Study protocol

Title: Qualitative Study on Pain Registration through Innovative Health Technology (QualiPain)

29.09.2018, Version 2.0

The information in this study protocol is to be treated as strictly confidential. It only serves to inform the sponsor, the examiners, the study staff, the ethics committee, the authorities and the patients. This study protocol may not be passed on to third parties without the consent of the sponsor or the head of the clinical trial.

I. Signatures

Prof. Dr. med. Dirk Rades (Lead investigator, medical contact person – responsible for the conduction of the study)

Signature Date

Dr. Matteo Bonsanto (Contact person Department of Neurosurgery)

Signature Date

Content

II. Synopsis

Sponsor	University Hospital Schleswig-Holstein (UKSH), Campus Lübeck
Lead investigator	Prof. Dr. med. Dirk Rades, Chief Physician of the Department of Radiotherapy at the University of Lübeck
Title	Qualitative Study on Pain Registration through Innovative Health Technology
Acronym	QualiPain
Indication	Patients with chronic or acute pain related to illness or treatment who rate their pain as 4 or higher on the Numerical Rating Scale (NRS).
Phase	*Not applicable*
Treatment	No treatment of the patients is planned in connection to this qualitative study. The study is limited to the conduction of qualitative interviews. The usual pain therapy is not affected by this study.
Primary objective	Evaluation if and how the registration of pain related to illness or treatment can be improved through the use of health technological solutions from a patient perspective.
Secondary objectives	1. Investigation of the patient experience of pain 2. An evaluation of if patients would be willing to register pain assisted by health technological devices, either themselves or assisted by health care professionals.
Study design	It is an explorative, qualitative study. It is a multi-centric study that is conducted in a total of three clinics in Denmark and Germany.
Study population	**Inclusion criteria:** Patients who meet all of the following criteria can be included in the study: • 18 years or older • Pain Intensity > 4 (Numerical Rating Scale 0-10) • Legally competent • Signed declaration of consent **Exclusion criteria:** Patients are not included if: • Lack of willingness to cooperate • Lack of consent • Lack of ability to follow instructions • Younger than 18 years
Study duration and timeframe	Start of patient recruitment: September 2018 End of patient recruitment: November 2018 Data analysis and reporting: September – December 2018 Duration of interview per patient: approximately 30 minutes
Number of participants	An inclusion of 8-10 patients is planned.

Number of centers	A total of 3 centers will participate in the study.
Statistical methods	*As this is a qualitative study, no statistical methods will be applied.*
GCP Conformity	*The present study will be conducted according to the current version of the internationally approved guidelines for Good Clinical Practice (ICH-GCP).*
Financing	The study is a subproject of the third-party funded project InnoCan. InnoCan is funded by the European Regional Development Fund as part of the Interreg Deutschland-Danmark program.

1. Responsibilities

Sponsor:

University Hospital Schleswig-Holstein (UKSH), Campus Lübeck
Ratzeburger Allee 160, 23538 Lübeck, Deutschland

Financing:

The study is funded by the third-party funded EU (Interreg) project InnoCan.

Lead Investigator / medical contact person:

The responsibility for this study is placed at the Department of Radiotherapy, Lübeck University (Prof. Dr. Rades). The Department of Radiotherapy in Lübeck is part of both the University of Lübeck and the University Hospital Schleswig-Holstein (UKSH). The clinic will help recruit patients on its own ward.

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Department involved in the study on site:

The Department of Neurosurgery at Lübeck University treats a large number of patients with acute and chronic pain. The clinic will help recruit patients on its own ward.

Contact person:
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Danish study center:

The oncological department of the Zealand University Hospital in Næstved will function as a Danish study center. Patients with pain due to illness or treatment are also here invited to take part in 30-minute qualitative interviews. The interviews in Denmark and Germany are based on the same interview guide.

Contact person:
Senior physician Niels Henrik Holländer
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Conduction of qualitative Interviews:

The Department Production, Research and Innovation (PFI) at the Region Zealand, Denmark has in depth experience with the support of innovative projects and research at Danish and German hospitals. Currently PFI is a project partner in the Interreg 5a project Innocan – Innovative high technological cancer treatment Denmark – Germany. Furthermore, PFI has great competencies in medical anthropology. PFI will conduct qualitative interviews with the participating patients. German is the native language of the interviewer.

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Design expertise:

The Designschool Kolding (DSK) in Denmark will participate in the interviews with their expertise in the field of design. It will contribute with in depth design and user experience (UX) expertise to the study. The DSK has the competencies to communicate and visualize future-oriented designs of e.g. apps or other technical devices and to design them in such a way that they can be integrated as well as possible into the everyday life of users.

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2. Objective and rationale of the study

The study aims to investigate whether and how the registration of pain related to disease or treatment can be optimized through the application of health technology solutions from a patient's perspective. A health technology solution could e.g. be an app or a device to measure vital signs. The objective of this study is to investigate if such a solution would be accepted by patients with acute or chronic pain, and how a suitable solution should be designed to meet the needs of the patient. Existing methods for pain registration as well as opportunities for the development of new methods will be investigated and evaluated in the interviews.

In order to investigate this question, the interview contains several topics, including:

- The patient's everyday experience of pain, e.g. how patients cope with every day pain and if they document their pain.
- Experiences with and thoughts about a regular recording of pain.
- An evaluation of if patients would be willing to register pain assisted by health technological devices, either themselves or assisted by health care professionals.

The goal of the study is that the results can aid in the development of a new and improved form of pain registration. The results of the study are summarized in a report to the startup company Nextlabel OHG that will have the opportunity to develop a technological solution tailored to the needs of the patient.

Background

According to the German Pain Association (Deutsche Schmerzgesellschaft e.V.), around 23 million Germans live with chronic pain. Pain is also a common side effect in cancer patients that undergo radiotherapy.

International studies have shown that digital pain registration provides some benefits for patients and medical staff. For example, a Norwegian study has found that a digital solution help patients with late-stage cancer to communicate their pain to others, and thus improves communication with medical professionals[1]. Another study has shown that the digital solution enables patients to record pain more independently of medical personnel, which is generally considered an advantage by patients[2]. These studies mainly relate to information, where patients have used technology themselves.

To open up for new perspectives for the use of health technologies in hospital departments, it is important to involve users at the very beginning of the development process. Therefore, we will conduct qualitative interviews with patients about their pain experience in their everyday lives and their wishes to future pain registration.

Own preparatory work

Preparing for this study nine informative talks were conducted with doctors, nurses and physiotherapists from the Radiotherapy Clinic at the University of Lübeck, the Clinic for Radiotherapy at the University of Kiel and the Clinic for Neurosurgery at the University of

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[1] Jaatun, A. A. E. & M. G. Jaatun. 2016. Advanced Healthcare Services Enabled by a Computerized Pain Body Map. *The 6th International Conference on Current and Future Trends of Information and Communication Technologies in Healthcare (ICTH 2016).*

[2] Wilkie, DJ et al. 2003. Usability of a Computerized PAINReportIt in the General Public with Pain and People with Cancer Pain. *Journal of Pain and Symptom Management* Vol 25(3).

Lübeck. These conversations revealed that there is no uniform approach to pain registration, even though a detailed and continuous registration potentially can improve the diagnosis and treatment of pain and generate relevant data for research. Existing forms of pain registration include the Numerical Rating Scale (NRS), the Visual Analogue Scale (VAS), pain diaries and questionnaires about the treatment pathways.

A more detailed description of the applied methods can be found in section 6.

3. Recruitment of patients

This study includes patients who have chronic or temporary pain related to illness or treatment. The patients are recruited in two ways:

Firstly, a brochure (Appendix 1) will be laid out in the waiting areas of the clinic for Radiotherapy and the Clinic for Neurosurgery at the University of Lübeck. Interested patients then have the opportunity to call or e-mail a contact person, who informs them in person about the course of the study. After informing about the study a doctor who takes part in the project hands out patient information and a copy of the declaration of consent, which needs to be signed by the patient and the doctor (Appendix 2).

Secondly, patients treated by the research doctors in the clinics are approached and informed about the study. If the patient is interested in participating, the patient information and the declaration of consent as described above are handed to the doctor. Then an interview appointment is agreed upon.

Only patients who are at least 18 years old and who themselves experience that pain affects and limits their everyday life are included. The patients have the opportunity to withdraw their consent at any time, whereupon every data collected is deleted immediately or anonymized at the patient's request. An anonymization of data may be necessary if the patient has already been interviewed at the time of drop-out.

8-10 patients are enrolled in the study. The participating patients receive no financial compensation. Patients are included in the studies according to the qualitative sampling plan shown in Table 1.

Table 1: Qualitative sampling plan

Sex		Age			Pain Quality	
Male	Female	18-49	50-79	>80	Acute	Chronic
3	3	1	1	1	2	2

4. Inclusion and exclusion criteria

Inclusion criteria:

Patients who meet all of the following criteria can be included in the study:

- 18 years or older

- Pain Intensity > 4 (Numerical Rating Scale 0-10[3])
- Legally competent
- Signed declaration of consent

Exclusion criteria:

Patients are not included if:

- Lack of willingness to cooperate
- Lack of consent
- Lack of ability to follow instructions
- Younger than 18 years

5. Study type

It is an explorative qualitative study.

The study is multi-centric and takes place in Denmark and Germany in a total of three clinics. From September to November 2018, patients will be interviewed once using a standardized interview guide. The duration of the interview is approximately half an hour. Upon completion of the interviews no further patient related activities will take place as part of the study.

6. Study plan

In order to be create a good communication with the patient, a semi-structured interview format is used[4] [5]. The interviews have no direct influence on the diagnosis or treatment of the patients and thus no modification to the standard therapy is made.

An anthropologist from PFI as well as a design engineer from DSK will conduct the semi-structured interview individually or together. Since it is an explorative study, the interview is based on a thematic interview guide (Appendix 3). This gives the patient the opportunity to talk about topics that are important to him or her. At the beginning of the interviews, the participants are provided with a brief introduction to the study to make sure they are informed and feel comfortable with the interview situation. The subsequent questions provide the participants with the opportunity to share their experiences from their own perspective. It is important that the questions are posed in an understandable language. The interviewer ensures that all relevant topics are covered during the interview period.

Visual aids can also be used to evaluate whether patients would be willing to use technological devices to self-register or for registration assisted by medical specialists. Two documents have been created by the Design School Kolding to provide visual aid during the interview (Appendix 5).

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[3] Anhang 4

[4] Kvale, S. & Brinkmann, S. 2009. Interview: Introduktion til et håndværk. Hans Reitzel Kbh.

[5] Rubow, Cecilie. 2003. Samtalen som deltagerobservation. In: *Ind i Verden. En Grundbog i Antropologisk Metode.*

Both documents are only intended as a visual supplement to the interview guide. The patient has the opportunity to comment on the documents, thereby making the documents the starting point for further reflections and discussion with the patient. Through the use of qualitative methods and visual aids, the user (here: the patient) is put in the center and it is taken into account how changes (e.g. the use of new products, systems or services) in the everyday life of the user can create meaning and can be integrated as good as possible.

7. Adverse events / serious adverse events

The patient's involvement is reduced to the interview. For this reason, there are not expected any adverse events relevant to the study. If participating in an interview is a psychological burden for the patient, the patient is at all times free to stop participation without giving a reason.

8. Data acquisition and documentation

Information on the age and gender of the participants is recorded in connection to every interview. Interviews are recorded using a dictaphone after patient consent and pseudomized through the assignment of a number. The personal data of the participating patients are recorded in a patient identification log and are kept inaccessible to third parties in the department of radiotherapy even after the study has been completed. All study results are anonymized and summarized in a final report. The report will be forwarded to Nextlabel OHG after completion of the study. Except for the final report, Nextlabel OHG does not receive any of the collected data. A scientific article may be published subsequently. All interview excerpts used in the article will be completely anonymized.

The data collected in the interviews will be kept at PFI for analysis purposes and will be completely anonymized after the end of the study and no later than December 31, 2018. All contact details of the participating patients are kept in the Department of Radiotherapy in Lübeck. The study-specific data are stored/archived for a period of 10 years.

There is no electronic data transfer. Instead data transmission takes place through the personal exchange of encrypted USB sticks. The data collection and storage of data take place in agreement with the General Data Protection Regulation (GDPR [2016/679]).

9. Results and evaluation

The recordings of the qualitative interviews are analyzed and the results are summarized in an anonymized report. For the analysis, detailed notes on the sound recordings are written, and, if necessary, the interviews are partially transcribed. Subsequently, a thematic analysis is carried out to identify important topics of the interviews. It is evaluated, among other things, to what extent patients are already registering pain, e.g. with the help of an app or analogue and what possibilities there are for digital registrations in the future.

In addition, new and as of yet unknown, subject areas can be identified in the analysis, which can contribute to the development of an improved method for pain detection. The results of the qualitative analysis result in recommendations for the development of a pain app or other technological solution for pain registration. The technological solution developed can then be tailored precisely to the needs of the patients in the participating clinics. A scientific article may be published after the study is completed.

10. Time schedule

Timespan	**Action**
September-November 2018	Patient recruitment and interviews
September-December 2018	Data analysis and reporting

11. Conduction of the study

The study protocol as well as possible later changes to the protocol have been or will be written according to the Helsinki Declaration version from October 1996 (48th General Assembly of the World Medical Association, Somerset West, Republic of South Africa). Possible later changes to the study protocol will be send to the ethical committee as an amendment.

The study is conducted in accordance with the principles of the Good Clinical Practice (ICH-GCP) guideline.

The quality criteria for qualitative studies which are summarized in the guideline for publication of qualitative research results "Consolidated criteria for reporting qualitative research" (COREQ) [6] are considered in this study. The presentation of the study methodology and results will be based on the COREQ criteria.

Insurance
No special insurance protection (patient insurance) is required for the patients involved in the study. No commuting accident insurance has been made.

Benefit-risk-assessment
No risk is to be expected from the questioning of the patients, since patient participation is limited to the qualitative interview.

12. Registration of the study

The study will be registered at https://clinicaltrials.gov before study start.

13. References

1. Jaatun, A. A. E. & M. G. Jaatun. 2016. Advanced Healthcare Services Enabled by a Computerized Pain Body Map. The 6th International Conference on Current and Future Trends of Information and Communication Technologies in Healthcare (ICTH 2016).
2. Wilkie, DJ et al. 2003. Usability of a Computerized PAINReportIt in the General Public with Pain and People with Cancer Pain. Journal of Pain and Symptom Management Vol 25(3).
3. Anhang 4
4. Kvale, S. & Brinkmann, S. 2009. Interview: Introduktion til et håndværk. Hans Reitzel Kbh.
5. Rubow, Cecilie. 2003. Samtalen som deltagerobservation. In: Ind i Verden. En Grundbog i Antropologisk Metode.
6. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007; 19: 349-357.

Interreg Deutschland - Danmark

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INNOCAN

Dieses Projekt wird gefördert mit Mitteln des Europäischen Fonds für regionale Entwicklung.