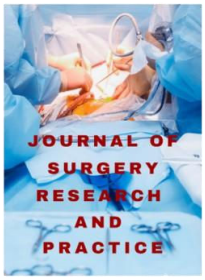

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*Research Article*

# Development and Measurement Properties of the Danish Translation of the Groin Hernia-Q: Protocol for a Validation Study

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## Abstract

Background: The patient reported outcome questionnaire Abdominal Hernia-Q is probably the most thoroughly validated patient-reported outcome measure specifically developed for patients undergoing ventral hernia repair. The present study aims to adapt and validate the Danish translation of the Abdominal Hernia-Q for patients undergoing groin hernia repair: the Groin Hernia-Q.

Methods: This validation study will involve a total of 250 participants and it is divided into two substudies. Substudy 1 will focus on adapting the Abdominal Hernia-Q into the Groin Hernia-Q and assessing its content validity using the QQ-10 questionnaire. Substudy 2 will evaluate the structural validity, internal consistency, test-retest reliability, measurement error and construct validity of the Groin Hernia-Q, while also utilizing and comparing the results to the Carolinas Comfort Scale and Short-Form 12. Participants will be recruited both in a clinical setting and electronically. Data collection will be conducted through the platform Research Electronic Data Capture (REDCap). In addition to questionnaire data, this study will also involve perioperative and patient-related data extracted from the Danish National Patient Registry and the Danish Hernia Database. This study is part of the AFTERHERNIA Project.

Conclusion: This study will provide a comprehensive validation of the Groin Hernia-Q, ensuring it becomes a valuable tool for assessing patient-reported outcomes in patients undergoing groin hernia repair. The questionnaire will contribute significantly to improved patient care through the AFTERHERNIA Project.

**Keywords:** Hernia; Surgery; Questionnaire; PROM; Validation

## Introduction

Groin hernia repair is a frequently performed surgical procedure and globally more than 20 million repairs are performed each year [1]. Although the majority of patients experience recovery from surgery without enduring long-term complications, a subset of patients encounters less favorable outcomes. When determining the success of groin hernia repairs, the outcomes of interest often include short-term outcomes like early postoperative pain, convalescence time and surgical site occurrences, as well as long-term outcomes such as chronic pain and hernia recurrence [2,3]. However, recent qualitative evidence suggests that hernia repair outcome assessment should be broader in scope and could include factors such as cosmetic appearance, satisfaction with the surgeon and overall patient satisfaction [4,5]. Patient-Reported Outcome Measures (PROMs) are useful tools to assess these broader aspects, however, many PROMs designed for patients undergoing groin hernia repair are insufficiently validated for the purpose [6]. In contrast, the questionnaire Abdominal Hernia-Q (AHQ), which is designed specifically for patients undergoing ventral hernia repair, has undergone extensive development and rigorous psychometric validation [4,7,8].

Consequently, we aim to develop and validate a new PROM for patients undergoing groin hernia repair, named the Groin Hernia-Q (GHQ). We will construct this new PROM by revising and adapting the AHQ to accommodate the specific patient-

reported outcomes of interest for groin hernia patients. This protocol also outlines the methodology for the adaptation and validation of the Danish translation of GHQ. The study seeks to assess the following measurement properties of the Danish GHQ: content validity, structural validity, internal consistency, test-retest reliability, measurement error and construct validity.

**Methodology**

The study is designed according to the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) study design checklist for PROM instruments (COSMIN Checklist) [9]. The terminology and definitions applied in this study follow the guidance from the COSMIN Initiative [10,11], some of which are detailed in Table 1. The present study is divided into two substudies and the general study design is outlined in Fig. 1.

**Substudies**

*Substudy 1*

Substudy 1 is focused on the development of the GHQ and on demonstrating its content validity. The development of the GHQ will be performed by revising and adapting the pre- and postoperative form of the AHQ, to optimize it for patients undergoing groin hernia repair. This process will be carried out by an expert panel with patient input and it will be based on existing qualitative evidence on the subject [5].

Subsequently, we will conduct a quantitative and qualitative evaluation of the content validity of the GHQ. First, 50 patients with a groin hernia, who have not received a repair, will be recruited in a clinical setting and requested to complete the preoperative form of the GHQ along with the QQ-10 [12]. The QQ-10 is a questionnaire designed to assess the content validity of other questionnaires. Concurrently, an additional 50 patients, who have received a groin hernia repair, will be invited to complete the postoperative form of the GHQ and also the QQ-10 [12]. The responses of both groups will be analyzed to obtain evidence for the content validity of the GHQ.

*Substudy 2*

Substudy 2 will demonstrate the structural validity, internal consistency, test-retest reliability, measurement error and construct validity of the GHQ. A total of 150 patients who have received a groin hernia repair will be invited to complete the postoperative form of the GHQ, the Carolinas Comfort Scale (CCS) [13] and the Short-Form 12 (SF-12) [14]. The results from the postoperative form of the GHQ will be analyzed to assess its structural validity and internal consistency. Results from selected items and sumscores from the three questionnaires will be correlated according to prespecified hypotheses to provide evidence for the construct validity of the GHQ.

After a period of 2-4 weeks, the postoperative form of the GHQ will be readministered to the same cohort of patients. Results from the two different administrations of the postoperative form of the GHQ will be analyzed to provide evidence for the test-retest reliability and measurement error of the postoperative form of the GHQ.

*Participants and Recruitment*

Eligibility criteria for participation are listed in Table 2. The preoperative patient cohort for assessing the content validity of the preoperative form of the GHQ in Substudy 1 will consist of 50 patients. These patients will be recruited through consecutive sampling in a hospital setting and recruitment will continue until 50 complete responses are obtained.

The postoperative cohorts of 50 and 150 patients in Substudy 1 and 2, respectively, will be identified based on surgical procedure codes extracted from the Danish National Patient Registry. Eligible patients will be recruited through purposive sampling from a random sample of patients who received a groin hernia repair between 1 January 2023 and 31 December 2023. Recruitment will continue until the necessary number of complete responses has been acquired (Table 3).

*Sample Size*

For Substudy 1, a sample of 100 patients is necessary. The COSMIN Checklist requires at least 50 participants for studies performing a quantitative assessment of content validity [9]. In the present study, two separate assessments will be performed in two different cohorts of 50 patients each and thus a total of 100 patients will be included. In Substudy 2, a total of 150 patients is required. The COSMIN Checklist demands a population of at least seven times the number of items in the questionnaire being

studied when assessing structural validity with factor analysis [9]. The postoperative form of the AHQ contains 16 items and it is anticipated that the number of items in the upcoming GHQ will not exceed 21. This necessitates 147 complete responses, rounded to 150, for the first administration of questionnaires in Substudy 2. For the assessment of test-test reliability and measurement error, 100 participants are required [9]. Consequently, it is only necessary for 100 participants to respond to the second administration of questionnaires in Substudy 2.

*Expected Non-Response and Estimated Loss To Follow-Up*

We estimate that we will need to contact approximately 1,000 patients in total to obtain the necessary number of complete responses for all questionnaires. An adaptive design approach will be employed and we will stop recruitment when we have received the necessary number of complete responses. In the preoperative patient cohort in Substudy 1, a response rate of 50% is expected. These patients will be recruited face-to-face by a study representative, they will complete the questionnaires in person and the questionnaire burden for these patients is limited. Consequently, a high response rate can be expected, but a conservative estimate of 50% was chosen. For the two postoperative cohorts in Substudy 1 and 2, a moderately low response rate of 25% is expected as these patients will be recruited digitally without prior contact with study representatives. For the second administration of questionnaires in Substudy 2, a loss to follow-up of 50% is estimated, but only 100 complete responses are necessary.

| Measurement Properties | Definitions |
|---|---|
| Content validity | "The degree to which the content of a PROM is an adequate reflection of the construct to be measured" |
| Structural validity | "The degree to which the scores of a PROM are an adequate reflection of the dimensionality of the construct to be measured" |
| Internal consistency | "The degree of the interrelatedness among the items" |
| Reliability (test-retest) | "The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions, e.g. [...] over time (test-retest)" |
| Measurement error | "The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured" |
| Construct validity (hypothesis testing) | "The degree to which the scores of a PROM are consistent with hypotheses [...] based on the assumption that the PROM validly measures the construct to be measured" |

**Table 1:** COSMIN measurement properties and definitions. Selected measurement properties as defined by the COSMIN Initiative. Definitions are quoted from the COSMIN manual [11]. COSMIN: COnsensus-based Standards for the selection of health Measurement Instruments; PROM: patient-reported outcome measure.

| | |
|---|---|
| *Patients are eligible if the following conditions are met:* | |
| - | Received a groin hernia repair between 1 January 2023 and 31 December 2023. |
| - | ≥18 years old at the time of groin hernia repair. |
| - | Groin (inguinal or femoral) hernia repair by Lichtenstein or Transabdominal Preperitoneal (TAPP) methods, including robot-assisted TAPP and conversion from TAPP to Lichtenstein. |
| - | Acute or elective repair. |
| *Patients will be excluded if the following conditions are met:* | |
| - | Participation in studies in conflict with the present protocol. |
| - | Psychological, geographical and social conditions that would hinder adherence to the protocol. |
| - | Non-mesh repair. |
| - | Other concomitant surgical procedure (e.g., bowel resection or concomitant umbilical hernia repair). |
| - | Exempt from using Digital Post. |
| - | Not possible to retrieve contact information through the Danish National Patient Registry, such as patients living abroad or patients with nondisclosure of stress address. |

**Table 2:** Eligibility criteria. For the preoperative patient cohort, all conditions apply except for the four surgical criteria and the two criteria related to Digital Post and contact information. Instead, these patients are required to have at least one groin hernia.

| Strength and Direction of Correlation | Items/domains | |
|---|---|---|
| | GHQ item* | Other instrument |
| Strong positive correlation (r≥0.50) | #1a | Bodily Pain domain of the SF-12 (item #8) |
| Strong positive correlation (r≥0.50) | #1a | Pain domain of the CCS (items #1b, #2b, #3b, #4b, #5b, #6b, #7b, #8b) |
| Moderate/strong positive correlation (r≥0.30) | #2b | Movement Limitation domain of the CCS (items #2c, #3c, #4c, #5c, #6c, #7c, #8c) |
| Moderate/strong positive correlation (r≥0.30) | #2b | Physical Functioning domain of the SF-12 (items #2 and #3) |
| Strong positive correlation (r≥0.50) | #1b | Mesh Sensation domain of the CCS (items #1a, #2a, #3a, #4a, #5a, #6a, #7a, #8a) |
| No/low positive correlations (r<0.30) | #3a, #4a, #5a and #6a | Mental Health domain of the SF-12 (items #9, #10, #11) |
| Moderate positive correlation (r≥0.30; r<0.50) | #8a | Role Emotional domain of the SF-12 (Items #6, #7) |

**Table 3:** Hypotheses for construct validity. CCS: Carolinas Comfort Scale; GHQ: Groin Hernia Q; r: Pearson's rho; SF-12: Short-Form 12. * The listed item numbers refer to the postoperative form of the Abdominal Hernia-Q, as the GHQ has not yet been developed. The listed hypotheses will be revised and aligned with the GHQ before data collection commences.

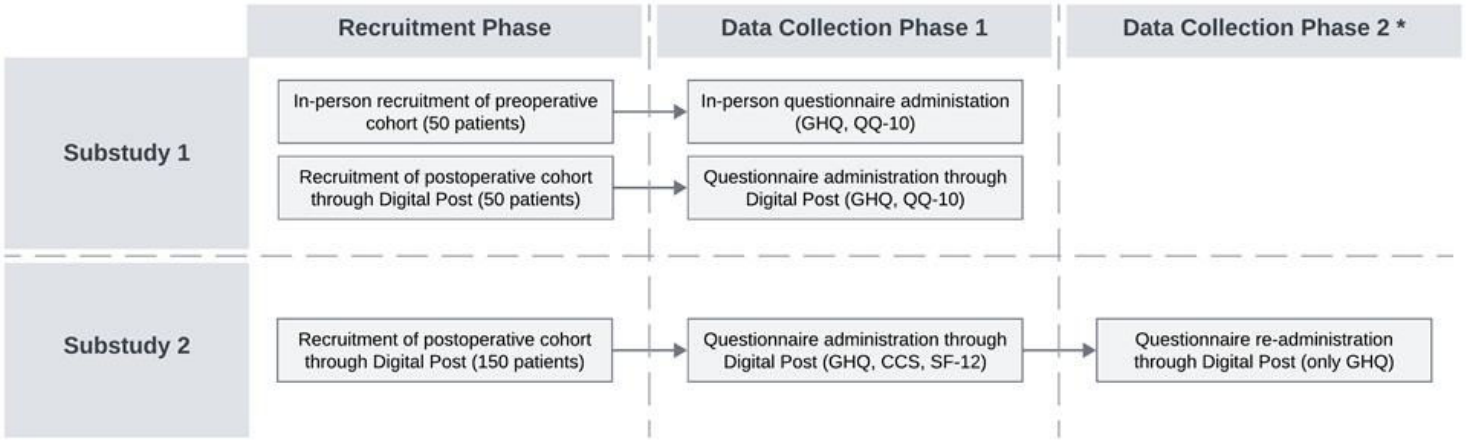


**Figure 1:** Study design and data flow. Basic timeline for Substudy 1 and 2. CCS: Carolinas Comfort Scale; GHQ: Groin Hernia-Q; SF-12: Short-Form 12. * 2-4 weeks after Data Collection Phase 1.

**Questionnaires**

*Abdominal Hernia-Q (AHQ)*

The AHQ is a novel PROM specifically designed to assess the quality of life in patients undergoing ventral hernia repair. Developed with extensive patient involvement, the AHQ provides both pre- and postoperative forms, featuring items across seven domains, aimed at capturing the comprehensive impact of hernias and their treatment on patients' lives. The seven domains in the AHQ are: expectations, self and others, surgeon and surgical team, sensation, function, appearance and overall satisfaction. The preoperative instrument includes eight items and the postoperative instrument includes 16 items. The response for each item is scored on a 4-point Likert scale with three different types of descriptors [7]:

- 1) All of the time, 2) Most of the time, 3) Some of the time, 4) None of the time
- 1) Strongly disagree, 2) Somewhat disagree, 3) Somewhat agree, 4) Strongly agree
- 1) Very unsatisfied, 2) Somewhat dissatisfied, 3) Somewhat satisfied, 4) Very satisfied

The psychometric evaluation during the development of the AHQ involved both content validity, structural validity, internal consistency, test-retest reliability and construct validity (incl. convergent validity and known-groups validity). The content validity of the AHQ was ensured through a series of concept elicitation interviews and focus group interviews with patients [4]. The structural validity was assessed through principal component analysis, identifying several different factors. The preoperative form contained a physical component (pain, sleep, physical functioning, mental health) and an appearance component (body image, mental health). The postoperative form contained the same two components as well as a surgical team component (satisfaction, preparedness for surgery). High internal consistency was demonstrated with Cronbach's alpha values for the pre- and postoperative form of 0.86 and 0.90, respectively [7].

Test-retest reliability was assessed with two repeated administrations and responses were correlated with Pearson's correlation coefficients. Correlation coefficients for the preoperative form ranged from 0.67 to 0.84 across items. Correlation coefficients for the postoperative form ranged from 0.57 to 0.86 across items [8]. The construct validity was investigated through correlations with the SF-12 [14] and the Hernia-Related Quality-of-Life Survey (HerQLes) [15]. In the prospective testing, the AHQ correlated well with the HerQLes (preoperative form: $r = 0.67$; postoperative form: $r = 0.67$). The preoperative form of the AHQ showed a strong correlation with the SF-12 in 7 of 8 domains of the SF-12 ($r \geq 0.50$), however, the correlation for one of these domains was not statistically significant. The postoperative form of the AHQ showed a strong correlation with five domains of the SF-12 ($r \geq 0.50$) and for the remaining three domains the correlation was moderate ($0.30 \leq r < 0.50$). The AHQ has recently been translated and face-validated in Danish (manuscript in preparation).

*Groin Hernia-Q (GHQ)*

The GHQ will be developed as part of Substudy 1 by revising and adapting the AHQ for patients who have received groin hernia repair. The revision and adaptation will be conducted by an expert panel including both clinicians and hernia researchers with input from patients who have undergone groin hernia repair. The adaptation process will be rooted in existing qualitative data, which suggests that patient-reported outcomes of interest following groin hernia repair are somewhat analogous to ventral hernia repair [5]. However, it is expected that cosmesis may be a comparatively less important outcome following groin hernia repair and conversely, sexual function may be considered a more important outcome of groin hernia repair [5,16,17]. To reflect this, the adaptation process will seek to revise and/or eliminate items related to cosmesis and we aim to incorporate selected items from the Sexual Inguinal Hernia Questionnaire (SexIHQ) and another unnamed questionnaire about postoperative sexual dysfunction previously described in the literature [18,19]. Ultimately, as part of Substudy 2, the GHQ will be thoroughly tested and validated after development.

*QQ-10*

The QQ-10 [12] is a validated 13-item tool designed to assess the face validity, feasibility and utility of patient questionnaires in healthcare. Developed from patient feedback, each item reflects key themes identified by patient user groups as essential to understanding patients' perspectives on the usage of questionnaires in their care. Ten items are scored on a 5-point Likert scale ranging from "Strongly agree" to "Strongly disagree". The remaining three items have free text response options [12].

*Carolinas Comfort Scale (CCS)*

The CCS [13] is a disease-specific PROM designed for patients who have undergone hernia repairs, particularly focusing on outcomes related to the use of mesh. Validated through extensive research, the CCS offers a robust and sensitive disease-specific measure, demonstrating reliability and validity across various hernia types. The CCS includes 23 items and each item contains six response options ranging from "No symptoms" to "Disabling symptoms" on an ordinal scale [13].

*Short-Form 12 (SF-12)*

The SF-12 [14] is a generic PROM designed to measure general health status. It is derived from the Short-Form 36 [20] and aims to replicate its findings in a shorter format, making it practical for large-scale studies and routine clinical use. The SF-12 assesses physical and mental health through 12 items, covering areas such as physical functioning, bodily pain, general health perceptions, vitality, social functioning, emotional role limitations and mental health. Four items are scored as "Yes/No", two items are scored on 3-point ordinal scales, three items are scored on 5-point ordinal scales and three items are scored on 6-point ordinal scales [14].

*Data Collection and Data Sources*

The questionnaires will be completed through Research Electronic Data Capture (REDCap) [21]. The postoperative patient cohort will receive invitations to participate through Digital Post, which is an online personal communication service available to all Danish residents [22]. Non-responders will receive reminders after one, two and three weeks. Additional reminders via telephone will be carried out if necessary. The preoperative patient cohort will complete the questionnaires in person at their preoperative consultation in an outpatient clinic. Besides questionnaire data, the study includes demographic and health data from the Danish National Patient Registry [23] and operative data from the Danish Hernia Database [24,25]. The data will be merged using the unique personal identification numbers, which is mandatory for all residents in Denmark [26].

*Content Validity*

The content validity of the GHQ will be assessed quantitatively using the QQ-10 items #1-10 [12]. Both relevance, comprehensibility and comprehensiveness of the GHQ will be evaluated. Results from the two subscales of the QQ-10, "value" (items #1-6) and "burden" (items #7-10), will be analyzed separately. Results will be averaged across items within each subscale, transformed into a 0-100 scale and presented as percentages [12]. On the "value" subscale, a score ≥60% will be considered adequate and on the "burden" subscale a score <40% will be considered acceptable. In addition, qualitative feedback from items #11-13 of the QQ-10 will be analyzed thematically and summarized to identify potential improvements in item wording or structure.

*Statistical Analysis*

The statistical analysis aims to evaluate the structural validity, internal consistency, test-retest reliability, measurement error and construct validity of the GHQ. First, descriptive statistics will be presented for all variables to summarize the characteristics of the study population. Continuous variables will be expressed as means with standard deviations or medians with interquartile ranges, depending on data distribution. Categorical variables will be reported as frequencies and percentages.

Confirmatory Factor Analysis (CFA) will be used to assess the structural validity of the GHQ. We will test the original three-factor model of the AHQ (physical, appearance and surgical team) and explore a potential four-factor model, including a new domain related to sexual health. The model fit will be assessed using the Comparative Fit Index (CFI), Root Mean Square Error of Approximation (RMSEA) and Standardized Root Mean Square Residual (SRMR).

Internal consistency of the GHQ will be evaluated using Cronbach's alpha for each identified subscale. A Cronbach's alpha ≥ 0.7 will be considered indicative of acceptable internal consistency. Test-retest reliability will be assessed by administering the GHQ twice to the same participants within a 2-4-week interval. Weighted Cohen's kappa coefficients will be calculated for each item to assess agreement between the two administrations. Kappa values will be interpreted as follows: <0.20 poor, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 good and 0.81-1.00 very good reliability.

Measurement error will be evaluated by calculating the percentage of agreement between the two administrations of the GHQ. Both positive and negative agreement percentages will be calculated for each item. A percentage of agreement ≥ 70% will be considered acceptable. Construct validity will be examined by testing predefined hypotheses on the relationships between GHQ scores and scores from the Carolinas Comfort Scale (CCS) and Short-Form 12 (SF-12) using Pearson's correlation coefficients. Correlations will be classified as strong ($r \geq 0.50$), moderate ($r \geq 0.30$ and $< 0.50$) or weak ($r < 0.30$). A minimum of 75% of the predefined hypotheses should be confirmed to support construct validity.

Missing data will be handled according to the COSMIN guidelines. If less than 5% of data are missing, a complete case analysis will be performed. For missing data greater than 5%, multiple imputation will be used to handle the missing data. Sensitivity analyses will be conducted to assess the robustness of the results. These will include analysis stratified by age, gender and type of surgical repair. Additionally, Exploratory Factor Analysis (EFA) will be used to explore potential alternative models of the GHQ's factor structure if the CFA fails to confirm an acceptable model fit. All tests will be two-tailed with a significance level set at $p < 0.05$. Confidence intervals will be reported at the 95% level. All statistical analyses will be conducted using R statistical software.

*Ethical Considerations*

The project is approved under the Danish Data Protection Agency (p-2023-14805). Data for the project are derived from the Danish Health Data Authority (FSEID-00006834). Under Danish law, obtaining ethical review board approval for this project is neither possible nor necessary. Informed consent will be secured from all participants. The project presents no risk to the individuals participating in the studies. The project adheres to the Declaration of Helsinki [27].

## Discussion

The development including adaptation and validation of the GHQ represent a step forward for accurate assessment of patient-reported outcomes in patients undergoing groin hernia repair. This questionnaire will form a strong evidence base for the many groin hernia-related studies in the AFTERHERNIA Project (manuscript in preparation), as well as in other projects focusing on patient-reported outcomes after groin hernia repair.

## Strengths and Limitations

A key asset of this study is its foundation in the elaborate COSMIN methodology, which will ensure a thorough and transparent validation processs [9-11]. Furthermore, the use of the already extensively validated AHQ as a starting point for this study is a major benefit. By building upon a well-established framework, the study will produce a robust and valid tool for accurate assessment of patient-reported outcomes in patients undergoing groin hernia repair. This approach not only reinforces the study's methodological rigor but also facilitates meaningful comparisons with existing research on ventral hernia repair outcomes.

The risk of non-response bias due to insufficient response rates is the main potential limitation of this planned study. To counteract this risk, we plan a thorough follow-up involving repeated reminders, both digital and by phone. Personalized invitations, in-person recruitment for the preoperative cohort and the use of the Danish Digital Post service are integral parts of this strategy to enhance participation and minimize the impact of non-response bias on the study's outcomes.

## Future Perspectives

The GHQ will be implemented along with the AHQ in the AFTERHERNIA Project. The AFTERHERNIA Project has a planned series of nationwide surveys among patients undergoing groin and ventral hernia repair in Denmark, aiming to better understand short- and long-term patient-reported outcomes after hernia repair. In the AFTERHERNIA Project, the GHQ will be distributed nationally to all patients who underwent groin hernia repair in Denmark over a ten-year period. Thus, the GHQ will significantly contribute to improved and patient-centered care in the coming years.

While the present study only seeks to develop and validate the GHQ in Danish, we aim to translate, adapt and cross-culturally validate the GHQ in an English-speaking population afterwards. This will not only expand the applicability of the GHQ but also facilitate international comparisons of patient-reported outcomes, thereby enhancing the global understanding of hernia repair outcomes. By extending its use beyond Denmark, we aspire to contribute to the broader field of hernia care and improve patient outcomes worldwide.

## Conclusion

This protocol has outlined the methodology for demonstrating the measurement properties of the GHQ, based on COSMIN terminology and guidelines. The described study will provide a comprehensive evaluation of the measurement properties of this new PROM and despite the outlined limitations, the rigorous methodology and comprehensive validation process ensure that the GHQ will be a valuable tool for assessing patient-reported outcomes in patients undergoing groin hernia repair.

## Conflict of Interests

The authors have no conflict of interest to declare related to this article.

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**Ethical Approval**

Ethical clearance for this study is not required according to Danish Law. Informed consent will be obtained from all participants.

**Informed Consent**

Written informed consent was obtained from all individual participants included in the study.

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