery.
Secondary hypotheses are that PASC reduce readmissions to hospital, length of hospital stay, and mortality up to 30 days after surgery.

Complications are in this trial observations of the surgical complications registered in patients' medical records and coded according to the International Classification of Diseases – 10th version (ICD-10) by surgeons or ward doctors. One or more complications per hospital stay per patient will be given the values zero or one, as the main outcome variable. Similarly, secondary outcomes. i.e. mortality, will be given zero or one (for events).

Statistical power
In protocol version 1.0, the sample size was calculated to be 4200 cases across the clusters. Based on data from a pilot of PASC feasibility (Harris et al, 2023), an update was required. The sample size analysis was updated in protocol 2.0 (30th June 2021):
The pooled overall proportion of surgery-related complications (i.e. infections, bleedings, cardiac or lung related) has previously been estimated to be 15% and is the primary outcome for the present analysis (Storesund et al, 2020). We propose that the inclusion of PASC will lower this proportion by at least 5% (corresponding to a 33.3% relative risk reduction). Using the stepped wedge power analyses command in Stata (*steppedwedge* command), we calculated that the lowest number of individuals required to detect the 5% reduction is 5320. The calculation was carried out using a non-standard stepped wedge design (see diagram below): 7 wards x 20 months x 38 patients (on average). We further assumed that the intra-cluster correlation (ICC) was 0.05 and that the type I error and type II error were 0.05 and 0.20, respectively.



Statistical analyses
Descriptive statistics: Descriptive statistics, including percentage and means with 95% confidence intervals, will be used to quantify sample characteristics of the participating wards and participants. To investigate potential bias in characteristics due to self-selection, characteristics for participants and the source population will be compared for each participating wards. We will further quantify bias by calculating the ratio of proportions for categorical data and difference in means for continuous data. *Analytical statistics:* For investigating the effects of PASC on surgery-related complications, we will use binary logistic regression models using the control period as reference category. Correlation between outcomes on the same hospital (ICC) will be considered by including a random intercept for the hospitals

in the various models (exchangeable correlation assumed). To account for potential temporal trends in the outcome, we will include calendar month as a continuous (linear or nonlinear) term in all models. Additional adjustment would be required if selection bias is present.

Variables are gender (0/1), age (in years), comorbidity (ASA-classification 1-5), type of anesthesia (general, spinal/regional, or combination – nominal scores), type of surgery (nominal scores), length of surgery (knife-time in minutes/hours), type of hospital (nominal scores), and month of surgery (1-27). Outcome variables: complication (one or more) up to 30 days after surgery, readmission to hospital within 30 days, mortality up to 30 days after surgery, and length of hospital stay.

Non-response and selection bias

Preliminary data collection suggests that the participation rate for PASC is 50% (Harris et al, 2022). If participation probability is associated with characteristics that also are related to the outcome under study, effects of PASC on surgery-related complications could be biased. In the table example below, the risk of complication in complete data with no self-selection would be 15% and 10% for the control and intervention periods, respectively. With 50% non-response (and strong selection on characteristics) in the intervention period, the corresponding risk of complication could be only 5%. Thus, a large risk reduction in the intervention period could be ascribed selection rather than the intervention. Fortunately, our study is prospective in that the outcome is measured after the intervention take place. Accordingly, only the difference in patient characteristics between control and intervention period can affect the difference in future outcome. Following this, regression adjustment for difference in patient characteristics would probably be sufficient to adjust for selection bias (1).

Protocol deviation and intention to treat (ITT)

Protocol violations for the PASC intervention may include incomplete response to questionnaire, not operated after all, or other aspects that might imply that the patients should not be included for analyses. In such cases, we will still include subjects as if they had been treated (intention to treat analyses). If we were to exclude patients due to protocol violation (per protocol analysis), this could lead to serious bias which is not possible to correct using adjusted regression analyses.

This description of statistical analysis and power analysis was performed by biostatistician and Professor Roy Miodini Nilsen in collaboration with Professor Arvid Steinar Haugen, in the updated 2.0 version of the protocol.

Reference

Harris et al. Development and validation of patients' surgical safety checklist. BMC Health Services Research. 2022; 22:259.

Harris et al. Feasibility of implementing a surgical patient safety checklist: prospective cross-sectional evaluation. Pilot and Feasibility Studies (2023) 9:52

Hernan MA, Hernandez-Diaz S, Robins JM. A structural approach to selection bias. Epidemiology. 2004;15(5):615-25.

Storesund A, et al. Clinical Efficacy of Combined Surgical Patient Safety System and theWorld Health Organization's Checklists in Surgery - A Nonrandomized Clinical Trial. JAMA Surgery. 2020;155(7):562-570.

Statistical analysis plan b) on the PASC checklist on patients self-screening on their risk of malnutrition prior to surgery.

The main hypothesis is that PASC reduce the risk of nutritional events after surgery. Nutritional complications are a primary outcome based on ICD-10 codes, and secondary outcome are comparison of patients and healthcare staffs' risk assessments by comparing use of the Malnutrition Screening Tool (MST) (Ferguson et al, 1999). Three MST items are scored from 0-7, where a total sum score at 2 and above, represents patients being at risk of malnutrition. Secondary hypothesis is that patients can screen themselves of the malnutrition risks and just as well as the healthcare staffs' screening of the patients' malnutrition risks.

Descriptive analysis with frequencies, percentages, means, and standard deviations will be applied. A chi-squared test will be applied to detect differences in patient characteristics and clinical variables from baseline to intervention steps. A logistic regression model will be used to adjust for any variations in characteristics or clinical variables between control and intervention steps. Validity of the Malnutrition Screening Tool will be investigated with nutrition parameters of the scale and objective variables (ICD-10 codes). Agreement between patients' ratings and healthcare staffs' ratings on the malnutrition risk scale will be measured with percentages, Kappa and intraclass correlation (ICC) with absolute agreement as appropriate. Correlations will be performed with Pearsons' correlation or Spearman's rho, as appropriate.

Missing data will be managed by creating 200 imputed datasets and the imputation model included all variables to be included in adjusted regression model. Statistical analyses will be performed by Stata and in SPSS. All P-values are two sided and values $P < 0.05$ are considered statistically significant.

The statistical analysis plan was described in the protocol 1.0, 2.0 and 2.1, and further detailed here, by Professor Arvid Steinar Haugen.

Reference

Ferguson M, et al. Development of a Valid and Reliable Malnutrition Screening Tool for adult Acute Hospital Patients. Applied Nutritional Investigation. 1999; 15(6):458-464.

Statistical analysis plan for parts of both a) and c)

Statistical analysis plan for the Patient Safety Checklist Experience Questionnaire (PASC-EQ) and the PASC Implementation Questionnaire (PASC-IQ)

The main hypotheses for these parts of the study are that PASC have positive impact on patients experiences with using the checklist and the implementation of it. Hence, primary outcomes of these two studies are the PASC experience questionnaire (PASC-EQ) and the PASC implementation questionnaire (PASC-IQ).

The survey instruments

The PASC-EQ instrument was developed to measure patients' experiences with using the patient safety checklist in the intervention arm (Haugen 2017). The development was based on literature searches (Harris et al. 2020, Harris et al. 2022) and expert review of items suggested

by the research group. Items were reviewed by clinicians and researchers within patient safety and surgical safety checklists research group of PASC.

The PASC-EQ consists of 21 items representing 5 domains of patients' experiences with using the patient safety checklist (PASC). The domains are labelled as 1: Information on my surgery. 2: Patient safety. 3: Patient involvement. 4: Communication with healthcare personnel. 5: Engaging with healthcare services.

For the PASC Implementation Questionnaire (PASC-IQ) we added three dimensions, each with four items, to the survey. These items were inspired by the implementation form used by Weiner and colleagues (2017) and adapted for investigating the PASC implementation experiences.

For both questionnaires, all scores went from 'Disagree totally', 'Disagree', 'Nor disagree or agree', 'Agree', and 'Agree totally' (values 0-4).

Statistical power of the PASC trial on the PASC-EQ and PASC-IQ

According to Kline (2011, p. 225) the sample size required to perform Structured Equational Modelling (SEM) usually requires 3-400 cases for models when degrees of freedom are <10. With higher degrees of freedom, i.e. > 20, a smaller number of cases is required for a minimum power of 0.80. However, the sample size should never be less than 100 in any event (Kline, 2011). The degrees of freedom within PASC-EQ/PASC-IQ data, including 7 surgical clusters, are estimated to be 32. Accordingly, more than 200 cases (respondents) are a sufficient sample for conducting SEM (confirmatory factor analysis) with PASC-EQ/PASC-IQ data.

Statistical analysis

Descriptive statistics (i.e. frequencies, percentages, mean, standard deviations) will be used to assess patients' characteristics. To investigate the PASC-EQ/PASC-IQ impact on patients' experiences, chi-squared test will be used to test any differences between the intervention clusters, and patient characteristics. Independent samples t-test (ANOVA) will be used to investigate mean score difference between groups and patient characteristics as appropriate. If there are significant variation in patients' characteristics between the groups, linear regression model (General Linear Model) will be applied to adjust for it and to compare across the PASC-EQ/PASC-IQ domains. Missing data will be managed by creating 200 imputed datasets and the imputation model included all variables that to be included in adjusted regression model.

The validity and reliability of the questionnaires will be investigated. For the internal consistency of PASC-EQ/PASC-IQ Cronbach's alpha (scores between 0 and 1, preferably >0.7) will be applied. Spearmans' rho will be used to assess correlations between the dimensions. Explanatory factor analysis and indicators will be assessed. Psychometric evaluation will be performed by measuring the hypothesized structure model with fit indicators as X^2, CFI, TLI, and RMSEA (Bollen 1989, Kline 2011). These analyses will be performed in IBM SPSS version 29 and IBM SPSS AMOS version 26, and a two-sided P value at 0.05 will be considered statistically significant.

The description of the planned statistical analyses, including the sample power analyses, were originally performed for the 2.0 protocol update, by Professor Arvid Steinar Haugen, Department of Anaesthesia and Intensive Care, Haukeland University Hospital, Bergen,

Norway; and Faculty of Health Sciences, Department of Nursing and Health Promotion, Acute and Critical Illness, Oslo Metropolitan University, Oslo, Norway.

The text was up-dated 30th August 2024 prior to analysis, by Professor Arvid Steinar Haugen.

References

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Harris et al. Patients' and healthcare workers' recommendations for a surgical patient safety checklist – a qualitative study. BMC Health Services Research. 2020; 20:43.

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Weiner et al. Psychometric assessment of three newly developed implementation outcome measures. Implementation Science. 2017; 12:108.

Statistical analysis plan part d) for the PASC Health Economic Impact (PASC-HEI)

Health economic evaluations of patient safety interventions in healthcare are limited, though previously we have evaluated the cost-effectiveness of the World Health Organization's Surgical Safety Checklist (Healey et al. 2022). It is vital to evaluate the impact of new patient safety interventions on costs and benefits for patients and society. Hence in the PASC trial we aim to investigate the health economic impact of the Patient Safety Checklist (PASC) in the PASC Stepped Wedge Cluster Randomized Controlled Trial (Haugen, 2017).

The main hypothesis is that the PASC is cost-effective for both patients and society. Primary outcome is costs associated with implementation of the PASC, where length of hospital stay is a major component for the overall treatment cost (Healey et al, 2022).

Statistical power of the PASC trial on PASC-HEI

The statistical power of the PASC trial is based on sample size calculations referred to in the protocol and in the Statistical Analysis Plan for the trial, where 2660 in each arm with a total of 5320 cases would be required to detect a 5% reduction of events. The clinical data from the trial and health economic data such as the costs of PASC implementation and the cost of length of stays in hospitals, would be regarded to be adequate also for the cost-benefit analysis (Healey et al, 2022). The implementation variables include cost for time spent on implementation meetings with managers and staff, staff salaries, printing of checklists, mail costs, and digital distribution of the PASC checklist costs. Further, the variables also include costs for the patients due to actions taken after using the PASC checklist, like going to their general practitioner, dentist, nutritional diets (risks of malnutrition), and other relevant actions caused by the checklist intervention. The patient data is based on the clinical trial data and a patient survey (PASC health economic impact survey – "PASC HEI") forwarded to a random sample drawn from within the trial. An adequate sample was calculated to 50 respondents from each cluster,

in each arm, 700 in all with a response rate at 50% (see sample calculations for the HLQ and EQ-5D-3L).

Statistical analysis plan of the PASC-Health Economic Impact data

Descriptive analysis with frequencies, percentages, mean scores, standard deviations will be applied for the patient characteristics, both for the PASC-HEI survey and for the economic evaluation of the trial. To investigate the PASC intervention impact on the health economic survey, a chi-squared test, or an independent samples t-test (ANOVA) will be used as appropriate to test for any differences between the trial arms. If there are significant variation in patients' characteristics between the two arms, a linear regression model (General Linear Model) will be applied to adjust for it and to compare effects. Analysis will be performed in SPSS 29.0 (IBM Corp, Armonk, NY) and a two-sided P value at 0.05 will be considered statistically significant.

For the evaluation of implementation costs in combination with the clinical outcome data (i.e. complications and length of stay) the analysis builds on empirical data from the trial and our previous analysis methods published by Healey et al. (2022). In the cost-effectiveness analysis the mean difference in the absolute probability of the hospital admission is linked to a procedure being complication free, from control to intervention arms. We will investigate 30-days complication-free hospital admissions per 100 admissions. Ordinary least squares regression with a binary approach will be used to identify mean differences of the total costs per admission and the probability of hospital admissions without complications. A nonparametric approach will be used to estimate standard errors on mean cost effects with 95% confidence intervals.

We will estimate the cost impact of the PASC for a hospital bed-day equivalent and express the estimated cost difference as a ‘‘quality adjusted life year’’ (QALY). In Norway, the cost-effectiveness threshold is estimated by Woods et al (2016) to be between 43% and 93% of gross national income (GDP) per capita. We will present QALY equivalent effectiveness of the PASC as the lower, mid-point and upper-bound of this range (Healey et al, 2022).

Missing data on cost of hospital admissions and clinical covariates will be replaced with missing imputation (assumed missing at random) to reduce loss of power in the regression analysis (Azur et al, 2011). Missing data will be managed by creating 200 imputed datasets and the imputation model included all variables that to be included in adjusted regression model (Healey et al 2022). To test for sensitivity of the cost-effectiveness of the PASC implementation we use an upper and lower quartile excess bed-day cost from UK data to adjust for the Norwegian per diem costs (NHS, 2017).

The sample size calculation and the statistical analysis plan to be used on PASC-HEI was originally described in the 2.0 protocol, and updated 30th August 2024, by Professor Arvid Steinar Haugen, Department of Anaesthesia and Intensive Care, Haukeland University Hospital, Bergen, Norway; and Faculty of Health Sciences, Department of Nursing and Health Promotion, Acute and Critical Illness, Oslo Metropolitan University, Oslo, Norway.

References

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Statistical analysis plan e) for the EuroQol-5D-3L (EQ-5D-3L) in the PASC trial

The main hypothesis is that PASC improve the quality of life. Primary outcome is the EQ-5D-3L.

EQ-5D-3L has three levels (1, 2, 3) on five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. There is also a visual analogue scale from 0-100 on overall health today.

Sample size and power analysis for EQ-5D-3L

Mean scores for EQ-5D-3L runs from 0.0-1.0. An orthopaedic patient population was indexed at 0.5 (Jansson, 2011). Sample power was calculated in IBM SPSS Sample Power 3. For a given effect size (population mean difference at 0.5 vs. 0.6), with standard deviation at 0.3, a sample size at 200 in the control group and 200 in the intervention group will provide a two-sided alpha at 0.05, with power at 0.914.

Figure 1. Original sample size and power analysis in SPSS.

Updated sample power analysis, 30th August 2024, by Professor Arvid Steinar Haugen. A post hoc analysis of a required sample in the control and intervention steps of the trial, with n=125 and 200, respectively. This was based on anticipated final numbers of respondents to the survey.

Independent samples t-test with One-Way ANOVA, performed with IBM SPSS version 29. For a sample with 125 patients in the control group and 200 patients in the intervention group, with standard deviation at 0.3 for both groups and a two-sided significance level at 0.05, the power of this sample size is 0.83.

Table 1 Power Analysis

		Test Assumptions			
	Power[b]	N[c]	Std. Dev.	Effect Size[d]	Sig.
Overall Test[a]	,830	325	,3	,242	,05

a. Test the null hypothesis that population mean is the same for all groups.
b. Based on noncentral F-distribution.
c. Total sample size across groups.
d. Effect size measured by the root-mean-square standardized effect.

Statistical analysis

Descriptive statistics (i.e. frequencies, percentages, mean, standard deviations) will be used to assess responding patients' characteristics, clinical variables, and surgical specialties (i.e. comorbidity, type of anesthesia or surgery, length of surgery) and EQ-5D-3L dimensions. To investigate the PASC intervention effect on EQ-5D-3L, a chi-squared test will be used to test any differences on patient characteristics between the trial arms. General Linear model with analysis of covariance will be used to investigate mean score difference between control and intervention arms. If there are significant variations in patients' characteristics and clinical variables between the two arms adjustments for these differences will be applied in the regression model to compare effects across the domains (Jansson, 2011). All analysis will be performed in SPSS 29.0 (IBM Corp, Armonk, NY) and a two-sided P value at 0.05 will be considered statistically significant.

The validity and reliability of the EQ-5D-3L will be investigated. The internal consistency will be measured by using Cronbach's alpha (scores between 0 and 1, preferably >0.7) and Pearsons' correlation or Spearman's rho as appropriate. Psychometric evaluation will be performed by measuring the hypothesized structure model of the EQ-5D-3L with fit indicators as X^2, CFI, TLI, and RMSEA (Bollen 1989, Kline 2011). The analysis will be performed in IBM SPSS version 29 and IBM SPSS AMOS version 26.

According to Kline (2011, p. 225) the sample size required to perform Structured Equational Modelling (SEM) usually requires 3-400 cases for models when degrees of freedom are <10. With higher degrees of freedom, i.e. > 20, a smaller number of cases is required for a minimum power of 0.80. However, the sample size should never be less than 100 in any event (Kline, 2011). The degrees of freedom within EQ-5D-3L, including 7 surgical clusters are anticipated to exceed this number on degrees of freedom. Accordingly, in all, more than 200 cases (respondents) are sufficient sample for conducting SEM (confirmatory factor analysis) with the EQ-5D-3L data. Missing data will be managed by creating 200 imputed datasets and the imputation model included all variables that to be included in adjusted regression model.

The sample size calculation and the statistical analysis plan to be used on EQ-5D-3L data were described in protocol version 2.0 (30th June 2021), along with the description of statistical analysis of the HLQ survey, and updated 30th August 2024, by Professor Arvid Steinar Haugen, Department of Anaesthesia and Intensive Care, Haukeland University Hospital, Bergen, Norway; and Faculty of Health Sciences, Department of Nursing and Health Promotion, Acute and Critical Illness, Oslo Metropolitan University, Oslo, Norway.

References

Bollen K. Structural equations with latent variables. Wiley-Interscience publication. Mexico. 1989. ISBN 0-471-01171-1.

Jansson K-Å, Granath F. Health-related quality of life (EQ-5D) before and after orthopedic surgery. Acta Orthopaedica 2011; 82(1):82-89.

Kline RB. Principles and Practice of Structural Equation Modeling. Third edition. The Guiltford Press. New York, USA, 2011.

Statistical analysis plan f) for PASC impact on patients' health literacy

The main hypothesis is that PASC improve surgical patients' health literacy. The primary outcome is the nine dimensions in the Health Literacy Questionnaire (HLQ), developed by Osborn et al 2013).

Statistical power and sample size required for HLQ in the PASC trial

A power analysis was performed to assess the required number of participants in the survey. It was based on mean score results in a previous Norwegian study of health literacy in a population of patients with skin diseases (Wahl, 2021). The lowest number of individuals required to detect a clinical meaningful mean score difference at 0.30 between the baseline and intervention groups would be n = 103 patients in each arm of the PASC trial. A standard deviation at 0.66 in both arms were assumed. Power was estimated at 90% and a type I error at 0.05. Previous research experiences on surveys in Norwegian hospitals indicate that patients' responses could possibly be 35% (Boge, 2019). Hence, we include 50 patients per cluster with a total of 350 patients in the baseline group and 350 patients in the intervention group to ensure enough respondents.

The survey instrument

The HLQ consists of 44 questions with 9 domains that represent patients' health literacy. The domains are labelled as 1: Understood and supported by health professionals. 2: Satisfactory information to handle own health. 3: Active management of own health. 4: Social support of own health. 5: Consider health information. 6: Active cooperation with health professionals. 7: Navigation through the healthcare system. 8: Possibilities to find right health information and 9: Understand the health information to be able to know what should be done.

Statistical analysis

Descriptive statistics (i.e. frequencies, percentages, mean, standard deviations) will be used to assess patients' characteristics (i.e. age, gender, comorbidity, educational level, societal status). To investigate the PASC intervention effect on health literacy, a chi-squared test will be used to test any differences between the trial arms. General Linear Model will be used to investigate mean score difference between control and intervention arms. If there are significant variation in patients' characteristics between the two arms a linear regression model will be applied to adjust for it and to compare effects across the nine domains on health literacy (Osborne, 2013).

All analysis will be performed in SPSS 29.0 (IBM Corp, Armonk, NY) and a two-sided P value at 0.05 will be considered statistically significant.

Validity and reliability of the HLQ will be investigated. The internal consistency will be measured by using Cronbach's alpha (scores between 0 and 1, preferably >0.7) and Spearman's rho for correlations between the dimensions. Psychometric evaluation will be performed by measuring the hypothesized structure model of the HLQ with fit indicators as X^2, CFI, TLI, and RMSEA (Bollen 1989, Kline 2011). This analysis will be performed in IBM SPSS version 29 and IBM SPSS AMOS version 26.

According to Kline (2011, p. 225) the sample size required to perform Structured Equational Modelling (SEM) usually requires 3-400 cases for models when degrees of freedom are <10. With higher degrees of freedom, i.e. > 20, a smaller number of cases is required for a minimum power of 0.80. However, the sample size should never be less than 100 in any event (Kline, 2011). The degrees of freedom within PASC-EQ/PASC-IQ data, including 7 surgical clusters, are 32. Accordingly, more than 200 cases (respondents) are sufficient sample for conducting SEM (confirmatory factor analysis) with PASC-EQ/PASC-IQ data. Missing data will be managed by creating 200 imputed datasets and the imputation model included all variables that to be included in adjusted regression model.

The sample size calculation and the statistical analysis plan to be used on HLQ data were described in protocol version 2.0. The SAP was up-dated 30th August 2024. The original statistical plan and the update was made by Professor Arvid Steinar Haugen, Department of Anaesthesia and Intensive Care, Haukeland University Hospital, Bergen, Norway; and Faculty of Health Sciences, Department of Nursing and Health Promotion, Acute and Critical Illness, Oslo Metropolitan University, Oslo, Norway.

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Wahl AK, Hermansen Å, Osborne RH, Larsen MH. A validation study of the Norwegian version of the Health Literacy Questionnaire: a robust nine-dimension factor model, Scand. J. Public Health. 2021, 49(4):471-478.

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