RESEARCH PROTOCOL

SPLASH-study: Survey to Profile Men with Low Back Pain and Lower Urinary Tract Symptoms.

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Changelog:

Version number	**Status**	**Date (YYYY_MM_DD)**	**Author**	**Changes made**
0.1	Concept	2020_06_12	TV	Initial concept
0.2	Concept	2020_10_28	TV	Further development of protocol.
0.3	Concept	2021_09_16	TV	Further development of protocol.
0.4	Concept	2021_10_11	TV	Final concept version
0.5	Concept	2022_02_23	TV	Final check concept
1.0	Final	2022_02_25	TV	Final version to be submitted to the VCWE.
2.0	Final	2022_04_14	TV	Revised Appendix 1 according to VCWE comments. Preparations for submission to METc.
2.1	Final	2022_06_28	TV	Changes made accordingly to comments of the METc, including track changes. Added §6.5.
2.2	Concept	2022_11_02	TV	Added 'general population' as a source for participants after new insights from research in primary care.
2.3	Final	2022_11_30	TV	Approved version by METC after the amendment was submitted (2.3). Some small grammatical changes were made. Version is uploaded to FigShare for pre-registration on OSF.
2.3.1	Final	2022_11_30	TV	Updated survey URL in preview mode.

Description of changelog:

0.n: *describes minor changes*

n.0: *describes concept or final state changes or amendments with substantial changes.*

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Study details

Version	2.3.1
Date	2022-11-30
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1. Introduction

Low back pain and lower urinary tract symptoms.

Low back pain and lower urinary tract symptoms often coexist and show similar comorbidities and risk factors.(1–4) Low back pain is characterized by pain from the 12th rib to the buttock with a prevalence of 7.5% in a global population.(5) The prevalence of mild or severe lower urinary tract symptoms of men 40 years and older, are nearly identical at a rate of 6%.(6) Increasing age is known to be a relevant risk factor for lower urinary tract symptoms.(7–9)

Coexistence.

Large epidemiological studies demonstrated low back pain and lower urinary tract symptoms are more likely to occur simultaneously.(10) Adjusted models for an increased BMI, smoking and age (10), yielded high odds ratios, which suggests a clinically relevant association between low back pain and lower urinary tract symptoms exists. In women, research found the pre-existing state of low back pain or incontinence to be an important predictor for a recurring episode of either condition.(1) Similarly, newly developed symptoms of low back pain or incontinence also increased the risk of developing the other condition.

Problems due to low back pain.

Low back pain is known to co-occur with suffering on a wide variety of domains. People with low back pain are known to have a reduced level of physical activity due to their physical limitations (11) and are known to have increased physical disability.(12) Also, low back pain impacts overall health, including a reduced quality of life (13–15) mental health, anxiety, stress and depression (12,16,17) and co-occur with sleep disturbances (18,19) and increased numbers of comorbidities (20–22).

Problems due to lower urinary tract symptoms.

Likewise, lower urinary tract symptoms are known to negatively affect quality of life (23–25) and mental health (26), stress, anxiety and depression (27). It is known to co-occur with comorbidities (8) such as arthritis (28) or obesity (29). Like low back pain, it is debilitating on physical function and sleep disturbances are, partially due to nocturia, frequent.

The ICF model.

The international classification of functioning, disability and health (ICF) describes how persons handle their health and functioning in daily life.(30) The ICF consists of domains on body functions, body structures, activities and participation and contextual factors including environmental factors and personal factors. Using measures on all ICF domains to characterize the overall health of men may provide insight in the bother and severity experienced by men with lower urinary tract symptoms and low back pain, compared to men with only one complaint, see figure 1.

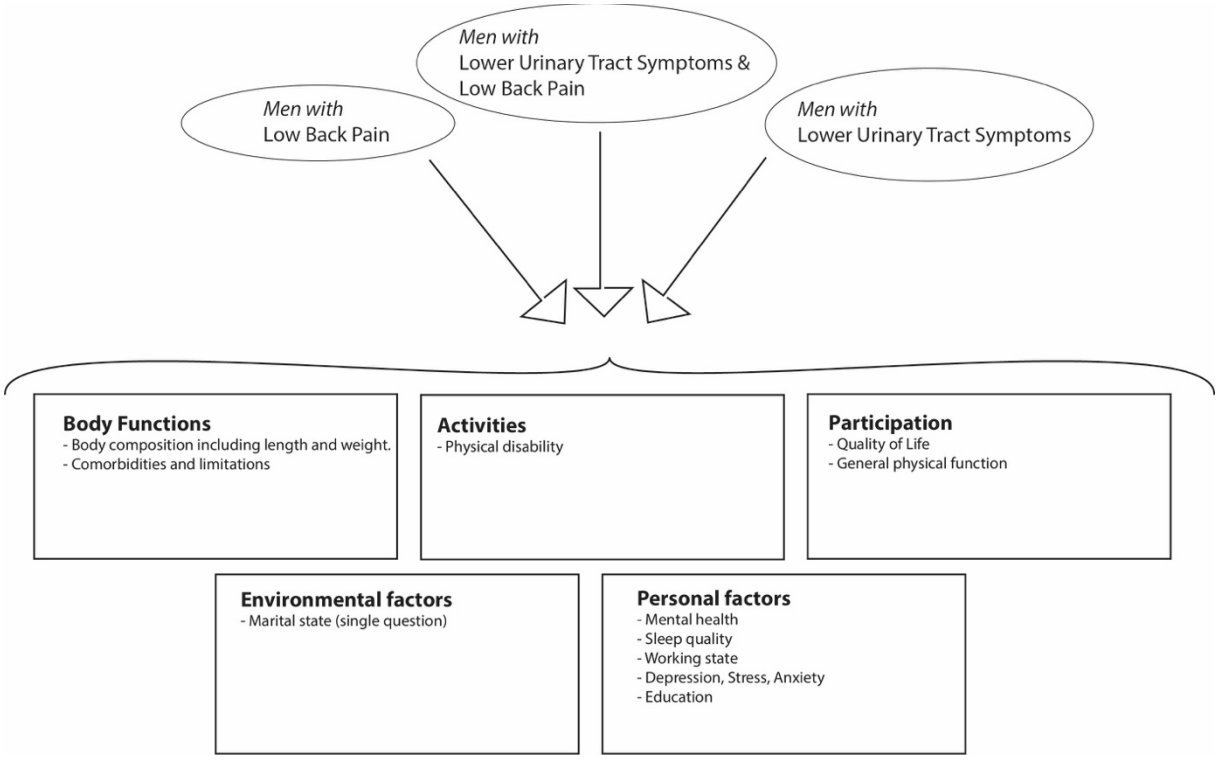

Figure 1. Lower urinary tract symptoms and low back pain in a ICF model.

Who is involved?

In the Netherlands, physiotherapists, pelvic health therapists and general practitioners provide care to men with lower urinary tract symptoms and low back pain. However, a patient may visit any professional for their primary complaint and may receive incomplete care if seemingly irrelevant symptoms remain untreated. Therefore, it is important to figure what professionals are involved in the healthcare of men with either low back pain or lower urinary tract symptoms, or in men with both complaints. Thus, we hypothesize that men with these complaints seek different health care providers, in a wide variety and not necessarily following a logical pattern. This may lead to inadequate and costly care. Also, we expect men to not necessarily visit health

care provides, yet still dealing with low back pain or lower urinary tract symptoms. Therefore, we address these men in a general population to participate in this study. Nonetheless, not much research explored the association between low back pain and lower urinary tract symptoms and its impact on daily life from an ICF point of view. To better understand the complexity of the association between low back pain and lower urinary tract symptoms and its clinical implications, research is needed that explores the multifactorial components affected by the presence of both conditions.

1.1 Aim

The goal of this study is to expand our knowledge on the prevalence of men with both lower urinary tract symptoms and low back pain. Subsequently, more knowledge is obtained on complaints from a wide range of domains, including demographics, comorbidities, physical and mental health, physical function quality of life, depression, anxiety, stress and sleep quality in men of 40 years and older seeking healthcare for either of these conditions.

1.2 Research questions

The research questions are:

1. What is the prevalence of both lower urinary tract symptoms and low back pain in a population of men of 40 years and older seeking care for either lower urinary tract symptoms or low back pain from a (pelvic health) physiotherapist or general practitioner in primary care in the Netherlands?

2. What is the difference between men, 40 years and older, with low back pain and/or lower urinary tract symptoms given their demographics, comorbidities, physical and mental health, physical function, quality of life, depression, anxiety, stress and sleep quality.

3. What model can characterize men with lower urinary tract symptoms and low back pain compared to groups of men with either low back pain or lower urinary tract symptoms based on demographics, comorbidities, physical and mental health, quality of life, depression, anxiety, stress and sleep quality, consulting a (pelvic health) physiotherapist, general practitioner in primary care in the Netherlands?

1.2 Independent variables

The independent variable is group assignment, with a distinction of three groups:

1. Men with low back pain;
2. Men with lower urinary tract symptoms;
3. Men with low back pain and lower urinary tract symptoms.

The variables, both dependent and independent are presented in a hypothetical model in figure 2.

1.3 Dependent variables

In this study, the dependent variables are:

- Demographics: age, height, weight, (previous) work, socioeconomic status, level of education, use of medication.
- Comorbidities of low back pain and lower urinary tract symptoms.
- Physical and mental health.
- Depression, Anxiety, Stress.
- Health Related Quality of Life.
- Sleep quality.

1.3 A-priori formulated hypothesis.

The following hypothesis are formulated:

1. Men with both low back pain and lower urinary tract symptoms experience an increased bother on physical and mental health, reduced quality of life, higher levels of depression, anxiety, stress, lower sleep quality and more comorbidities compared to men with only low back pain or lower urinary tract symptoms and therefore present as a distinct group from men with only low back pain or lower urinary tract symptoms.
2. Men with low back pain and lower urinary tract symptoms or both complaints do not seek care specifically from a general practitioner, physiotherapist or pelvic health physiotherapist, but rather meet with these professionals varyingly or not at all.

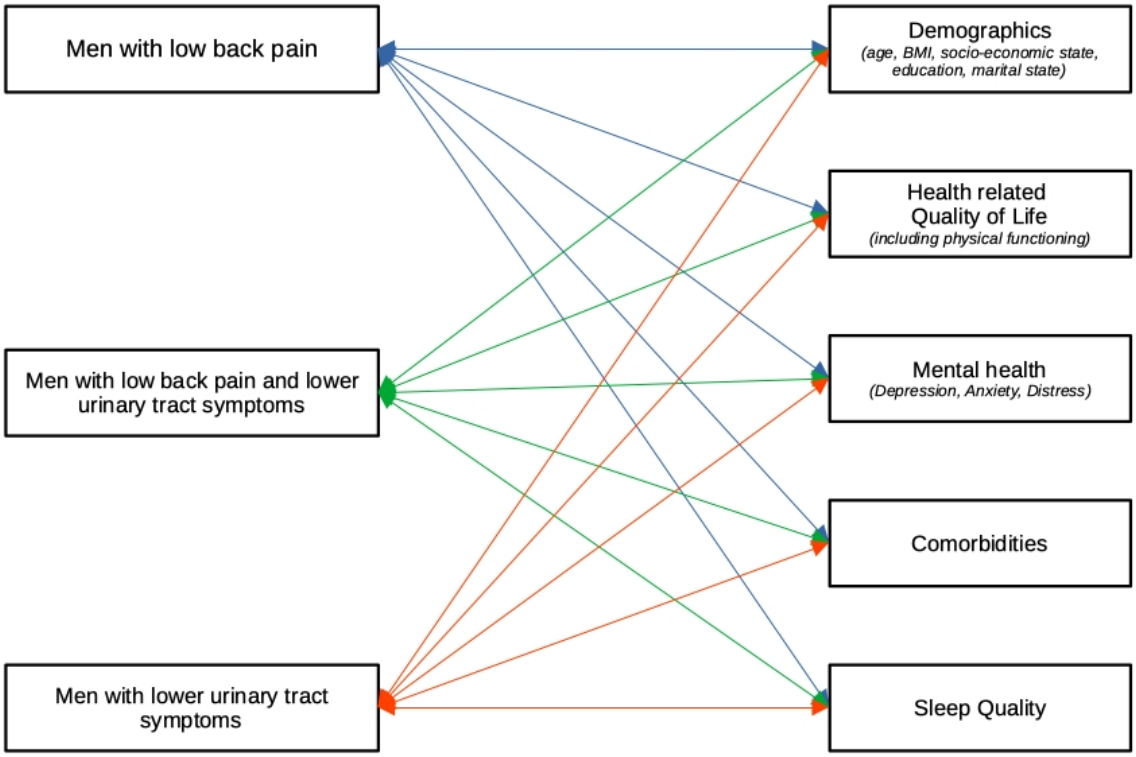

Figure 2. Hypothetical model presenting the assumptions between the independent variables (left) and dependent variables (right).

2. Research design & methods

2.1 Study design

A web-based online survey is created, using Qualtrics, based on a cross-sectional study design. All men who seek healthcare from participating healthcare professionals are invited to the survey through a flyer with an URL to the survey. This ensures that healthcare professionals are only a distributor of the survey, instead of taking part in the selection of participants.

2.2 Setting

Two different settings are used to generate survey responses: setting 1 (see §2.2.1) is based on collecting data through distribution of flyers by health care professionals to their patients. Setting 2 (§2.2.2) describes distribution of information on the survey in a general population.

2.2.1 Setting 1: recruiting participants via health care professionals.

General practitioners and (pelvic health) physiotherapists are asked by the coordinating researcher to participate in the selection of participants. Persons will include themselves through the inclusion and exclusion questions that are presented first in the survey.

The invitation of new healthcare professionals to help with the selection procedure is performed according to figure 3 below. Each colour represents three phases:

1. **Phase 1 (Green):** In the region of Amsterdam, healthcare professionals are selected to participate from the inception of the study.
2. **Phase 2 (Yellow):** Regions adjacent to Amsterdam are invited to participate and invite patients. Phase 2 starts two months after inception of the study
3. **Phase 3 (Orange):** The most remote regions from Amsterdam are invited to participate and invite patients. Phase 3 starts three months after inception of the study.

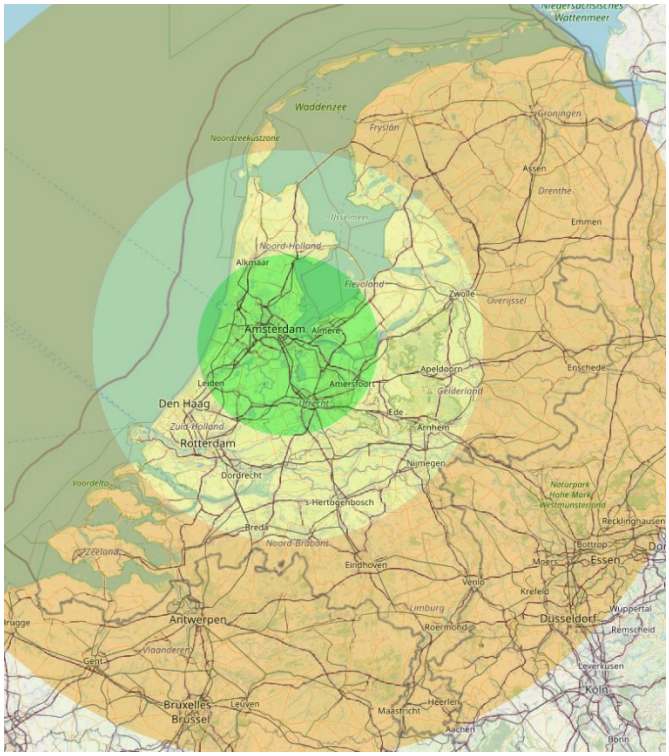

Figure 3. Phases of recruitment, including phase 1; green, phase 2: yellow, phase 3: orange.

2.2.2 Setting 2: recruiting participants from the general population in the Netherlands.

Although many men with low back pain and/or lower urinary tract symptoms may seek healthcare from a relevant health care professional, many may not. This could be due to earlier experiences with healthcare for their complaints (i.e.: 'knowing what to do'), financial problems or other limitations. Therefore, we also distribute the survey in the general population in the Netherlands, through local and national newspapers, online social media or online adverts and patient federations (for low back pain, incontinence). These strategies may be carried out in different order, depending on the effectiveness of each strategy and financial aspects.Appendix 4 describes several strategies for the recruitment in a general population.

2.3 Participants

Participants are eligible for study participation after meeting the selection criteria and inclusion criteria.

The selection criteria are only relevant to the healthcare professionals to narrow down who to provide a flyer to. These criteria are: male patients of 40 years and older who seek care for low back pain and/or lower urinary tract symptoms.

If the selection criteria are not accurately followed and not eligible patients (e.g. women or kids) still enter the URL on the flyer, then the first few inclusion questions would stop these individuals from further participation.

The inclusion and exclusion criteria are:
Inclusion criteria:

1. Male patients, 40 years and older.
2. Have low back pain, and/or lower urinary tract symptoms.
3. Able to speak, read and understand the Dutch language.

Exclusion criteria:

1. Unable to mobilize, i.e.: not being able to walk with or without walking aids.
2. Underwent surgery to the spine, lower extremities, prostate, or urine tract in the last 12 months.
3. History of malignancy related to the prostate, spine, pelvis, abdominal or hip regions.
4. Presence of neurological diseases, e.g.: multiple sclerosis or Parkinson's disease.

5. Nerve root involvement or other signs of specific low back pain, including:
    a. Pain radiating from the spine to below the knee
    b. Weakness, tingling or numbness in the (lower) leg.
    c. Bilateral leg pain.
    d. Osteoarthritis of the spine or joints in the lower extremities.
    e. Rheumatic diseases.

2.4 Sample size

Following the statistical procedures, described in more detail in §4.1 and table 1, a sample size is calculated based on the events per variable (EPVm) in a multinomial logistic regression analysis. De Jong et al. 2019 showed a EPVm of n = 3 to be able to discriminate, although any number lower than 10 may be insufficient for calibration of the model. (31)

For this study, 10 numerical variables and 3 categorical variables were selected as primary predictor variables in a multinomial logistic regression model based on the three groups as outcome (see §1.2). Within this multinomial logistic regression model, there are 2 submodels. The number of numerical variables yield an equal amount of regression coefficients, whereas this is the number of categories – 1 per variable for categorical variables. In total, n = 17 variables are analysed. The aim is to collect equal sized groups, thus with a relative frequency of $(\frac{1}{3}, \frac{1}{3}, \frac{1}{3})$ for the outcome variable. In this case, according to de Jong et al., with a EPVm of 15, the sample size is $\frac{17*2*15}{1/3}$ = 1020, or 340 per group. (31)

3. Data collection

3.1 Survey flow

From start to finish, participants follow these steps (see figure 4):

Participants recruited through flyers distributed by a health care professional:

a. Visit healthcare professional (i.e. pelvic health physiotherapist, physiotherapist or general practitioner) seeking help for complaints related to low back pain and lower urinary tract symptoms.
b. Healthcare professionals provide every ≥40 year old male patient with low back pain and/or lower urinary tract symptoms a flyer to participate in the survey. (continue at c)

Participants recruited from a general population after :

c. Potential participants enter the URL provided on the flyer/adverts and click the button on the website if willing to start the survey.
d. Participants read the informed consent and patient information file provided at the start of the survey. The informed consent is 'signed' digitally, see §6.
e. Participants fill in the survey questions. The first few questions are aimed at including or excluding participants from further participation. Excluded participants do not fill in the remaining questions of the survey and are presented with the survey ending.
f. End of survey; participants are provided with contact details to mail the researchers to opt-in for future research projects and a debriefing.

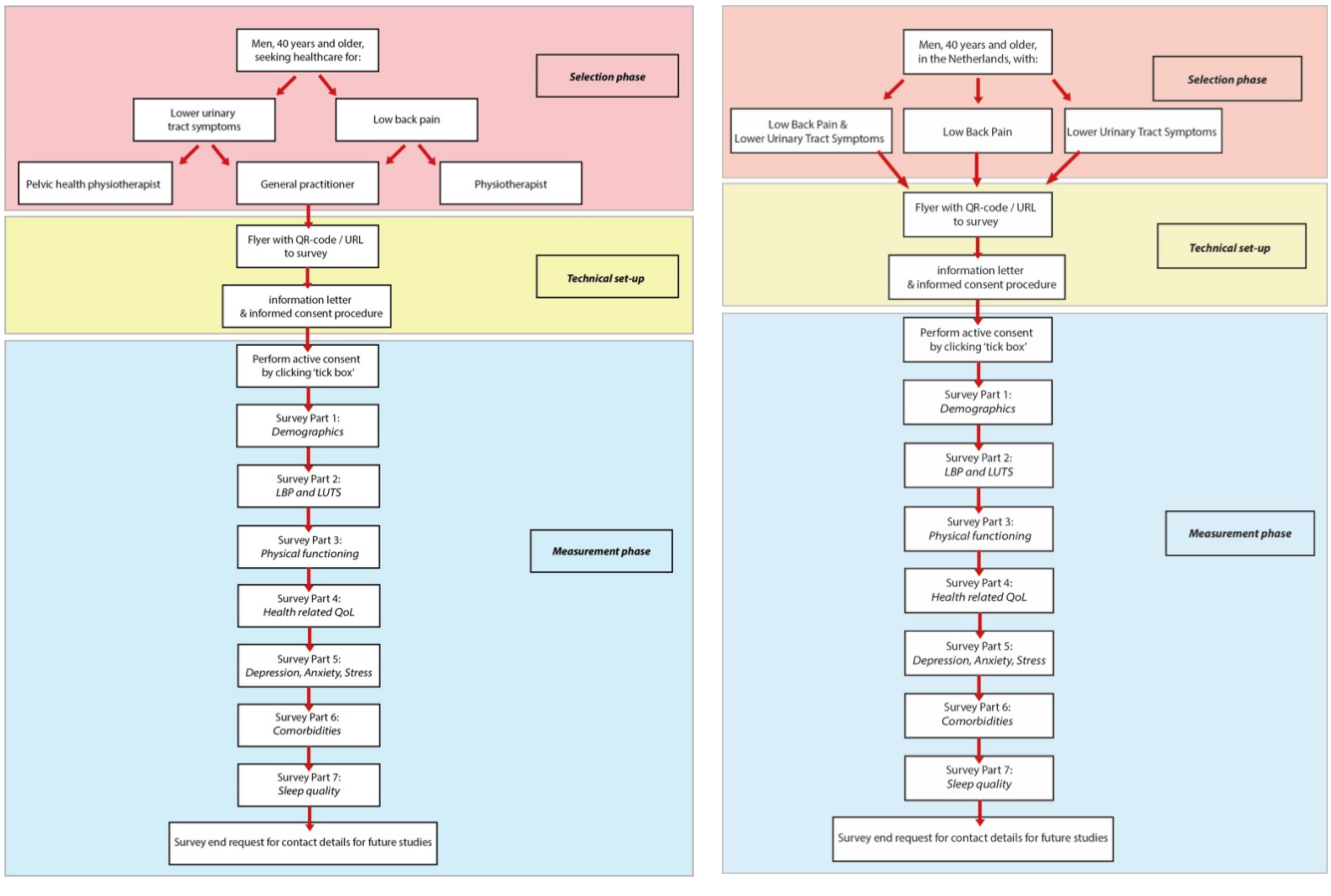

Figure 4. Flowchart of the technical management, selection, inclusion and measurement of participants. **A.** shows the inclusion and flow of participants directed towards the survey by flyer distribution from healthcare professionals. **B.** shows the inclusion and flow of participants drawn from a general population in the Netherlands. (*LBP: low back pain, LUTS: lower urinary tract symptoms, QoL: Quality of Life.)*

3.2 Survey items

All participants are provided the same set of questions, although specific questions regarding low back pain or lower urinary tract symptoms are omitted in case either condition is not present.

3.2.1 Demographics

To provide insight in the population, the following demographics are measured: age, body length, body weight, level of education, employment status, use of medication and marital state.

Number of items: 11 (some conditional on previous questions)
Scoring: different types of items, including free text and multiple choice with ranging options

3.2.2 Health related quality of life, mental health and physical health

Health related quality of life is measured using the PROMIS-GH-10, which contains a physical and mental health score. The physical score is based on items 3, 7, 9 and 10. A total t-score is calculated based on the items. The PROMIS-GH-10 was validated and tested in populations with low back pain.(13,15)

The PROMIS-GH-10 consists of 10 items, of which nine with a 5-point scale, ranging from good or never (1 point) to bad or always (5 points) and one 11-point numeric pain rating scale. (15)

3.2.3 Physical functioning.

Physical functioning is measured by several instruments and the impact of low back pain on physical ability was added to the core outcome set. (32) However, the Roland Morris Disability questionnaire (RMDQ) would not be useful in men suffering from lower urinary tract symptoms only. Therefore, in line with recent research, we prefer to use the PROMIS Physical Functioning 10 Short Form (PROMIS-PF-10), which is comparable to the RMDQ.(33) Compared to the 6 item or 4 item versions, the 10 item version provides a more detailed insight.(34)

The PROMIS-PF-10 consists of 10 items with a 5-point scale, ranging from good or never (1 point) to bad or always (5 points).(34)

3.2.4 Depression, Stress, Anxiety

To measure the level of depression, stress and anxiety, the DASS-21-R questionnaire is used. It consists of 21 items with a 4-point scale, ranging from 0 to 3. Higher scores indicate higher probability of depression, stress or anxiety. A possible multiplication by factor 2 is possible, to make scores comparable to the DASS-42. A Dutch translation was validated and the DASS-21 shows a good construct validity with other measures or depression, anxiety and stress.(35,36)

Stress is measured by items: 1, 6, 8, 11, 12, 14, 18.
Depression is measured by items: 3, 5, 10, 13, 16, 17, 21.
Anxiety is measured by items: 2, 4, 7, 9, 15, 19, 20.

3.2.5 Sleep quality

The level of sleep quality is measured by the Pittsburgh Sleep Quality Index (PSQI). Developed in 1988 to measure sleep quality in clinical populations, it is able to detect generic sleeping problems between 'bad and good' sleepers with good sensitivity and specificity.(37) The questions that may be filled in by a care-giver do not influence the scoring of the PSQI and are therefore omitted from this survey.

The PSQI consists of 19 items, with a variety of question types, including open ended questions, multiple choice or categorical options.(38)

3.2.6 Healthcare providers.

In case low back pain or lower urinary tract symptoms are present (see §3.3), participants are asked to fill in questions on seeking care for their complaints and what healthcare provider was involved. Also, each QR code contains an identifier to find out whether the participant received the flyer from a general practitioner, physiotherapist or pelvic health physiotherapist. For anonymity, a tracing ID for each individual therapist or general practitioner is not added.

3.2.7 Comorbidities.

Comorbidities are measured using questions based on the Self-Administered Comorbidity Questionnaire (SCQ) with the removal of questions on osteoarthritis, rheumatoid arthritis, malignant diseases, and the addition of widespread musculoskeletal pain. Each question asks for the presence of a comorbidity, which is, if present, followed up by a numeric rating scale (range 0: no disability to 10, highly

disabled) that measures disability caused by the comorbidity. A second question is added to see if patients take medication or receive treatment for their comorbidities.

Measured comorbidities are: anemia (and other blood disorders), colitis ulcerosa (and other disorders related to the intestines), depression, diabetes mellitus, heart diseases, high bloodpressure, liver disease, kidney disease, widespread musculoskeletal pain, lung disorders and a free text field that enables participants to mention other not categorized conditions or disorders.

3.3 Groups based on characteristics and symptoms.

Based on the scores on specific items of the survey, three groups are formed. As the nature of this study is exploratory, this forms an a-priori definition of groups, which may change if this creates a better discrimination of the model. For the a-priori definition, the group defining variables are:

3.3.1 ICIQ-MLUTS for lower urinary tract symptoms

The ICIQ-MLUTS (International Consultation on Incontinence Questionnaire – Male Lower Urinary Tract Symptoms module) is a questionnaire used to investigate symptoms and bother. The symptoms are measured by 13 items with a rating scale from 0 to 4, indicating no or seldom complaints to high frequent symptoms respectively. Each item is accompanied by a 0 to 10 bother score item. Bandwidths of scores are recognized for 0 to 16, 17 to 26 and 27 or higher for severity, relating to mild, moderate and severe complaints respectively. For bother, band scores were 0-22, 23-81 and 82 or higher with identical labels.(39)

3.3.2 Low Back Pain Measures

Low back pain is measured by two different scores, as described in the Core Outcome Set by Chiarotto et. al.(32) These include a score on pain, measured by the Numeric Pain Rating Scale (NPRS), which in our case is set to pain in the past 7 days and related questions to pain in the past or number of recurring episodes.

1. Men with low back pain.
    - Having low back pain in the last 0 to 6 weeks or longer lasting with pain at the time of filling in the questionnaire, characterized by a numeric pain rating scale of ≥1.

- No lower urinary tract symptoms, scoring 16 or lower on the severity scale of the ICIQ-MLUTS

2. Men with lower urinary tract symptoms.
    - No low back pain in the last 0 to 6 weeks, characterized by a numeric pain rating scale of 0.
    - Lower urinary tract symptoms, scoring 17 or higher on the severity subscale of the ICIQ-MLUTS.

3. Men with low back pain and lower urinary tract symptoms.
    - Low back pain in the last 0 to 6 weeks or longer lasting with pain at the moment of responding to the survey, characterized by a numeric pain rating scale of 0.
    - Lower urinary tract symptoms, scoring 17 or higher on the severity subscale of the ICIQ-MLUTS.

4. Analysis

4.1 Analysis of outcomes

Prevalence

The prevalence of men with low back pain and lower urinary tract symptoms seeking healthcare for only one complaint is calculated based on the scores on the ICIQ-MLUTS or low back pain questions.

Group membership based on variables.

Second-order multivariate regression analysis is performed using MANOVA design. Of course, assumptions should be met: 1) independent observations, 2) the dependent variables are multivariate normal and 3) the population covariance matrices are equal across all levels. If these assumptions are violated, a non-parametric alternative using ranked data, as described in detail by Finch, 2005. (40)

Differences between groups

Differences between groups for each of the independent variables are analysed in a univariate manner using ANOVA testing with post-hoc Bonferonni corrections. Pretesting assumptions should be met, i.e. normal distribution for the independent variables, which is tested by Kolmogorov-Smirnov tests and eye-balling normality plots.

If a skewed distribution is observed in the independent variable for either of the three groups, the non-parametric Kruskal-Wallis test is used.

Exploratory analysis using Principal Component Analysis and Multinomial Logistic Regression.

Multinomial logistic regression analysis can be used to predict the classification into the three groups, described in §1.2. All predictor variables, primary and secondary, (see §2.4) are described in Table 1. Multinomial logistic regression analysis equals binary logistic regression with addition of submodels accounting for the number of the outcome variable. In this study, three groups are a-priori formulated and therefore results in 2 submodels.

Table 1. Overview of independent variables (predictors) and implications for statistical analysis.

Question(naire)	**Type of variable**	**Primary or secondary?**
Demographics		
- Age	Numerical	Primary
- Body length	Numerical	Secondary
- Body height	Numerical	Secondary
- BMI	Numerical	Primary
- Level of education	Categorical, k=7	Primary
- Work, retired	Categorical, k=4	Secondary
Health care professional for LBP	Categorical, k=2	Primary
Health care professional for LBP, specification of discipline	Categorical, k=7	Secondary
Health care professional for LUTS	Categorical, k=2	Primary
Health care professional for LUTS, specification of discipline	Categorical, k=7	Secondary
PROMIS-PF-10	Numerical	Primary
PROMIS-GH-10	Numerical	Secondary
- PROMIS-GH-10 Physical subscore	Numerical	Primary
- PROMIS-GH-10 Mental subscore	Numerical	Primary
DASS-21-R	Numerical	Secondary
- Stress subscore	Numerical	Primary
- Depression subscore	Numerical	Primary
- Anxiety subscore	Numerical	Primary
Comorbidities	Numerical	Primary
Type and severity of comorbidities present	Numerical	Secondary
PSQI (total score)	Numerical	Primary
- Subscores/components, n=7	Numerical	Secondary

However, multicollinearity may exist and cause overfitting of the model on the dataset, which limits generalizability of the model. Therefore, reduction of the data may be necessary. In short, the following steps will be undertaken:

1. Assess the data by inspection of graphs and descriptive analysis of individual variables
2. Assess assumptions needed for principal component analysis or singular value decomposition.
3. Perform principal component analysis to check for multicollinearity and reduction of data.
4. Reconstruct the components to original variables
5. Use the original variables to perform multinomial logistic regression analysis.
    a. Test the model based maximum likelihood
    b. Bootstrap the model based on the data to evaluate variability of the model.
    c. If necessary and overfitting is still expected, use of Lasso or Ridge Regression techniques to make the model perform better.

A more detailed analysis plan is published on the UvA/HvA Figshare before analysis commences, after consulting with a statistician.

Cluster analysis

In case no fitting model is found, cluster analysis may be used to identify groups based on the previously mentioned predictor variables. This may lead to clusters different from our a-priori formulated groups of three (see §1.2)

If cluster analysis is performed, a statistician with expertise on cluster analysis will be consulted.

4.2 Software

The following software is used: IBM SPSS Statistics for windows, version 27 (IBM Corp., Armonk, N.Y., USA.) and R (R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/) are used to perform descriptive and initial inferential statistics. R-package “nnet” is used for Multinomial Logistic Regression, R-package “hkmeans” is used for k-means cluster analysis.

5. Data management

The data collected through this study is defined not directly identifiable, however, do contain medical items. Therefore, the following paragraphs describes the data management. Paragraph 5.1 to 5.7 provide an outline of the data management. An in-depth description of the files collected, stored, archived and managed during the study is provided in appendix 3. This data management plan is uploaded to the UvA/HvA FigShare, where the latest version can be found.

5.1 Data entry, anonymized and identifiable data

All data is collected through the survey system Qualtrics. Qualtrics is a widely used application to create, distribute and collect surveys. The Hogeschool van Amsterdam and Qualtrics signed a Data Processing Agreement.

All data is stored on servers from Qualtrics in the EU and follows GDPR legislation. Information and Security protocols were followed and a Data Protection Impact Assessment was deemed not necessary by the Chief Privacy Officer of the Hogeschool van Amsterdam.

Anonymity.

The survey is started after participants provide their informed consent, see §6.2. Through the informed consent procedure or the survey, no names or contact details are collected and linked to the data. All responses are linked to a consecutive number and not to names, addresses or contact details. This also ensures that in case of a data breach, responses cannot be traced back to an individual, as no names, addresses or any other contact details are collected. Given the size and composition of the sample, the Chief Privacy Officer deemed it nearly impossible to match or identify individuals based on responses.

As the data does contains medical information from the questionnaires within the survey, access to Qualtrics is only provided to researchers with access, as described in §5.2.

Future research

Participants may show interest in the study or want to help with future research. To maintain anonymity by design, the questionnaire never asks for mail-addresses. Interested participants should mail the researchers for any inquiry about this study.

5.2 Access and rights

The persons having access to the research data are provided in table 2. This table is also added in the data management plan, in Appendix 6, where it is updated twice per year. By design, no-one without appointed rights can access the responses of participants.

Table 2. Access and Rights to research data.

Name	University	Mail-address	Access	Task	Rights
Tom Vredeveld	HvA	t.vredeveld@hva.nl	Qualtrics, ResearchDrive, UvA/HvA FigShare	Researcher	View, edit.
Michel Coppieters	VU	m.coppieters@vu.nl	Qualtrics, ResearchDrive UvA/HvA FigShare	Principal investigator	View, edit.
Annelies Pool-Goudzwaard	VU	a.l.pool-goudzwaard@vu.nl	Qualtrics, ResearchDrive UvA/HvA FigShare	Principal investigator	View, edit
Stephan Ramaekers	HvA	s.p.j.ramaekers@hva.nl	Qualtrics, ResearchDrive UvA/HvA FigShare	Researcher	View, edit.
Anne de Jong	HvA	a.s.de.jong@hva.nl	Qualtrics, ResearchDrive, UvA/HvA FigShare	Data steward	View, edit, create and lock database (Qualtrics)
Students HvA	HvA	Yet unknown (see § 5.3)	Excel export	Research assistants	View selected data frames with anonymized data.
Students VU	VU	Yet unknown (see § 5.3)	Excel export	Research assistants	View selected data frames with anonymized data.

HvA: Hogeschool van Amsterdam, VU: Vrije Universiteit,

5.2.1 Students working with research data

Students of the Vrije Universiteit and Hogeschool van Amsterdam (Amsterdam University of Applied Sciences), may participate in the study, for example by performing analysis on secondary outcomes. Students always work with data and follow the Standard Operating Procedure for Students Working with Research, see appendix 7. As part of this Standard Operating Procedure, students sign a Non-Disclosure Agreement (appendix 8). For research integrity, see §6.5

5.3 Data file types

The following data file types are used throughout the study and are described in table 3.

Table 3. Files and exports.

Files	**File types**	**Contains identifiable data**	**Stored where?**
Qualtrics exports	.csv or .tsv	No	Stored on ResearchDrive folder
R-project datasets and analysis	.Rproj and .r	No	Stored on ResearchDrive folder
Excel datasets	.xslx or .csv	No	Stored on ResearchDrive folder
SPSS datasets	.sav, .sps or .spv	No	Stored on ResearchDrive folder
Data codebooks	.docx or .pdf	No	Stored on ResearchDrive folder and UvA/HvA FigShare.
Metadata	.xml, .txt, .docx or .pdf	No	Stored on ResearchDrive folder and UvA/HvA FigShare.

5.4 Storage of research data

Qualtrics

Like beforementioned, data stored on Qualtrics from survey responses contains high-risk data, including names and contact details. The data on Qualtrics is all stored in one place and therefore response data is removed from Qualtrics every 10 responses. This data is then stored in two identical databases in separate folders on the ResearchDrive. By performing this periodic removal of all responses on Qualtrics, no data is stored on Qualtrics by the end of the study.

ResearchDrive

All data that is exported from the Qualtrics database, to be used with analysing software, is saved on the ResearchDrive, not on personal computers or harddrives. ResearchDrive is a Dutch initiative of cloud-storage for research groups. The folder where data is stored is shared only with researchers mentioned in §5.2 All data on the ResearchDrive are stored on servers within the EU.

5.5 Archiving of research data

UvA/HvA FigShare

The research data is archived after final publication of the manuscript. The data is archived on a UvA/HvA FigShare, which acts, besides a study registration platform (see §2.5), also as an archiving data repository.

On this repository, all data is stored in AES-256 encrypted folders, to which the researchers in §5.2 have access.

The server is managed by the data steward of the Hogeschool van Amsterdam, Faculteit Gezondheid (Anne de Jong). The data is stored for a period of 10 years.

Also, the pseudonymized data will be stored at designated storage for archiving at the Vrije Universiteit.

6. Ethics & Research integrity

6.1 Participant information file in the survey

All participants are informed through the participant information file, which is added at the start of the survey in short. It is available in the Dutch language and added in a separate file in the appendix 1.

At the beginning of the survey, participants are also provided with an URL to the full participant information form and consent form, following the template documents of the METC VUmc. This information provided to participants contains information on the goal of the study, topics covered and length of the survey, use of data collected through the survey and privacy statements and is added in appendix 1.

6.1.1 Flyer

The flyer is provided by healthcare professionals to potential participants. It contains short information on the goal of the study and a QR-image and separate URL. Both options lead to the same survey, however three separate flyers are created, adding a parameter to trace which discipline provided the flyer. Therefore, three nearly identical flyers are created, with different URL's or QR codes, and specification is added at the bottom.

Also, contact-details of the researchers are provided in case potential participants exist may have any remaining questions. The flyer is added in appendix 2.

6.1.2 Research project website

The informed consent form and participant information files are uploaded to the projects UvA/HvA FigShare page. A specific project website is created on a subdomain of the Hogeschool van Amsterdam website, where the informed consent and participant information file can be found. The information that is presented on the website, can be found in appendix 3.

6.2 Informed consent

Informed consent is provided by each participant before starting the survey. Digitally, information is provided (see §6.1), to which participants need to consent by clicking a specific button, which forms the first question of the survey. In case a participant decides not to provide consent, the survey directs to the end-message.

The informed consent describes the rights for participants as described in the declaration of Helsinki (41) and GDPR legislation for the storage of personal data.

6.3 Study registration

After approval by the METC of the VUmc this study protocol will be uploaded and registered on the Open Science Framework (https://osf.io). The registration number (or DOI identifier) will be added to the UvA/HvA FigShare project page and the information letter for participants.

6.4 Open Science & FAIR data management.

This study is designed to have its documentation to be publicly available through UvA/HvA FigShare project page of the FigShare data repository of Amsterdam University of Applied Sciences (UvA/HvA FigShare).

The data of the study contains high-risk data and thus will not be published for any other than described in §5.2

This study follows the FAIR principles of data management (42) which are described in more detail in §5.

6.5 Intellectual Property Agreement Hogeschool van Amsterdam – Vrije Universiteit

Researchers from both the Hogeschool van Amsterdam (HvA) and Vrije Universiteit (VU)are involved. The HvA acts as the sponsor of the study, yet the data will also be archived on designated systems of the VU (see §5). Therefore an intellectual property agreement between the researchers of the HvA and VU will be signed.

6.6 Student participation integrity

As described in §5.2.1, students that participate in the study, for example, by performing secondary analyses on a sub-set of the data, should sign a non-disclosure agreement on research integrity and the protection of intellectual property based on this study.

7. Study time frame

Date (YYYY-MM-DD)	What	Who
2022-03-25	Online modules in Qualtrics completed, ResearchDrive organized, Flyer printed on paper	TV
2022-03-25	Estimated: approval or changes needed to protocol	TV
2022-04-10	*Changes to the protocol if major or minor revisions apply from the VCWE. (optional)*	*TV*
2022-05-01	Submit protocol to METc – VUmc for exempt of WMO.	TV, AP.
2022-06-01	*Revise protocol, if needed for METc approval.*	*TV, SR, MC, AP.*
2022-12-01	Start with handing out of flyers at the participating healthcare professionals from phase 1.	TV, healthcare providers
2023-01-01	Start with handing out of flyers at the participating healthcare professionals from phase 2 and subsequently phase 3.	TV, healthcare providers
2024-08-01	Completion of data collection.	TV
2024-10-01	Submission of manuscript to selected journal.	TV, SR, MC, AP.

Deadlines in italic are optional and depend on (final) decisions of review boards or elsewise.

TV: Tom Vredeveld, SR: Stephan Ramaekers, MC: Michel Coppieters, AP: Annelies Pool-Goudzwaard, HvA: Hogeschool van Amsterdam, VU: Vrije Universiteit

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Appendix 1: Participant information: presented at survey.

Onderzoek naar klachten bij lage rugpijn en/of plasklachten bij mannen.

Inleiding

Geachte heer,

Wij vragen u vriendelijk om mee te doen aan een wetenschappelijk onderzoek
Meedoen is vrijwillig. Om mee te doen is wel uw toestemming nodig.

Dit onderzoek wordt uitgevoerd door de Hogeschool van Amsterdam. De toetsingscommissie van de METc van VUmc heeft beoordeeld dat dit onderzoek niet onder de Wet medisch-wetenschappelijk onderzoek met mensen (WMO) valt.

Voordat u beslist of u wilt meedoen aan dit onderzoek, krijgt u uitleg over wat het onderzoek inhoudt. Lees deze informatie rustig door en vraag de onderzoeker uitleg als u vragen heeft. U kunt er ook over praten met uw partner, vrienden of familie.

1. Doel van het onderzoek

In Nederland hebben veel mannen rugpijn. Ook zijn er mannen die moeite of pijn hebben met plassen. Rugpijn en plasklachten komen vaak samen voor. Het is onbekend of klachten erger zijn als een man rugpijn én plasklachten heeft. Daarom willen we graag weten wat de klachten zijn van mannen met rugpijn, mannen met plasklachten of mannen die beide klachten hebben. Op deze manier kunnen we een vergelijking maken.
Als u meedoet komen wij meer te weten over de kenmerken van mannen die zowel rugpijn als plasklachten hebben. Hierdoor kunnen wij hen beter herkennen en onderzoeken. Dit helpt om eerder door te kunnen verwijzen naar de juiste zorgverlener. Maar kan ook leiden tot een betere behandeling van rugpijn en plasklachten.

De conclusies worden samengevat in een (wetenschappelijke) publicatie.

2. Wat meedoen inhoudt

Tijdens het onderzoek vult u één keer een vragenlijst. U kunt deze vragenlijst online invullen. Dat kan op de computer, telefoon of op een tablet zoals een iPad. Het invullen van de vragenlijst duurt ongeveer 25 minuten. Alleen de gegevens die u invult gebruiken wij voor het onderzoek. U kunt anoniem meedoen.

De vragen gaan onder andere over rugpijn, plasklachten, lichamelijke of psychische klachten, werkzaamheden en slaapkwaliteit. Het kan zijn dat u een vraag krijgt die niet voor u van toepassing is. Dan staat bij de vraag vermeld wat te doen.

3. Mogelijke voor- en nadelen

U heeft zelf geen (direct) voordeel van meedoen aan dit onderzoek. Uw deelname kan wel bijdragen aan meer kennis over de behandeling van rugpijn of plasklachten.

- Nadelen kunnen zijn: extra tijd die het u kost (ongeveer 25 minuten)

4. Als u niet wilt meedoen of wilt stoppen met het onderzoek

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig en anoniem.
Doet u mee aan het onderzoek? Dan kunt u zich altijd bedenken. U mag tijdens het invullen van de vragenlijst stoppen. U hoeft niet te zeggen waarom u stopt. De gegevens die tot dat moment zijn verzameld, worden gebruikt voor het onderzoek.

5. Gebruik en bewaren van uw gegevens.

Voor dit onderzoek is het nodig dat een aantal medische gegevens worden verzameld en gebruikt. Dit gebeurt anoniem. Uw naam hoeft u niet te vermelden. We willen bijvoorbeeld weten hoe lang u bent en welke lichamelijke klachten u heeft. De verzameling vindt alleen plaats via de vragenlijst.

Uw gegevens

Al uw gegevens blijven vertrouwelijk. Voor het onderzoek worden uw onderzoeksgegevens gedeeld met onderzoekers van de Vrije Universiteit Amsterdam. De onderzoeksgegevens zijn bij publicatie in een (wetenschappelijk) tijdschrift en bij de Vrije Universiteit Amsterdam niet te herleiden naar u.
Als u dit wilt, wordt u na het einde van het onderzoek op de hoogte gesteld van de belangrijkste uitkomsten van het onderzoek. Hiervoor kunt u uw mailadres opgeven. Dit mailadres wordt niet gekoppeld aan uw antwoorden op de vragenlijst.

Aan het begin van de vragenlijst kunt u toestemming geven door op een knop te klikken. Dan geeft u toestemming voor het verzamelen, bewaren en inzien van uw antwoorden op de vragenlijst.
De onderzoeker bewaart uw gegevens 10 jaar. Daarna worden de gegevens vernietigd.
Uw gegevens kunnen worden ingezien door direct betrokken onderzoekers van de Hogeschool van Amsterdam en Vrije Universiteit Amsterdam. Andere personen hebben geen toegang tot uw gegevens.

Later gebruik gegevens.

Wij willen uw antwoorden op de vragenlijst graag bewaren. Misschien kunnen we daar later extra onderzoek mee doen. Het gaat dan om gedetailleerder onderzoek naar klachten bij rugpijn of plassen. Uw gegevens worden 10 jaar bewaard in het archief van de Hogeschool van Amsterdam en de Vrij Universiteit Amsterdam. Als u zelf benaderd wilt worden door onderzoekers voor toekomstig onderzoek, kunt u ook hiervoor een mail sturen na afloop van de vragenlijst.

Dit onderzoek staat ook in een Open Science Framework register. Deze website bevat geen informatie die herleidbaar is tot u als persoon. Wel kan de website een samenvatting van de resultaten tonen. U vindt dit onderzoek via de projectpagina: *www.hva.nl/splash*

Meer informatie over uw rechten bij verwerking van gegevens

Voor meer informatie over uw rechten bij de verwerking van uw persoonsgegevens kunt u contact opnemen met de onderzoekers van dit onderzoek van de Hogeschool van Amsterdam via dr. Stephan Ramaekers, s.p.j.ramaekers@hva.nl en Tom Vredeveld, t.vredeveld@hva.nl. De Hogeschool van Amsterdam is verantwoordelijk voor het volgen van de regels voor de verwerking van uw persoonsgegevens.
Indien u ontevreden bent over hoe wordt omgegaan met uw privacy dan kunt u een klacht indienen bij de Functionaris Gegevensbescherming via functionarisgegevensbescherming@hva.nl. Ook kunt u zelf terecht bij de Autoriteit Persoonsgegevens via https://autoriteitpersoonsgegevens.nl/.

6. Geen vergoeding voor meedoen

Voor het meedoen aan dit onderzoek krijgt u geen onkostenvergoeding.

7. Heeft u vragen?

Bij vragen kunt u contact opnemen met de uitvoerend onderzoeker Tom Vredeveld (t.vredeveld@hva.nl).
Overige informatie over dit onderzoek kunt u vinden op de projectwebsite, via: *www.hva.nl/splash*

Contactgegevens

Hoofdonderzoekers:

Prof. Dr. A.L Pool-Goudzwaard (a.l.goudzwaard@vu.nl)
Prof. Dr. M.W. Coppieters (m.coppieters@vu.nl)
Dr. S.P.J. Ramaekers (s.p.j.ramaekers@hva.nl)

Uitvoerend onderzoekers:

T. Vredeveld (t.vredeveld@hva.nl), 06 211 55 901
Heeft u vragen over uw onderzoeksdata, dan kunt u terecht bij:

Data Stewards (Hogeschool van Amsterdam)

opensciencesupport@hva.nl

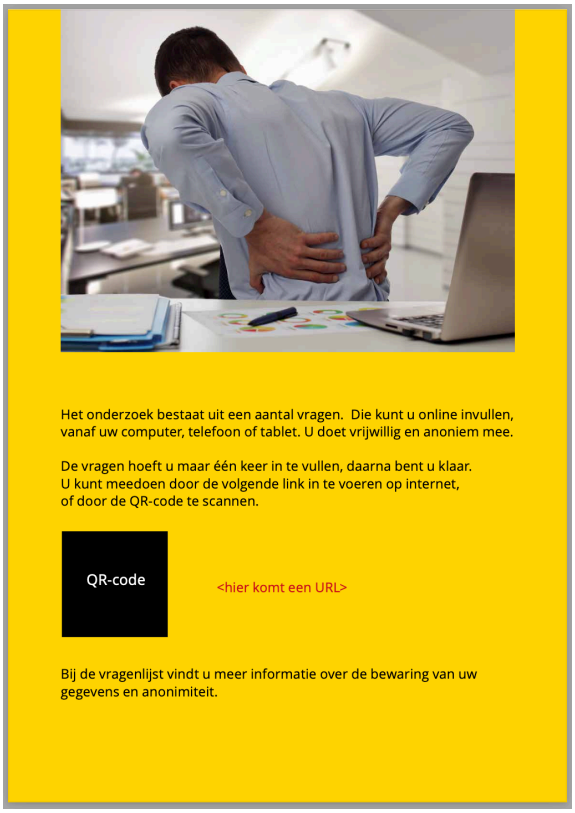
Dank voor uw aandacht.

Bijlage: Toestemmingsformulier proefpersoon

Onderzoek naar klachten bij lage rugpijn en/of plasklachten bij mannen.

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn antwoorden op de vragenlijst op de manier en voor de doelen die in de informatiebrief staan. De vragenlijst vul ik anoniem in.
- Ik geef toestemming om mijn gegevens nog 10 jaar na dit onderzoek te bewaren binnen de Hogeschool van Amsterdam en Vrije Universiteit van Amsterdam.
- Ik mag de onderzoekers na afloop van het onderzoek (01-08-2024) per email (t.vredeveld@hva.nl) benaderen voor de uitkomst van het onderzoek.
- Ik wil meedoen aan dit onderzoek.
- Door akkoord te gaan met de eerste vraag van de vragenlijst, geef ik toestemming voor het gebruik van mijn gegevens die ik invul bij de vragenlijst.

Appendix 2: Participant information: flyer



The QR code and URL's provided in the flyer will be included once the survey is completed and METC approval is obtained. On the inside, the line states: 'Versie 2.0 – alle deelnemers – d.d. 1 november 2022 – FT', of which 'FT' stands for physiotherapy, 'BFT' dictates a version for pelvic health physiotherapists and 'HA' dictates a version for general practitioners. The text does not change for these versions.

Appendix 3: Participant information: website information

The following text will be added on the website of the Hogeschool van Amsterdam, hosted on a subdomain. It will contain a URL to provide interested participants to download the informed consent form and participant information. The information can already be accessed here: https://www.hva.nl/urban-vitality/gedeelde-content/projecten/professioneel-redeneren/rugpijn--plasklachten-bij-mannen.html
The text is only provided in Dutch. The current version is 25th of February 2022, which is displayed at the bottom of the page.

RUGPIJN EN PLASKLACHTEN BIJ MANNEN?
Klachten in het dagelijks leven.

Project
Rugpijn én plasklachten: het lijkt een vreemde combinatie. Toch komt het vaak voor, ook bij mannen. Rugpijn kan leiden tot beperkingen in het dagelijks leven, moeite met werk of sport. Plasklachten kunnen net zo hinderlijk zijn. Denk aan pijn bij het plassen, moeite met het ophouden van urine of in de nacht meerdere keren uit bed moeten. Helaas weten we niet of mannen met beide problemen hier dagelijks meer hinder van ondervinden dan mannen die alleen plasklachten of rugpijn hebben. Daarom doen de Hogeschool van Amsterdam en de Vrije Universiteit er onderzoek naar om de zorg voor deze mannen te verbeteren.

VRAGENLIJST

We vragen mannen met rugpijn en/of plasklachten, ouder dan 40 jaar om een vragenlijst in te vullen. De antwoorden geven inzichten in hoe mannen met rugpijn verschillen van mannen met plasklachten en mannen die beide klachten ervaren.

De vragenlijst gaat over de mate van rugpijn en plasklachten, demografische gegevens en mentaal en fysiek welbevinden. Fysiek functioneren, aanwezigheid van andere aandoeningen of ziektes en slaapkwaliteit. En over de aanwezigheid van depressie, stress of angst.

MEEDOEN

Met dit onderzoek kun je alleen meedoen nadat je een flyer van je huisarts of fysiotherapeut hebt ontvangen met een link naar het onderzoek.

INFORMATIE EN TOESTEMMINGSVERKLARING

Voorafgaand aan de vragenlijst krijg je informatie aangeboden over de vragenlijst, het doel van de studie en over de verzameling, het gebruik en de bewaring van je gegevens. Lees meer in de informatiebrief en toestemmingsverklaring (*URL naar informatiebrief en toestemmingsverklaring, zie appendix 1*).

MEER WETEN EN CONTACT

Heb je vragen over dit onderzoek? Of wil je meer weten over de toestemmingsverklaring? Neem contact op met de onderzoekers via Tom Vredeveld: t.vredeveld@hva.nl.

RESULTATEN

De resultaten van de studie worden na afloop op deze pagina gepubliceerd.

Appendix 4: General population strategy

To draw participants from a general population, several tactics are devised and are described below. Texts may differ in final lay-out, spelling and grammatic. Texts are provided in Dutch.

1. **Adverts by local or national newspaper or through newsletters from Dutch patient federations.**
   Strategy:
   In alternating order, based on effectiveness or financial aspects, adverts are placed in local Dutch newspapers or in national newspapers.
   Local Dutch newspapers are sampled by selecting per city, starting with cities with a community of more than 60.000 inhabitants to be certain of a representative sample.

   Main text:
   Rugpijn en plasklachten. Het lijkt een vreemde combinatie. Toch hebben veel mannen hier last van.

   Rugpijn kan leiden tot beperkingen in het dagelijks leven, moeite met werk of sport. Plasklachten kunnen net zo hinderlijk zijn. Denk aan pijn bij het plassen, moeite met het ophouden van urine of in de nacht meerdere keren uit bed moeten om te plassen.

   Helaas weten we niet of mannen met beide problemen hier dagelijks meer hinder van ondervinden dan mannen die alleen plasklachten of rugpijn hebben.

   Onderzoekers van de Vrije Universiteit, Hogeschool van Amsterdam en SOMT University of Physiotherapy, onderzoeken aan de hand van een vragenlijst de klachten en beperkingen die mannen met rugpijn en/of plasklachten ervaren in het dagelijks leven.

   Heeft u rugpijn of plasklachten en bent u ouder dan 40 jaar? Doe dan mee aan ons onderzoek!

   < QR CODE & LINK NAAR VRAGENLIJST >

   Met het eenmalig, anoniem, invullen van een vragenlijst helpt u mee om de

behandeling van mensen met rugpijn en plasklachten te verbeteren.

Aan het eind van de vragenlijst krijgt u een score-overzicht.

2. Digital adverts

Strategy:

Online digital adverts will be displayed on general news and community websites.

Basic banners that may be used alongside the advert texts.

Texts are identical to the newspaper adverts, see above.

3. Social media adverts

Strategy:

Social media accounts of the Amsterdam University of Applied Sciences (Centre of Expertise Urban Vitality) and Vrije Universiteit (Faculty of Behavioural and Movement Sciences) will be used to distribute the survey, accompanied by the following texts:

Texts are identical to the newspaper adverts, see above.

Appendix 5: Survey

A preview online version of the survey can be found here:
https://edu.nl/bkhg8

To reduce page size, questions are not reported here. A PDF version will be uploaded, simultaneously with this research protocol, to the project FigShare page, here: <URL>. The survey is only provided in the Dutch language.

Appendix 6: Data management plan

SPLASH: Survey to Profile Men with Low Back Pain and Lower Urinary Tract Symptoms
Version: 1.0, final, February 25th, 2022.

General Information

Author of data managementplan:

T. Vredeveld, researcher at the Amsterdam University of Applied Sciences and Vrije Universiteit Amsterdam. (t.vredeveld@hva.nl)

Name of data management support staff consulted during the preparation of this plan and date of consultation.

Anne de Jong - Data steward at the Faculty of Health, Hogeschool van Amsterdam.
Mail: a.s.de.jong@hva.nl
Ellis Hensen - Privacy manager at the Faculty of Health, Hogeschool van Amsterdam.
Mail: e.b.hensen@hva.nl

1. What data will be collected or produced, and what existing data will be re-used?

1.1 Will you re-use existing data for this research?

If yes: explain which existing data you will re-use and under which terms of use.
No

1.2 If new data will be produced: describe the data you expect your research will generate and the format and volumes to be collected or produced.

The data is gathered for this study contains only the answers to the survey provided by the participants. The survey does not include: name, address, contact details or any other numbers that make direct identification or persons possible. Also, IP-adresses or other digital information is not collected.

Overall, the following data is gathered from the survey and in the analysis of the data after the data is exported from Qualtrics to a research environment.

Survey data

Type	Format	Description	Location	Est. volume
Survey responses	.xlsx	All medical information gathered through the questionnaires within the survey.	Qualtrics	100 mb

Exported data, meta-data and others

Type	Format	Description	Location	Est. volume
Analysis scripts R	.R, .Rproj	Scripts used to perform changes to data or statistical calculations	ResearchDrive	20 mb
Analysis scripts SPSS	.sps	Scripts used to perform changes to data or statistical calculations	ResearchDrive	20 mb
Codebook	.pdf, .xlsx	Document with a description of the dataset it is related to	ResearchDrive	20 mb
XML metadata	.xml	Descriptive file accommodating large text files.	ResearchDrive	20 mb
Readme data	.txt	Descriptive text file that provides details on folder structure and naming of files	ResearchDrive	20 mb

1.3 How much data storage will your project require in total?
0 – 10 GB

2. What metadata and documentation will accompany the data?

2.1 Indicate what documentation will accompany the data.
Metadata of each database includes:

1. Codebooks.
2. XML files.
3. Readme files for folders.
4. Analysis scripts.

Codebooks
A codebook is a PDF document or Excel file that explains and dictates the dataset (of any type of file, .R matrices, SPSS .sav files or .xslsx and .csv) and includes a description of (at least):

- Variable name: Name of the variable, containing no special characters, spaces. Only underscores (_) or hyphens are allowed (-)
- Variable label: Description of the contents of the variable
- Variable missing values: given a specified number or range
- Variable missing definitions: describes the specified number assigned as 'missing value', frequently used abbrevations are:
    - MCAR: Missing completely at random - missing values unrelated to the data
    - MAR: Missing at random – missing values in a more general meaning (i.e., due to collection error or missing of values).
    - MNAR: Missing not at random – missing data that has a cause which is not necessarily known beforehand or during the study.
- Label values: In case of a categorical variable, each number of that variable has a meaning and should therefore be specified.
- Type of variable: String, categorical (ordinal or nominal), continuous (linear or ratio)
- Number of decimals: if applicable.

XML files
A XML datafile is provided for finalized databases and contains:

```
<?xml version="1.0"?>
<Document>
<Title> TITLE OF THE DOCUMENT </Title>
  <Creator>
     <Name>Tom Vredeveld</Name>
  <Mail>t.vredeveld@hva.nl</Mail>
  <Phone>+31(6)211 55 901</Phone>
  <OrcidID>https://orcid.org/0000-0003-0563-817X</OrcidID>
  </Creator>
<Subject>N/A</Subject>
<Description>N/A</Description>
<Publisher>
  <PublisherName>Centre of Expertise Urban Vitality, Amsterdam University of
Applied Sciences</PublisherName>
<URL>www.hva.nl</URL>
</Publisher>
<Contributors>
```

<Contributor1>Name1</Contributor1>
<Contributor2>Name2</Contributor2>
<Contributor3>Name3</Contributor3>
<Contributor*i*>...</Contributor*i*>
</Contributors>
<Type>N/A</Type>
<Format>N/A</Format>
<Identifier>N/A</Identifier>
<Source>N/A</Source>
<Language>Dutch</Language>
<Relation>N/A</Relation>
<Coverage>N/A</Coverage>
<Rights>N/A</Rights>
</Document>

Readme files
Each folder is provided with a toplevel and lowlevel README.

Toplevel README contains the following description:

Project: <projectname>
Date: <date of the last update of this README>
Description: <short description of the project>
Funder: <involved sponsors>
Contact: <provide mail adress of the README author>
File organization: <description that provides folder structure and naming of the data>

- RawData: describes the raw data including the metadata collected during this project
- AnalyzedData: describes the analyzed data, including alterations to the data, syntax, and the metadata
- Manuscript: include all paper drafts of the manuscript(s), including text, figures and reference libraries
- Proposal: includes all versions of the research proposal and its appendices
- Trial Master File: includes all the documents as eventually presented in the Trial Master File.

Naming <naming of the data>

All files will be named as follows:
“YYYY_MM_DD ProjectName - <description> - Version (optional)
(Example 1: 2019_07_04_ABC_Manuscript_v1
(Example 2: 2022_01_01_XYZ_Rawdata)

Storage

<Afhankelijk van de studie wordt hier beschreven waar de data te vinden is, inclusief de back-ups>

Lowlevel README contains the following description:

Description of files in the subfolder: “Location/Sublocation/subfolder/directory-path”
YYYY_MM_DD - ProjectName_File1: File 1 describes the <description> - YYYY_MM_DD ProjectName_File2: File 2 describes the <description> - YYYY_MM_DD - ProjectName_File3: File 3 describes the <description>

Analysis scripts.

All analysis scripts in study are:

- SPSS .sps files. Remarks are added with a (*) asterisk symbol at the beginning of the line.
- R syntax .r files. Remarks are added with (#) hashtag at the beginning of the line.
- Every analysis script starts with a multiple remark signs (e.g. ** or ##) on the first lines with a short description of the use of the script.

2.2 Indicate which metadata will be provided to help others identify and discover the data.
See 2.1

Other metadata is created by uploading items to UvA/HvA FigShare, including date of uploaded items, author and affiliations. To items that are published a DOI can be assigned to increase findability of the documentation or datasets.

3. How will data and metadata be stored and backed up during the research?

3.1 Describe where the data and metadata will be stored and backed up during the project.
Institution networked research storage

During the study the two following systems are used:

1. Qualtrics. Qualtrics is an online survey tool used to create questionnaires and keep track of the incoming responses. The Amsterdam University of Applied Sciences signed a DPA with Qualtrics. All data that is gathered through Qualtrics is stored on EU servers and complies with the AVG/GDPR legislation.

2. ResearchDrive. The Amsterdam University of Applied Sciences uses the ResearchDrive which is used as a project cloud storage during the study. All datasets that are exported from Qualtrics are saved on the ResearchDrive in designated folders.

ResearchDrive employs a Two-Factor authentication system (2FA) to increase security. However, Qualtrics does not. Therefore, data is downloaded, exported to ResearchDrive and removed from Qualtrics every 10 responses.

3.2 How will data security and protection of sensitive data be taken care of during the research?
Additional security measures (please specify)
Data security for this study is reached by:

Authorization matrix
An authorization matrix is created and updated every half year and uploaded to the folder structure of the ResearchDrive and updated in this Data Management Plan.

Last update of the matrix: 25th of February, 2022.

Name	University	Mail-address	Access	Task	Rights
Tom Vredeveld	HvA	t.vredeveld@hva.nl	Qualtrics, ResearchDrive, UvA/HvA FigShare, identification key file	Researcher	View, edit.
Michel Coppieters	VU	m.coppieters@vu.nl	Qualtrics, ResearchDrive, UvA/HvA FigShare	Principal investigator	View, edit.

Annelies Pool-Goudzwaard	VU	a.l.pool-goudzwaard@vu.nl	Qualtrics, ResearchDrive, UvA/HvA FigShare, identification key file	Principal investigator	View, edit
Stephan Ramaekers	HvA	s.p.j.ramaekers@hva.nl	Qualtrics, ResearchDrive, UvA/HvA FigShare, identification key file	Researcher	View, edit.
Anne de Jong	HvA	a.s.de.jong@hva.nl	Qualtrics, ResearchDrive, UvA/HvA FigShare	Data steward	View, edit, create and lock database (Qualtrics)
Students HvA	HvA	Yet unknown (see paragraph: 5.3)	Excel export	Research assistants	View selected data frames with pseudonymized data.
Students VU	VU	Yet unknown (see paragraph: 5.3)	Excel export	Research assistants	View selected data frames with pseudonymized data.

Regular back-ups from Qualtrics to ResearchDrive.
Regular back-ups from the data on Qualtrics are made and stored on the ResearchDrive to ensure security of the data. This is performed as Castor EDC is a system that is used to input data, change or remove data during the measurements of participants. To prevent loss or erroneous (unnoticed) data input, a back-up is made every 10 survey responses from participants on the ResearchDrive in a specific folder.

Removal of data from Qualtrics.
The data from Qualtrics is deleted after every 10 responses, to ensure safe storage of the collected data.

4. How will you handle issues regarding the processing of personal information and intellectual property rights and ownership?

4.1 Will you process and/or store personal data during your project? If yes, how will compliance with legislation and (institutional) regulation on personal data be ensured?

Yes

Data
Every response that is collected from a participant is personal data, however cannot be used to identify individuals. Still, the data is archived during the study on the ResearchDrive and protected by allowing specific access to reseachers. This is noted in an authorization matrix, which can be found in 3.2. The authorization matrix is updated twice per year.

4.2 How will ownership of the data and intellectual property rights to the data be managed?

An agreement is signed between S.P.J. Ramaekers (HvA) and M. Coppieters (VU) to ensure the ownership and intellectual property rights.
The access rights to the data are managed through an authorization matrix which is updated every half-year.

5. How and when will data be shared and preserved for the long term?

5.1 How will data be selected for long-term preservation?

All data from this project is archived for 10 years, after the end of data collection of the study. The data will be stored protected in a VeraCrypt encrypted container After this period, the data is deleted.

5.2 Are there any (legal, IP, privacy related, security related) reasons to restrict access to the data once made publicly available, to limit which data will be made publicly available, or to not make part of the data publicly available?

If yes, please explain.
Yes

The data does not contain information that can be used to identify persons, however may contain medical information as answered through the survey. Therefore, only restricted access to the study data is setup during and after the study.

5.3 What data will be made available for re-use?

Only the metadata, as specified in 2.1, are made available for re-use.

5.4 When will the data be available for re-use, and for how long will the data be available?

The meta-data available as soon as article is published.

Data that includes direct answers to the survey can only be re-used under supervision of authorized researchers. Researchers that are interested in working with the data from outside the project members (i.e., the Faculty of Health at the Amsterdam University of Applied Sciences, or outside, national and international researchers) may find the metadata published on FigShare and contact details of the principal and coordinating investigators for further inquiry.
As the data contains medical details, the data itself is publicly not available.

5.5 In which repository will the data be archived and made available for re-use, andunder which license?

UvA/HvA FigShare is an institution version of FigShare, used for A) publishing of meta-data and B) archiving of the data.

5.6 Describe your strategy for publishing the analysis software that will be generatedin this project.

The analysis scripts, as described in 2.1 are available for publication on a dedicated FigShare project page.

6. Data management costs

6.1 What resources (for example financial and time) will be dedicated to datamanagement and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

All data (and metadata) are stored or archived on systems of the Hogeschool van Amsterdam which are widely available to all researchers. Therefore, no additional costs are made.

Appendix 7: Standard Operating Procedure - Safe Practices for Students Working with Research Data.

1. Introduction

1.1 Goal

This standard operating procedure (SOP) provides guidelines and recommendations for students from the Amsterdam University of Applied Sciences to work safe and secure with research data. All data is stored on systems of the Amsterdam University of Applied Sciences during the study and changes were made accordingly to the original SOPs and NDA as provided by the Vrije Universiteit.
The goal of this SOP is to provide a clear overview of data-access, safe, efficient and responsible use of the research data.

The SOP consists of two parts: 1) details of data storage and working with types of data and 2) a non-disclosure agreement (NDA) that must be signed (see §1.3)

1.2 Training and preparation

Students must read the SOP and sign the agreement before working with the data. If any questions remain after reading the SOP, students must seek contact with the responsible researcher or author of this SOP.

1.3 Responsibility of the Standard Operating Procedure.

Researchers: T. Vredeveld (t.vredeveld@hva.nl phone no.: 06-21155901) and Principal Investigators Prof. Dr. A.L. Pool-Goudzwaard (a.l.goudzwaard@vu.nl) and Dr. S.P.J. Ramaekers (s.p.j.ramaekers@hva.nl) are responsible for signing the agreement with students and adherence to the SOP during the study.

2.0 Working with Research Data for HvA Students.

2.1 Types of Data

The following data risk classification is used by the Vrije Universiteit, Faculty of Behavioural and Movement Sciences (found at: https://fgb-rdm.nl/Security/PrivacyRisks.html), with alterations made to match the Amsterdam University of Applied Sciences.

Blue data

Privacy Risk	Little to no risk
Description	Data that cannot be re-identified whatsoever, regardless of the vulnerability of the subjects or the sensitivity of the information.
Impact of a Breach	Research subjects suffer no direct harms and the Amsterdam University of Applied Sciences will suffer no damage to its reputation**
Examples	• Highly variable physical measurements, e.g. blood pressure, heart rate, blood glucose, body temperature • Likert scale responses in questionnaire data • Coded qualitative data • Summary statistics **NB**: If any of the above examples are part of a record about a research subject that contains data from a higher risk category, then the data are not anonymous. They are only anonymous if they are not linkable to the higher risk data.

***NB: Although research subjects will not be directly harmed, the conclusions drawn from research results or the misuse of published research software can impact the wider population to which the research subjects belong. Such ethical considerations should be discussed with the Scientific Board that approved the study.*

Green data

Privacy Risk	Low-risk
Description	Data that can only be re-identified with great effort and that are about benign topics from non-vulnerable subjects
Impact of a Breach	• Harm to research subjects is minimal and the likelihood that harm would occur is very low • Damage to the reputation of the Amsterdam University of Applied Sciences may still occur although it is less likely and the impact would be lower
Examples	Blue data in which a random identification code is attached to each record so that every record can be re-identified with the help of a key file Data that contain unique records for some or all research subjects: • Neuro-imaging from non-vulnerable subjects that has been de-faced • Extensive kinematic measurements from non-vulnerable subjects • Any other measurements that contain sufficient information to create a unique profile for one or more research subjects • Questionnaires about benign topics and answered by non-vulnerable research subjects that have been processed to be less identifiable, but which still contain demographic information about each subject

Yellow data

Privacy Risk	Moderate-risk
Description	• Data that could be fairly easily re-identified that are about benign topics and from non-vulnerable subjects

	OR • Data that can only be re-identified with great effort and that are about: • benign topics from vulnerable subjects; • sensitive topics from non-vulnerable subjects; *OR* • both
Impact of a Breach	Severity of harm to research subjects and/or damage to the reputation of the Amsterdam University of Applied Sciences is moderate to high, but the likelihood that such harms or damages would occur is low
Examples	• IP- and MAC-addresses of research subjects (vulnerable or not) • Raw questionnaire data about benign topics from non-vulnerable subjects containing detailed demographic information • Questionnaire data about sensitive topics and/or vulnerable populations that have been processed to make re-identification more difficult • Video recordings with faces blurred and voices modified • Transcripts of interviews in which the identifying information is replaced with pseudonyms • Repeated physical measurements that include the dates and times measurement occurred • Neuroimaging from vulnerable subjects that has been de-faced • Extensive kinematic measurements of vulnerable subjects or that are used to identify sensitive information such as abnormal movement patterns

Orange data

Privacy Risk	High-risk
Description	• Fully identifiable data about benign information from non-vulnerable subjects **OR** • Data that are fully identifiable or that could be fairly easily re-identified that are about benign topics from vulnerable subjects **OR** • Data that are fully identifiable or that could be fairly easily re-identified that are about sensitive topics from non-vulnerable subjects
Impact of a Breach	• Serious harm to research subjects and/or serious damage to the reputation of the Amsterdam University of Applied Sciences could occur. • Likelihood that such harm/damages would occur after a breach is moderate, but if the harm/damage does occur the consequences would be severe
Examples	• Key files containing names and contact information of research subjects (vulnerable or not) • Data containing date of birth and 6-digit postal code of research subjects (vulnerable or not) • Video observations of children playing

	• Video observations of team-building activities • Raw neuroimages of non-vulnerable subjects that haven't been de-faced • Raw questionnaire data about sensitive topics and/or from vulnerable subjects containing detailed demographic information • Genetic data from non-vulnerable subjects

Red Data

Privacy Risk	Very high-risk
Description	Data from vulnerable subjects, that are about sensitive topics and are either fully identifiable or are easily re-identified
Impact of a Breach	• Serious harm to research subjects and/or serious damage to the reputation of the Amsterdam University of Applied Sciences could occur • Likelihood that such harm/damages could occur after a breach is very high
Examples	• Video interviews with children talking about abuse • Raw transcripts of interviews with refugees about their home country • Open text responses (e.g. diary-type feedback) from patients with mental or physical health problems • Open text responses or detailed interviews with employees describing their satisfaction with their employer • Raw neuroimages of vulnerable subjects that haven't been de-faced • Genetic data from vulnerable subjects that indicates risk for disease or disorders

2.2 Data Storage Considerations

When the data risk classification is identified, you must follow the guidelines for each type of classification. These are:

Working with 'blue' or 'green' level data:

- Do not safe the data on publicly available datashares, including WeTransfer, Dropbox, Google Drive, instead use the dedicated ResearchDrive or personal harddrives.
- Do not store this data on USB-sticks or external hard-drives.
- If you are connected to a public Wi-Fi, connect through EduVPN. Do not connect to a password-free Wi-Fi network.
- Students must have Full-Disk Encryption enabled and activated. For Windows, for Mac.

Working with 'yellow' level data:

- Do not safe the data on publicly available datashares, including WeTransfer, Dropbox, Google Drive, instead use the dedicated ResearchDrive or personal harddrives.
- Do not store this data on USB-sticks or external hard-drives.
- Do not connect to a public Wi-Fi, or use EduVPN if it is not possible otherwise to connect to the internet
- Full-Disk Encryption must be enabled on a student's computer. For Windows, for Mac.
- Make sure no-one can view your computer screen. Do not work in open or public spaces, with roommates nearby of check for mirrors.

Working with 'orange' level data:

- This data may only be stored on an encrypted external hard drive. For example, use VeraCrypt to encrypt the hard drive.
- This data may not be stored elsewhere, i.e. USB-sticks, external hard drives, etc.
- Do not connect with public Wi-Fi networks, and use EduVPN, even if you need to connect your personal Wi-Fi networks.
- Make sure that your laptop or computer is not in a public space or can be seen elsewise and do not work with this data in a public space.
- The data can only be stored in encrypted folders on the ResearchDrive and need to be removed after working with the data and uploaded to the ResearchDrive.
- ResearchDrive needs to be activated with a 2-Factor Authentication, preferably Tiqr. Click this link to set up a 2-Factor Autentication Login.

Working with 'red' level data:

- This data may only be stored on an encrypted external hard drive or encrypted fodler on ResearchDrive, therefore Full Disk Encryption needs to be activated. For example, use VeraCrypt to encrypt the hard drive.
- Make sure that your laptop or computer is not in a public space or can be seen elsewise and do not work with this data in a public space.
- Do not connect with public Wi-Fi networks, and use EduVPN, even if you need to connect your personal Wi-Fi networks.
- You may only work with this data under supervision of your supervisor. Contact the principal investigator of the study if you are unsure who your supervisor is.
- ResearchDrive needs to be activated with a 2-Factor Authentication, preferably Tiqr. Click this link to set up a 2-Factor Autentication Login.

2.3 Back-ups and Returning Data

The data management plan of the study provides a back-up schedule and method or if questions remain contact your supervisor.

After you have completed working with the data, make sure to upload it to ResearchDrive to an allocated folder or transfer the data to your supervisor if such transfers apply. Then, remove all data from personal hard drives and use KillDisk to make sure it is thoroughly wiped.

2.4 Data Collection Considerations

Always safe data according to the above-described methods. Sometimes, data must be transferred when collecting data. There are two options for green, blue and yellow data:

1) Use surffilesender, use the encrypted sending option.
2) Use an encrypted USB-stick, using VeraCrypt.

NOTE: Orange and red data must never be transferred in such manners. Talk to your supervisor about transferring these types of data!

2.5 Other security concerns

Working on a laptop.

If you use a laptop to handle your data, make sure you lock it when leaving it unattended (Windows: windows key + L, MacOS: command + control + Q), and make sure login is password protected.

Passwords

A password should consist of more than 16 characters and be different for each application or encrypted file/folder/drive you use. You may use a KeePass manager (like KeePassXC) to store passwords offline, however make sure that the master password to the database is strong and easy to remember. Never store passwords unprotected, i.e., do not email passwords to yourself, use word documents, txt-files, etc.

Software updates

Make sure that your devices and applications are always running on the most up to date software versions.

- In MacOS, do this by going to system preferences > software update > click the checkbox “update my Mac automatically” (“Werk mijn Mac automatisch bij”)

- In Window, do this by going to the Start menu > Settings cog > Update & Security > Advanced options > click the checkbox “automatically download updates”

Full Disk encryption on Windows

Disk encryption may be difficult on some versions of Windows. Make sure that you have Windows 10 Education, Pro or Enterprise. Windows 10 Home does not support BitLocker for Full Disk encryption. You can check your Windows version vial Start menu > Settings > About.

For students, Windows 10 Education can be purchased through SurfSpot.

2.6 Data Documentation.

Please see the Data Management Plan of the specific study to be up to date on how to provide an adequate and clear name to files, build up folder structures and set metadata or README.txt files.

Make sure that all scripts (SPSS, MatLab, R, etc.) are accompanied with guiding text, most software packages allow lines starting with # or $ to be skipped when running the code. This allows for extra descriptive information on the script.

2.7 Data Breaches

Human beings are prone to making mistakes. Even if you followed all steps cautiously, it may happen. However, the largest mistake is not to report them. If your research data was compromised (whatever the level!), or in case your observe unsuspected behavior, please contact the data steward of the Faculty of Health from the Amsterdam University of Applied Sciences and the principal investigator of your study.

2.7 Support

Who	When	Where
Privacy officer Faculty of Health:	In case privacy or security of data is breached	e.b.hensen@hva.nl
Data Steward:	For general support of the management of data.	opensciencesupport@hva.nl
ServiceDesk ICTS:	Technical issues, loss of Data in any way.	servicedesk-icts@hva.nl

3.0 Non-Disclosure Agreement for Handling Research Data at the Amsterdam University of Applied Sciences.

UNDERSIGNED:

Name of student:	
Student number:	
Position:	
Study:	
Department:	
Faculty:	
University:	
E-mail:	

The Amsterdam University of Applied Sciences (Hogeschool van Amsterdam), hereafter HvA has the legal obligation to handle (personal/confidential) data with the upmost care. As a student working on a Bachelor or Master thesis, you play an important role in this. This statement describes the usage rules of good and safe handling of data from research projects at the HvA.

1. General

1.1 Only conduct research/analyses as described in the following table (hereafter "Data"). New use of the Data requires signing a Non-Disclosure Agreement for Handling Research Data at the Amsterdam University of Applied Sciences. Substantive modification of the original plan also requires signing a new Non-Disclosure Agreement

1.2 Description of the Data and the project:

2. Usage rules

2.1 Handle the Data with upmost care and act in accordance with the instructions given by the HVA.

2.2 Prevent incorrect or unauthorized use of the Data.

2.3 Do not use the Data to identify or contact individual participants.

2.4 Do not link the Data to any other data or database unless this is part of the research project.

2.5 Note that as a student of the HVA you have a confidentiality obligation to all confidential information, including personal details to which you have access in the context of the study. This obligation for confidentiality remains after graduation.

3. Destruction of Data

3.1 Your supervisor maintains the orginal or raw copy of the Data. After the resulting paper has been published or thesis has been completed, you must delete the Data and provide a copy off any changes to the Data to your supervisor.

4. Information security

4.1 Be aware that information security starts with you.

4.2 As a student, act according to the total Standard Operating Procedure - Safe Practices for Students Working with Research Data.

4.3 Maintain appropriate control over the Data and do not distribute Data in any form to any unauthorized entity or individual.

4.4 Only store the Data in a digital environment made available by the HVA and any keys linking these databases on a computer with adequate security controls. Also comply with the following:

a. Do not store the Data on unencrypted storage devices such as USB-sticks or mobile hard disks.

b. Make sure that the storage of the computer that you work on is encrypted (on Windows with Bitlocker and on MacOS with Filevault) or store data only on an encrypted USB stick. If you have a question on this topic contact the Open Science Support desk or your supervisor (opensciencesupport@hva.nl).

c. Make sure the operating system and software on your computer is up to date.

d. Use strong passwords and never share these.

e. Do not use public WiFi-networks when working with the Data, but work on the Eduroam network or use eduVPN.

f. Always lock your computer when you leave it.

4.5 Promptly report (or as soon as possible) incidents relating to the Data to the Servicedesk ICTS via servicedesk-icts@hva.nl or 020-5951402, your supervisor and Privacy Officer of the Faculty of Health: e.b.hensen@hva.nl 'Incidents' shall in any case include (a suspicion of):

a. loss or theft of login details;

b. loss or theft of ICT facilities, such as a computer, telephone or USB drive;

c. unauthorized access to ICT facilities, such as a computer, telephone or USB drive;

d. unauthorized or unintentional corruption, publication or amendment of or unintentional access to the Data;

e. the presence of harmful software, including a virus, Trojan, spyware, malware;

f. a phishing attack.

I hereby declare that:

1. I have read and I understand the Standard Operating Procedure (SOP) - Safe Practices for Students Working with Research Data and rules specificied in the Non-Disclosure Agreement.
2. I will use the Data according to the SOP, rules and obligations. When I am in doubt or when I have a question, I will contact my supervisor immediately.

STUDENT.	**SUPERVISOR.**
Signed by: Name Town/City: Date	Signed by: Name: Town/City: Date Phone number: E-mail address:

Should be signed twice, one copy should be provided to the student, one copy should be archived properly following research documents.

Appendix 8: Non-Disclosure Agreement for Study Participation of students.

Below is a Non-Disclosure Agreement for Study Participation of students.

VERKLARING TBV ONDERZOEK: Survey to Profile Men with Low Back Pain and Lower Urinary Tract Symptoms.
Ondergetekende: Naam: _____ Studentnummer: _____ Hierna te noemen: “Student”
Overwegende dat: - aan de Hogeschool van Amsterdam, gevestigd te Amsterdam, aan de Wibautstraat 3b (hierna te noemen HvA) onderzoek wordt verricht inzake “Survey to Profile Men with Low Back Pain and Lower Urinary Tract Symptoms” dat onder leiding staat van Tom Vredeveld, hierna te noemen het Onderzoek, - het Onderzoek plaatsvindt met de steun van HvA en dat alle gegevens, inclusief software, knowhow en overige informatie gegenereerd binnen het Onderzoek, alsmede (mogelijke) intellectuele eigendomsrechten, (hierna: de Onderzoeksresultaten) eigendom zijn van HvA gezamenlijk; - ondergetekende in het kader van zijn/ haar STAGE / STUDIE / AFSTUDEEROPDRACHT GETITELD …… werkzaamheden gaat verrichten aan bovengenoemd Onderzoek, en derhalve mogelijk een bijdrage zal leveren aan, of inzage zal krijgen in de Onderzoeksresultaten;

verklaart:

- afstand te doen van aanspraken en van alle intellectuele en industriële eigendomsrechten op de Onderzoeksresultaten en deze om niet in eigendom aan HvA over te dragen en de overdracht van deze rechten zodra mogelijk bij (onderhandse) akte te bevestigen;
- medewerking aan HvA te verlenen voor het verkrijgen en instandhouden van de intellectuele en industriële eigendomsrechten op Onderzoeksresultaten, waarbij HvA eventueel noodzakelijk daarvoor te maken kosten zal vergoeden;

- de Onderzoeksresultaten gedurende 5 jaar na ondertekening van deze verklaring geheim te houden en uitsluitend te gebruiken voor het verrichten van de werkzaamheden in het kader van het Onderzoek en voor geen enkel ander doel;
- voorafgaand aan een openbaarmaking van de Onderzoeksresultaten of andere informatie met betrekking tot het Onderzoek een concept van deze openbaarmaking aan HvA voor te leggen en niet over te gaan tot openbaarmaking daarvan dan na schriftelijke toestemming van HvA;

- dat alle data, waaronder (bijzondere) persoonsgegevens, verkregen in het kader van genoemd onderzoek vertrouwelijk zullen worden behandeld en niet met derden zullen worden gedeeld, tenzij HvA hier schriftelijk toestemming voor geeft;
- eventueel ter beschikking gestelde of verzamelde data, waaronder (bijzondere) persoonsgegevens na afronding van de werkzaamheden direct aan de HvA ter beschikking te stellen en alsdan de in eigen bezit zijnde data inclusief persoonsgegevens te vernietigen.

_____(plaats), _____(datum)

Student