UNIVERSITÄT ZU LÜBECK

UKE Institut und Poliklinik für Allgemeinmedizin

University of Lübeck
Nursing Research Unit
Institute for Social Medicine and Epidemiology
Ratzeburger Allee 160, 23562 Lübeck

Prof. Dr Katrin Balzer
Secretariat: Elena Teisch
Tel.: 0451 500-51261
Fax: 0451 500-51264

Information on the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)".

(Translation based on Version 1.3, 09.07.2022)

Dear Ladies and Gentlemen,

we would like to invite you to participate in the study "Expand-Care". The study is being conducted by the Nursing Research Unit at the University of Lübeck and the Institute for General Practice at the University Medical Center Hamburg Eppendorf. The study is funded by the Federal Ministry of Education and Research (BMBF).

The study was reviewed by an independent ethics committee. This committee did not raise any objections to the conduct of this study.

Your participation in the study is voluntary. If you do not wish to participate or if you later withdraw your consent, you will not suffer any disadvantages as a result.

Please read this information carefully. If you have any further questions regarding the study, please contact us, the study team:

Prof. Dr Katrin Balzer
Principal investigator
Katrin.Balzer@uksh.de
Tel.: 0451 500-52162

Katharina Silies
Research assistant
Katharina.Silies@uksh.de
Tel.: 0451 500-52161

What is the aim of this study?

The aim of this study is to find out whether nursing professionals with special additional qualifications should take on additional tasks in the care of residents in nursing homes. The aim is to improve nursing care and health of residents and to adapt care to their needs. The employment of nursing professionals with additional qualifications in nursing homes is now to be explored and we hereby invite you to participate.

Silies KT, *et al. BMJ Open* 2023; 13:e072955. doi: 10.1136/bmjopen-2023-072955

UNIVERSITÄT ZU LÜBECK

expand care

UKE Institut und Poliklinik für Allgemeinmedizin

What is the process of the study?

The study is being conducted in 11 nursing homes in Lübeck and Hamburg. Per nursing home, 15 residents can participate. The nursing homes are **randomly assigned to** two different groups. One group of nursing homes will receive further training, i.e. one of the facility's nursing staff will receive additional training and will apply what they have learned to nursing care and, for example, conduct structured personal conversations with residents. The other group of nursing homes receives care as usual (this means for you everything remains as before). The group allocation is random, which means you yourself, the nursing home and the study staff have no influence on which group the nursing home where you live is allocated to.

If you agree to participate in the study, study staff will collect information of interest from your resident record. In addition, you and a (specialist) caregiver responsible for you at your nursing home will be interviewed by a study staff member on various health-related topics using a questionnaire. This information will be collected at regular intervals at three points in time: at the beginning of the study, after three months and after six months. Your participation is expected to last a total of six months, after which the study will end. We will coordinate all appointments with you and the nursing staff of your institution. You will not incur any financial expenses during the entire study. Participation in the study will require about 30 minutes of your time twice for the interviews. This time expenditure cannot be compensated within this study.

What data is collected from me?

We would like to collect the following information from your resident file and from you as part of the survey:

- Your personal data (age, sex, marital status, degree of care, care aids, and whether you have powers of attorney or a living will).
- Information about your physical and mental health,
- Information from the documentation of the nursing home (e.g. medical diagnoses, medication and medical care, number of falls, hospitalisations, pressure ulcers).

Do I have to give my consent? What happens if I withdraw my consent?

Participation in this study is voluntary. You therefore do not have to participate. Even after you have given your consent, you can terminate your participation in the study at any time without giving reasons and without incurring any disadvantages.

If you would like to withdraw from participation at a later date, please contact the principal investigator Prof. Dr. Katrin Balzer. If you withdraw from the study, data that has already been collected from you can be deleted if you wish, provided that the data has not yet been completely anonymised (see section on data protection). In this case, a connection to your person is no longer given and deletion is therefore no longer possible.

Silies KT, *et al. BMJ Open* 2023; 13:e072955. doi: 10.1136/bmjopen-2023-072955

UNIVERSITÄT ZU LÜBECK

expand care

UKE Institut und Poliklinik für Allgemeinmedizin

What are the possible risks and benefits of participation?

Participation in the study is not associated with any risks for you. The applicable hygiene rules (e.g. personal protection equipment) will be observed during personal meetings. Participation in the study can have a direct benefit for you and for other residents of your nursing home, e.g. increased nursing care. In addition, the results of the study may help other residents in nursing homes in the future.

However, it is possible that you will not directly benefit from your participation.

What happens to the results of the study?

The findings will shed light on whether the integration of nursing professionals with expanded competencies in nursing homes leads to better care and quality of life for residents and should be introduced in the future. The results of the study will be presented anonymously to the general public and the professional public, e.g. in scientific journals and at congresses.

Who reviewed the study?

The ethics committee of the University of Lübeck has approved the study protocol (vote of: 11.05.2022; file number: 22-162).

Data protection information

In this study, Prof. Dr. Katrin Balzer, Nursing Research Unit, Institute for Social Medicine and Epidemiology, University of Lübeck, Ratzeburger Allee 160, 23562 Lübeck, Tel.: 0451 500-52162, e-mail: Katrin.Balzer@uksh.de is responsible for data processing. The legal basis for processing your data is your personal consent (Art. 6 para. 1a, Art. 9 para. 2a DSGVO). The data will be treated confidentially at all times.

Your data will only be collected for the purpose of this study and will only be used in the context of this study.
The data also includes personal identifying data such as name, address and date of birth. All data directly related to your person will be replaced by a letter-digit combination (pseudonymised). This largely excludes the possibility of your person being identified by unauthorised persons. Your data is stored and evaluated without reference to your name, i.e. your name is not mentioned anywhere.

Your data is stored in the Nursing research unit on the server of the Science Network of the University Hospital Schleswig-Holstein, Lübeck Campus and in the Institute and Polyclinic for General Medicine on the server of the University Hospital Hamburg-Eppendorf. Paper-based data is stored in lockable and protected cabinets. Only members of the study team have access to your data. These persons are obliged to maintain confidentiality. The data is protected against unauthorised access. All data is stored for 10 years in accordance with legal regulations and deleted after this period has expired.

Monitoring of the study implementation

For the purpose of reviewing the conduct of the study, competent employees of the initiator of the study or study partners commissioned by the initiator for the purpose of reviewing the quality of the

Silies KT, *et al. BMJ Open* 2023; 13:e072955. doi: 10.1136/bmjopen-2023-072955

conduct of the study may inspect the study documents available at the study centre. This can also be done after all relevant data have already been submitted. The reviewers may be, for example, monitors or auditors. For this measure, you release the members of the study team from their duty of confidentiality.

The provisions of the General Data Protection Regulation (DSGV) are complied with. Consent to the processing of your data is voluntary, you can revoke your consent at any time without giving reasons and without disadvantages for you. You have the right to receive information about the data concerning you, also in the form of a free copy. Furthermore, you can request the correction or deletion of your data. To do so, please contact the principal investigator: Prof. Dr. Katrin Balzer (see above for contact details). Anonymously collected or anonymised data cannot be deleted in the event of revocation, however, as it is not possible to trace the data back to individuals.

If you have any queries or complaints regarding data protection, please contact the data protection officer at the University of Lübeck: x-tention Informationstechnologie GmbH, Karl- Drais-Str. 4e, 86167 Augsburg, e-mail: datenschutz@uni-luebeck.de

In the event of a complaint, you can also contact the responsible data protection supervisory authority: Independent Centre for Data Protection Schleswig-Holstein, Holstenstraße 98, 24103 Kiel, e-mail: mail@datenschutzzentrum.de.

Please do not hesitate to contact us if you have any questions!

Thank you for your interest and best regards,

Prof. Dr Katrin Balzer

UNIVERSITÄT ZU LÜBECK

UKE Institut und Poliklinik für Allgemeinmedizin

University of Lübeck
Nursing research unit
Institute for Social Medicine and Epidemiology
Ratzeburger Allee 160, 23562 Lübeck

Prof. Dr Katrin Balzer
Secretariat: Elena Teisch
Tel.: 0451 500-51261
Fax: 0451 500-51264

Informed consent for participation in the study

" Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)"

I have received, read and understood the written study information for the above-mentioned study. I was informed in detail - verbally and in writing - about the aim and the course of the study, the risks and benefits of participation, my rights and obligations and the voluntary nature of participation.
I had the opportunity to ask all my questions. These were answered satisfactorily and completely.

Surname, first name resident

Date of birth

I was informed about the study by the following person:

Surname, first name study team member

Telephone number

I hereby declare my participation in the above study. I have been informed that my participation is voluntary and that I have the right to terminate it at any time without giving reasons and without incurring any disadvantages.

I agree to the collection and storage of the data mentioned in the study information, especially the personal data. I have been informed about the possibilities of the right to information and the right to object.

I have received the study information and a copy of this consent.

Place, date

Signature Resident

Place, date

Signature study team member

Declaration of consent for residents, translation based on version 1.3, 09.07.2022

UNIVERSITÄT ZU LÜBECK

UKE Institut und Poliklinik für Allgemeinmedizin

University of Lübeck
Nursing research unit
Institute for Social Medicine and Epidemiology
Ratzeburger Allee 160, 23562 Lübeck

Prof. Dr Katrin Balzer
Secretariat: Elena Teisch
Tel.: 0451 500-51261
Fax: 0451 500-51264

Information on the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)"

(Translation based on Version 1.3, 08.07.2022)

Dear Ladies and Gentlemen,

We would like to invite the resident(s) you care for to participate in the study "Expand-Care". The study is being conducted by the Nursing research unit at the University of Lübeck and the Institute for General Practice at the University Medical Centre Hamburg Eppendorf. The study is funded by the German Federal Ministry of Education and Research (BMBF).

The study was reviewed by an independent ethics committee. This committee did not raise any objections to the conduct of this study.

The resident's participation in the study is voluntary. If the resident does not wish to participate or if you later withdraw your consent, you and the resident under your care will not suffer any disadvantages as a result.

Please read this information carefully. If you have any further questions regarding the study, please contact us, the study team:

Prof. Dr Katrin Balzer
Principle investigator
Katrin.Balzer@uksh.de
Tel.: 0451 500-52162

Katharina Silies
Research assistant
Katharina.Silies@uksh.de
Tel.: 0451 500-52161

What is the aim of this study?

The aim of this study is to find out whether nursing professionals with special additional qualifications should take on additional tasks in the care of residents in nursing homes. The aim is to improve the nursing care and health of the residents and to adapt it to their needs. The employment of nursing professionals with additional qualifications in nursing homes is now to be explored and we hereby invite the resident(s) you care for to participate.

UNIVERSITÄT ZU LÜBECK

expand care

UKE Institut und Poliklinik für Allgemeinmedizin

Who can participate in the study?

We invite residents in nursing homes to participate in the study.

In addition, they should have a care degree 3 or higher **or** have a care degree 2 and **additionally** fulfil one of the following points:

OR

- several long-lasting conditions at the same time (e.g. diabetes, high blood pressure and Alzheimer's disease).
- unplanned hospitalisation or emergency medical treatment in the last 8 weeks

What is the process of the study?

The study is being conducted in 11 nursing homes in Lübeck and Hamburg. Per nursing home, 15 residents can participate. The nursing homes are **randomly assigned to** two different groups. One group of nursing homes will receive further training, i.e. one of the facility's nursing staff will receive further training and will apply what they have learned in their nursing care and, for example, conduct structured personal conversations with residents. The other group of nursing homes receives care as usual (i.e. everything remains as before). The groups are randomly assigned, i.e. you, the nursing home and the study staff have no influence on which group the nursing home in which the resident you care for lives will be assigned to.

If you consent to participate in the study on behalf of the resident you care for, study staff will collect information of interest from the resident's file. In addition, the resident him/herself, if possible, and a caregiver of the nursing home responsible for him/her will be interviewed by a study worker on various health-related topics using a questionnaire.

This information is collected at regular intervals at a total of three points in time: at the beginning of the study, after three months and after six months. Participation in the study is expected to last a total of six months, after which the study will end. We will coordinate all appointments with the resident and the nursing staff of the facility. There will be no financial costs for you or the resident during the entire study. Participation in the study will take about 30 minutes twice for the resident. This time expenditure cannot be compensated within this study.

What data is collected from the resident?

We would like to collect the following information from the resident's file and during the survey:

- Personal data (age, sex, marital status, degree of care, care devices and whether powers of attorney or a living will are available),
- Information on physical and mental health,
- Information from the documentation of the nursing home (e.g. medical diagnoses, medication and medical care, number of falls, hospitalisations, pressure ulcers).

UNIVERSITÄT ZU LÜBECK

expand care

UKE Institut und Poliklinik für Allgemeinmedizin

Do I have to give my consent? What happens if I withdraw my consent?

Participation in this study is voluntary. The resident does not have to participate. Even after consent has been given, you can terminate the participation of the resident in the study at any time without giving reasons and without any disadvantages for you or the resident you are looking after.

Furthermore, the interview will only be carried out if the resident himself/herself has given at least verbal consent. If the resident refuses, the interview will not be conducted or will be terminated.

If you would like to withdraw your participation at a later date, please contact the principal investigator Prof. Dr. Katrin Balzer (Katrin.Balzer@uksh.de). In the event of withdrawal from the study, data already collected from the resident can be deleted if desired, provided that the data have not yet been completely anonymised (see section on data protection). In this case, a connection to the person no longer exists and deletion is therefore no longer possible.

What are the possible risks and benefits of participation?

Participation in the study is not associated with any risks for you and the resident. The applicable hygiene rules will be observed during the personal meetings. Participation in the study may have a direct benefit for the resident and for other residents of the nursing home, e.g. increased nursing care. In addition, the results of the study may help other residents in nursing homes in the future.

However, it is possible that the resident you care for will not directly benefit from participation.

What happens to the results of the study?

The findings will provide information on whether the integration of nursing professionals with expanded competencies in nursing homes leads to better care and health of the residents and should be introduced in the future. The results of the study will be presented anonymously to the general public and the professional public, e.g. in scientific journals and at congresses.

Who reviewed the study?

The ethics committee of the University of Lübeck has approved the study protocol (vote of: 11.05.22; file number: 22-162).

Data protection information

In this study, Prof. Dr. Katrin Balzer, Section for Research and Teaching in Nursing, Institute for Social Medicine and Epidemiology, University of Lübeck, Ratzeburger Allee 160, 23562 Lübeck, Tel.: 0451 500-52162, e-mail: Katrin.Balzer@uksh.de responsible for data processing. The legal basis for processing the data is personal consent (Art. 6 para. 1a, Art. 9 para. 2a DSGVO). The data will be treated confidentially at all times. The data will be collected exclusively for the purpose of this study and will only be used within the scope of this study. The data also includes personal identifying data such as name, address and date of birth. All data directly related to the person will be replaced by a letter-digit combination (pseudonymised). This largely excludes identification of the person by unauthorised persons. The data is stored and evaluated without reference to the name, i.e. the name of the resident is not mentioned anywhere.

All data are stored in the Nursing research unit on the server of the Science Network of the University Hospital Schleswig-Holstein, Lübeck Campus and in the Institute and Polyclinic for General Medicine on the server of the University Hospital Hamburg-Eppendorf. Paper-based data is stored in lockable and protected cabinets. Only members of the study team have access to the data. These persons are obliged to maintain confidentiality. The data is protected against unauthorised access. All data is kept for 10 years and deleted after this period.

Monitoring of the study implementation

For the purpose of reviewing the conduct of the study, competent employees of the initiator of the study or study partners commissioned by the initiator for the purpose of reviewing the quality of the conduct of the study may inspect the study documents available at the study centre. This can also be done after all relevant data have already been submitted. The reviewers may be, for example, monitors or auditors. For this measure, you release the members of the study team from their duty of confidentiality.

The provisions of the General Data Protection Regulation (DSGV) are complied with. Consent to the processing of data is voluntary; you can revoke your consent at any time without giving reasons and without disadvantages for yourself or the resident. You have the right to receive information about the relevant data of the resident(s) looked after by you, also in the form of a free copy. Furthermore, you can request the correction or deletion of the data. To do so, please contact the head of the study: Prof. Dr. Katrin Balzer (see above for contact details). Anonymously collected or anonymised data cannot be deleted in the event of revocation, however, as it is not possible to trace the data back to individual persons.

If you have any queries or complaints regarding data protection, please contact the data protection officer at the University of Lübeck: x-tention Informationstechnologie GmbH, Karl- Drais-Str. 4e, 86167 Augsburg, e-mail: datenschutz@uni-luebeck.de. In the event of a complaint, you can also contact the competent data protection supervisory authority: Independent Centre for Data Protection Schleswig-Holstein, Holstenstraße 98, 24103 Kiel, e-mail: mail@datenschutzzentrum.de.

Please do not hesitate to contact us if you have any questions!

Thank you for your interest and best regards,

Prof. Dr Katrin Balzer

UNIVERSITÄT ZU LÜBECK

UKE Institut und Poliklinik für Allgemeinmedizin

University of Lübeck
Nursing research unit
Institute for Social Medicine and Epidemiology
Ratzeburger Allee 160, 23562 Lübeck

expand care

Prof. Dr Katrin Balzer
Secretariat: Elena Teisch
Tel.: 0451 500-51261
Fax: 0451 500-51264

Informed consent for participation in the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)".

I have received, read and understood the written study information for the above-mentioned study. I was informed in detail - verbally and in writing - about the aim and the course of the study, the risks and benefits of participation, my rights and obligations and the voluntary nature of participation. I had the opportunity to ask all my questions. These were answered satisfactorily and completely.

Surname, first name guardian/ Authorised representative _____ Date of birth _____

I was informed about the study by the following person:

Surname, first name study team member _____ Telephone number _____

I hereby declare the participation of the resident(s) in my care:

Surname, first name resident _____ Date of birth _____

in the above-mentioned study. I have been informed that participation is voluntary and that I have the right to terminate it at any time without giving reasons and without any disadvantage to me or the resident.

I agree to the collection and storage of the data mentioned in the study information, especially the personal data. I have been informed about the possibilities of the right to information and the right to object.

I have received the study information and a copy of this consent.

Place, date _____ Signature of guardian/ Authorised representative _____

Place, date _____ Signature study team member _____

Declaration of consent of guardian and authorised representative. Translation based on Version 1.3, 08.07.2022