BMJ Open

Improving professional health literacy in hospitals: study protocol of a participatory codesign and implementation study

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To cite: Lubasch JS, Voigt-Barbarowicz M, Lippke S, *et al*. Improving professional health literacy in hospitals: study protocol of a participatory codesign and implementation study. *BMJ Open* 2021;**11**:e045835. doi:10.1136/bmjopen-2020-045835

► Prepublication history and additional online supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-045835).

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Received 13 October 2020
Accepted 13 July 2021

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ABSTRACT

Introduction In connection with a hospital stay, patients have to make important health-related decisions. They need to find, understand, assess and apply health-related information, and therefore, require health literacy. Adequately responding to the needs of patients requires promoting the communication skills of healthcare professionals within healthcare organisations. Health-literate healthcare organisations can provide an environment strengthening professionals' and patients' health literacy. When developing health-literate healthcare organisations, it has to be considered that implementing organisational change is typically challenging. In this study, a communication concept based on previously evaluated communication training is codesigned, implemented and evaluated in four clinical departments of a university hospital.

Method and analysis In a codesign phase, focus group interviews among employees and patients as well as a workshop series with employees and hospital management are used to tailor the communication concept to the clinical departments and to patients' needs. Also, representatives responsible for the topic of health literacy are established among employees. The communication concept is implemented over a 12-month period; outcomes studied are health literacy on the organisational and patient levels. Longitudinal survey data acquired from a control cohort prior to the implementation phase are compared with data of an intervention cohort after the implementation phase. Moreover, survey data from healthcare professionals before and after the implementation are compared. For formative evaluation, healthcare professionals are interviewed in focus groups.

Ethics and dissemination The study protocol was approved by the Ethics Committee of the Medical Faculty of the University of Oldenburg and is in accordance with the Declaration of Helsinki. Study participants are asked to provide written informed consent. The results are disseminated via direct communication within the hospital, publications and conference presentations. If the intervention turns out to be successful, the intervention and implementation strategies will be made available to other hospitals.

Trial registration number DRKS00019830.

Strengths and limitations of this study

- Co-design with healthcare professionals to develop a communication concept.
- Mixed-methods study using qualitative and quantitative methods for exploring patients' and professionals' needs and experiences.
- Implementation of the intervention at the organisational level is a strength; however, at the same time, randomisation is not possible, and therefore, no causal conclusions can be drawn.
- Results may not fully apply to patients with particularly low health literacy because self-administered surveys requiring literacy are used, thus a validation of the results is required in the future.
- Participant recruitment and concept implementation are vulnerable to the impact of the COVID-19 pandemic.

INTRODUCTION

During a hospital stay, patients have to make important health-related decisions. Therefore, they need to find, understand, assess and apply health-related information and thus require adequate health literacy. However, research in eight European countries has shown that 47% of participants (in Germany, even 54%) have problematic or insufficient health literacy.[1 2] Health literacy levels seem to vary depending on sociodemographic characteristics such as sex,[3] education,[1] socioeconomic status[4] and migration status.[5] Furthermore, lower health literacy is associated with higher health risks as well as worse patient-reported and health-related

outcomes.[6] It is widely recognised that health literacy is based on the personal competencies and skills of each individual, but also depends on the demands and complexity of healthcare systems, organisations and living environments.[7]

Health action

Germany's National Action Plan for Health Literacy[7] proposes central strategies for promoting health literacy. Since communication and information deficits are prevalent in healthcare, the action plan calls for, inter alia, improving communication between health professionals and patients.[7] Identified problems encompass for example, the use of specialist jargon, lack of time, and a missing or incorrect assessment of patients' health literacy levels.[7 8] By facilitating healthcare professionals' understanding of health literacy as well as by training healthcare professionals' communications skills, patient health literacy can be improved and low levels of health literacy of patients can be compensated by adequate communication.[9] According to Kickbusch *et al.*,[9] 'professionals need to tailor their communication to meet the needs of their patients and see it as their responsibility to foster their health literacy' (p. 16). Apart from this, improving the health literacy of patients requires not only behavioural changes in healthcare professionals, but also wider changes within healthcare organisations.[8] The concept of a Health-Literate Healthcare Organisation (HLHO)[10] emphasises that health literacy principles need to be integrated into organisational objectives, infrastructure, policies and practices, workforce development and communication strategies. If this is achieved, HLHO can make it easier for patients to find, understand and use information and healthcare services in order to take care of their own health.[10] Also, these organisations will have created conditions which are conducive to a good professional–patient communication.

According to a review,[11] the success of organisation-wide complex interventions for quality improvement in patient care is often limited by implementation hurdles. Only about 50% of all quality improvement initiatives studied were actually successfully implemented. Due to the lack of consideration of contextual conditions, complex interventions such as interventions to promote a HLHO are often difficult to integrate into everyday clinical practice.[12] Implementation research therefore focuses on successful strategies for implementing evidence-based interventions in healthcare. Codesign is a participatory approach to the development of interventions that brings together staff and patient experience[13] and has been successfully implemented in a hospital setting by Jessup *et al.*[14] Codesigning interventions and implementation strategies with members of the target group within healthcare organisations can increase implementation success by addressing needs and capacities, identifying barriers and facilitators as well as by fostering organisational change processes.[14–16]

Principles of the intervention

The intervention encompasses a communication concept consisting of two parts: On the one hand, codesigned communication training for healthcare professionals will be implemented. On the other hand, codesigned supporting measures will be implemented in the hospital environment to improve the conditions for good communication.

Communication training

The communication training within the presented PIKoG study (As made for us—Improving professional health literacy in hospitals) is based on training units that were developed and evaluated in two previous projects. The original communication training was developed to promote health professionals' knowledge and understanding of health literacy in their patients within the EU study Intervention Research On Health Literacy among Ageing population (IROHLA), which has been successfully piloted in different European countries.[17] Results from the pilot study suggest that participation in this training subjectively improved healthcare professionals' knowledge about health literacy, understanding of health literacy needs, and awareness of the use of jargon. Moreover, the training improved patients' self-efficacy and resulted in enhanced patient autonomy in the decision making. One of the strengths of this training programme is the diversity of teaching methods used, which have been agreed on among health experts.[17 18] Within the EU study IMproving PAtient Centred Communication CompeTences (IMPACCT), the training was adapted to train medical students and nurses.[19 20] This communication training, which was previously developed in the IROHLA study and modified in the IMPACCT study, will now build the basis for the co-designed communication training in the presented PIKoG study. In the present study, adaptation to the needs and capacities of hospital employees is achieved in close collaboration with employees with regard to two aspects: the content of the communication training as well as the framework conditions of the training (length, timing, frequency, didactic methods). The training of the present study is conducted by experienced trainers. The research team responsible for evaluation is independent from the communication training team.

Supporting measures

The 10 attributes of a health-literate organisation according to Brach *et al.* offer a conceptual orientation for the development of the supporting measures, which are implemented in addition to the training.[10] Possible supporting measures might include the adaptation of the hospital mission statement, integration of the health literacy topic into existing quality management processes,[21] placement of posters and other information materials on the wards, providing easy access to health information and services, or designing and distributing

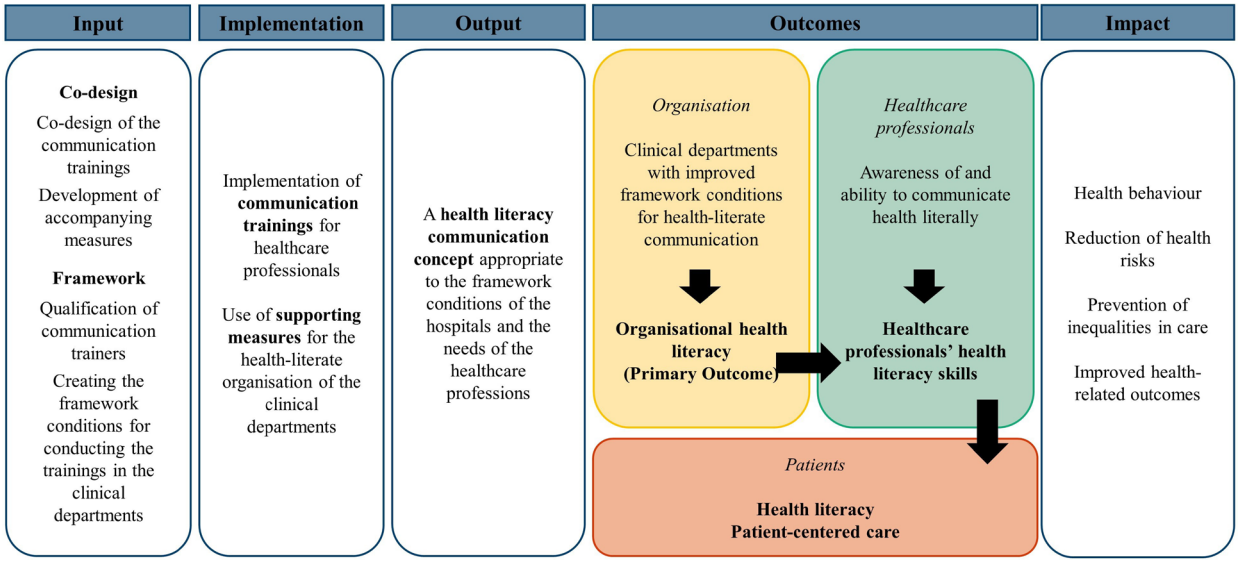

Figure 1 Logic model of the communication concept.

print, audiovisual and social media content that is easy to understand and act on.[10]

Aim of the study

The aim of the study is to codesign, implement and evaluate a communication concept for clinical departments of a hospital. The communication concept aims to improve health literacy at the levels of the healthcare organisation, healthcare professionals and patients.

METHOD AND ANALYSIS

Logic model of the study

The logic model (figure 1) that guides the evaluation of the communication concept was developed on the basis of the Medical Research Council Framework for the evaluation of complex interventions.[22] Organisational health literacy as the primary outcome is assessed from two perspectives, namely the healthcare professionals' perspective and the patient perspective.

Study location

The study is conducted in acute inpatient care at a university hospital. This non-profit general hospital in northwestern Germany offers approximately 400 beds. Four out of eleven clinical departments of this hospital (oncology, gynaecology, orthopaedics and visceral surgery) are participating in the study. The following are the main diagnoses treated at the four clinical departments: hip and knee disorders requiring joint replacement (approx. 750 cases annually), primary breast carcinoma (approx. 300 cases annually), gynaecological tumours (approx. 100 cases annually), lung carcinoma (approx. 100 inpatient cases annually), gastrointestinal tract disorders requiring surgery (approx. 150 cases annually), pancreas disorders requiring surgery (approx. 50 cases annually) and complicated hernias requiring surgery (approx. 35 cases annually). The 3-year study is conducted from October 2019 to September 2022.

Study design

The study is conducted in three (partly parallel) phases (see figure 2). In the development phase, a communication concept is designed using a participatory approach. In the implementation phase, this communication concept is implemented in the hospital setting. In the evaluation phase, effectiveness as well as the implementation process is examined in order to identify mechanisms of action and contextual factors.[22] The study design entails a quantitative pre–poststudy of experiences and outcomes in patients and healthcare professionals. The formative evaluation uses qualitative methods.

Development phase

The communication concept—communication training as well as supporting measures—is codesigned with the support of healthcare professionals providing acute inpatient care in different departments of one hospital. This approach takes into account the local context; it allows solutions to be developed that meet the needs of healthcare professionals and are more likely to be acceptable to them and therefore to be adopted and sustained.[23]

Hospital leaders as change agents

At the beginning of the study, meetings are held with healthcare professionals in leadership positions within the hospital and the clinical departments, who are identified as change agents in a position to drive change. These meetings aim at raising awareness and interest in the study, discussing roles and responsibilities within this study and developing a cooperation agreement. Throughout the study, steering board meetings with these partners are regularly conducted to create a sense of ownership of the study and to coordinate tasks.

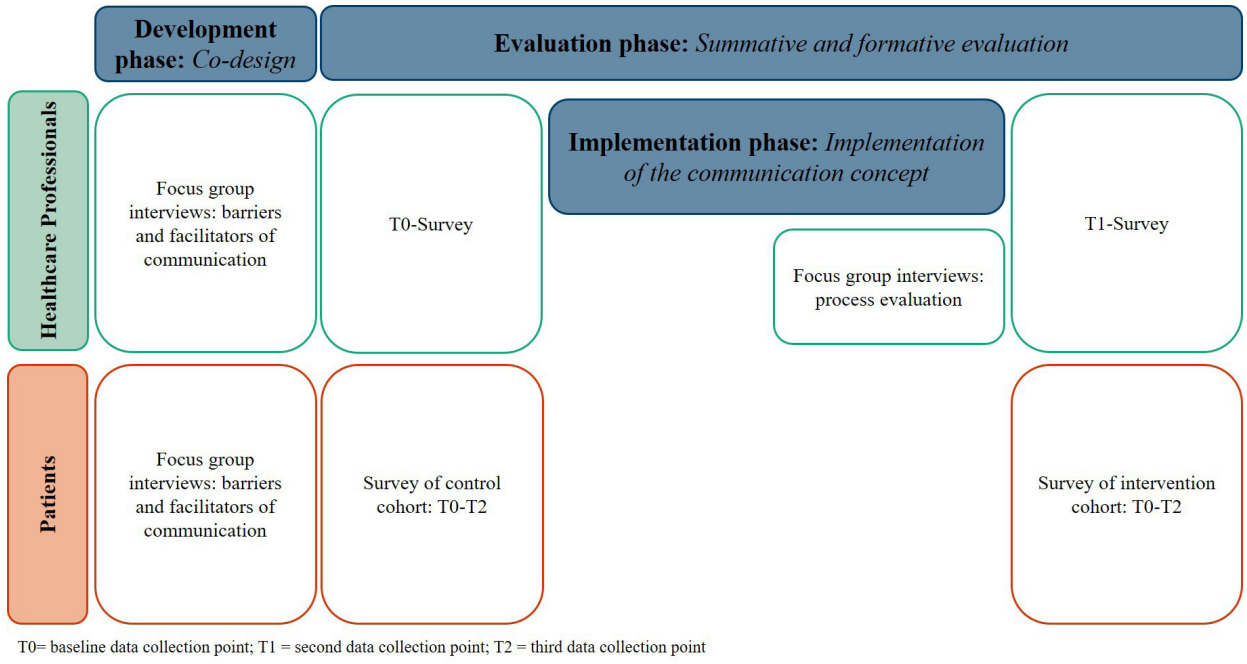

Figure 2 Study design.

Focus group interviews on barriers and facilitators of health literacy-sensitive communication

Focus group interviews (k=4 with healthcare professionals and k=4 with patients, total k=8) are carried out separately for each of the four participating clinical departments (see figure 2). Per participating clinical department, one focus group interview is conducted with healthcare professionals and another with patients treated in the respective department. These interviews aim to identify needs as well as barriers and facilitators to health literacy-sensitive communication (HL-COM) from the perspectives of healthcare professionals and patients. Following existing standards,[24–27] a semistructured interview guideline is developed for interviews with both healthcare professionals and patients on needs as well as barriers and facilitators based on their experience. The interview guideline (see online supplemental appendix) is developed based on the framework for patient–professional communication of Feldman-Stewart *et al*.[28] The framework emphasises that the communication between patients and healthcare professionals is influenced by individual characteristics as well as by characteristics of the conversational environment. Focus group discussions are held in German language. To enable the participation of patients without fluent German—a particularly vulnerable group of persons concerning health literacy—translators are asked to accompany those participants. To facilitate valuable discussions, 60–90 min of discussion are aimed at. Group discussions are moderated by two researchers.

Recruitment for the focus group interviews is based on purposeful sampling to cover different facets and perspectives of the discussed aspects. Hospital employees are approached by the hospitals leaders ('change agents'). Potential participants are then approached by the research team, which provides more information and asks them for written informed consent. Patients are recruited by the research team on the wards on the day the focus group is scheduled. Therefore, patients are informed about the study on the ward and then asked for written informed consent. The focus group interviews (k=4 with n=6–8 persons) with healthcare professionals are heterogeneous in terms of professional groups, sex and age. Healthcare professionals in this study are defined as physicians, nurses, physiotherapists, employees of the psycho-oncological service, social service personnel as well as central patient information staff. Patient focus groups (k=4 with n=6–8 persons) are heterogeneous in terms of sex and age as well as education and migration status[2] in order to consider potential health literacy differences.

Employee workshops and facilitator workshops

Methods of organisational development, typically carried out in a participatory workshop format, are used to codesign the communication concept.[16] In a participatory format, three employee workshops are conducted to which all healthcare professionals (as defined above) are invited. In the first employee workshop (kick-off), the study goals and approaches are explained to raise awareness and to identify needs. In the second employee workshop, the developed communication concept is discussed to identify potential deficits, while in the third employee workshop, study results are presented and discussed.

Moreover, each participating clinical department is asked to nominate two representatives ('health literacy facilitators') for the duration of the study. Representing different healthcare professional groups, they are asked

to steer and accompany the codesign and implementation process as multipliers in order to achieve the highest possible reach and acceptance in the departments. Therefore, health literacy facilitators as well as patient representatives (recruited via self-help groups with contact to the clinics) are invited to four facilitator workshops in a participatory format in order to monitor and reflect on the implementation process. To further integrate the patient perspective, patient advocates are invited to participate in the workshops. Patient advocates are volunteers in the hospital who act as contacts for patients' and relatives' concerns and are bound to professional secrecy. Focus group participants with interest in the topic can also serve as health literacy facilitators. In the first facilitator workshop, the needs, barriers and facilitators derived from the focus group interviews are presented and jointly discussed to inform the design of the communication concept. In the second facilitator workshop, the designed communication concept is explained and discussed. In the third facilitator workshop, the specific content and the framework conditions of the communication training (duration, timing, frequency, didactic methods) as well as the supporting measures are discussed, and the communication concept is finalised. In the fourth facilitator workshop, the (interim) study results as well as the needs for improvement derived from the formative evaluation are discussed.

Implementation phase

The codesigned communication concept will be implemented over the course of a year. The communication training as the central part of the communication concept is offered repeatedly to the healthcare professionals in order to achieve a wide reach within the departments. The training incorporates interactive teaching methods already piloted in IROHLA and IMPACCT, such as case studies, vignettes and role plays.[29] To allow constant improvement of the communication training, participants are asked to evaluate each session. In addition to the communication training, supporting measures are to be implemented. In order to increase the use of the supporting measures, they are repeatedly introduced and explained during the communication training sessions. Since the intervention is not fixed beforehand but codesigned together with the healthcare professionals over the course of the study, details cannot be provided at this time.

Evaluation phase

Sample

Patient survey

Patients are eligible for inclusion in the study if they are (1) older than 18 years of age, (2) hospitalised for at least two nights in one of the four participating clinical departments and (3) able to fill in the questionnaires in one of the available languages (i.e., German, English, Russian, Turkish or Polish), either alone or with the support of a friend or relative. Moreover, the study team offers help with filling in the questionnaire to facilitate the participation of illiterate or semiliterate patients. Assignment to the intervention or control cohort is determined by the patients' treatment period. Patients treated as inpatients in the clinical departments in the last 6 months prior to the start of the implementation phase are recruited for the control cohort. The intervention cohort is composed of all inpatients treated in the clinical departments in the 6 months after the end of the implementation phase. All patients are surveyed longitudinally: at hospital admission (T0), at hospital discharge (T1) and at a 3-month follow-up after discharge (T2).

Based on the annual patient volume of the clinical departments, n=743 patients can potentially be included in each of the two cohorts. In consideration of non-response, we assume that n=500 patients per cohort can be recruited.

Healthcare professional survey

All healthcare professionals of the four participating clinical departments are invited to participate in this study. In addition, healthcare professionals from central facilities, namely physiotherapy, psycho-oncological service, social service and patient information staff, are invited. Healthcare professionals are included if they have routine contact with patients being treated in one of the participating clinical departments. Participation requires sufficient knowledge of the German language (ability to read and complete the consent form and questionnaire). All eligible healthcare professionals (n=240) are surveyed prior to implementation of the intervention and after the intervention. A survey response rate of 50% can be assumed.

Healthcare professional focus group interviews

For the formative evaluation, one focus group interview is held for each of the participating clinical departments, with each focus group being heterogeneously composed of different healthcare professionals according to the criteria of purposeful sampling: physicians, nurses, physiotherapists, employees of the psycho-oncological service or social service as well as patient information staff.

Recruitment

Patient recruitment at hospital admission is handled by the research team. Recruitment of healthcare professionals is carried out with the help of supervisors in the clinical departments and in central facilities within the hospital.

Patient survey

Patients treated as inpatients in the clinical departments in the last 6 months prior to the start of the implementation phase are recruited for the control cohort. The intervention cohort is composed of all inpatients treated in the clinical departments in the 6 months after the end of the implementation phase. To ensure representativeness and comparability of both groups, all patients admitted to the hospital during each of the 6 months are asked

to participate. For the patient survey of the intervention and control cohorts, the research team recruits eligible patients on the day of their admission. Care is taken to choose a time when patients are not exposed to increased stress due to the admission processes. A suitable time is determined individually for each clinical department. Patients are given verbal and written information about the study and are asked to give their written consent.

For both the control group and the intervention group, the baseline questionnaire (T0) is handed out, and patients are asked to return the completed questionnaire in a sealable envelope as soon as possible during the first days of their hospital stay. All study documents are explained to potential participants verbally. For patients having difficulties understanding the documents particular time is taken to explain the study, help is offered to fill in the documents together and if possible, support is sought from accompanying persons. For non-German speakers, the study documents are offered in the most common foreign languages in Germany and if needed translators from within the hospital are consulted. The day before their discharge, patients receive the T1 questionnaire and are asked to complete and submit it in a sealable envelope before their discharge. The 3-month follow-up questionnaire (T2), including a stamped return envelope, is sent to the patients' home address by regular mail, with up to two reminders being sent out.[30]

Healthcare professional survey

For the healthcare professional survey, all eligible healthcare professionals are provided with written study information, a consent form and the questionnaire. Material provision is handled via their supervisors to increase the likelihood of study participation. Participants are asked to return the completed consent forms and questionnaires in sealable envelopes to mailboxes in the hospital. Employees are reminded to participate in the survey via posters attached to the mailboxes.

Healthcare professional focus group interviews

Healthcare professionals are contacted via their supervisors, scientific employees of the participating departments as well as the health literacy facilitators of the study and asked if they are interested to participate. Potential participants are then approached by the research team to inform them about the study and to ask for their written consent. Some workshop participants are also invited to participate in focus groups, if they showed interested. However, the overlap of persons participating in workshops and focus groups is desired to be limited to get additional insights.

Measures

Patient survey

Patient surveys include already validated measurement instruments (if available) as well as instruments adapted to the target group and self-developed items (see table 1).

Organisational health literacy as the primary outcome is assessed by means of a patient survey using a validated questionnaire to assess HL-COM.[31] Attributes of a HLHO are measured by means of 16 items (Cronbach's alpha=0.91).[31] The general health literacy of patients measured using the German version of the Health Literacy Questionnaire[32] is chosen as a secondary outcome (Cronbach's alpha=0.77–0.91).[33 34] As a further secondary outcome, patient-centred care is measured using the subscales 'appropriate communication' and 'personalised information', which were developed and are currently being validated in the ASPIRED study (Assessment of patient centredness through patient-reported experience measures).[35]

In this context, a limiting factor of the study is that these instruments have not been validated for patients with particularly low health literacy.

In the intervention cohort the questionnaires include items on the reach of the intervention[22] at T1, which are developed based on the actual communication concept to be implemented.

The following sociodemographic and disease-related patient characteristics are collected as context information and potential confounders: sex, age group, education, employment situation, migration status, mother tongue, duration of contact with the German language, chronic diseases, insurance status, disabilities (acquired or congenital), disability severity and degree, healthcare utilisation, diagnosis as indication for hospital stay, duration of hospital stay, transfer between wards, surgery during hospital stay and participation in another study during the hospital stay.

Healthcare professional survey

Healthcare professional surveys include already validated measurement instruments as well as instruments adapted to the target group and self-developed items (see table 1). As the primary outcome, organisational health literacy from the perspective of healthcare professionals is measured using the HLHO 10-item questionnaire (HLHO-10), which was validated using a sample of key persons in hospitals and is available in German (Cronbach's alpha=0.89).[36] The usability of the HLHO-10 to assess change over time has still be proven. Self-reported communication skills as a secondary outcome are measured by an instrument designed by Mackert *et al.*, which consists of 13 items each to be completed before and after communication training.[37] It covers perceived basic knowledge of health literacy, ability to deal with individuals of low health literacy and frequency of use of different communication techniques. The instrument is being translated from English to German.

As part of the formative evaluation, questions regarding the achievement of interventional reach, dose and fidelity[22] are developed after the communication concept has been finalised. Therefore, items are included to assess the use of the supporting measures for communicating health-related information.

Table 1 Data collection and analysis methods of the summative and the formative evaluation

	Data collection methods	Time points	Content	Measurement instruments	Data analysis
Summative evaluation	Survey of patients Control cohort: n=500 patients Intervention cohort: n=500 patients	T0—baseline: when admitted to hospital T1—follow-up: when discharged from the hospital T2—follow-up: 3 months after discharge from the hospital	Primary endpoint: organisational health literacy Secondary endpoints: health literacy, patient-centred care	HL-COM[31] HLQ (German version)[32–34] Scales 'appropriate communication' and 'personalised information'[35]	1. Descriptive statistics 2. Comparison of intervention and control cohort 3. Multivariable regression analysis, controlled for possible confounders
	Survey of healthcare professionals *n*=approx. 240 employees; assumed participation and response rate of 50%	T0—before implementation T1—after implementation	Primary endpoint: organisational health literacy Secondary endpoint: communication skills	HLHO-10[36] pre/post questionnaire of Mackert *et al*.[37]	1. Descriptive statistics 2. Comparison between T0 and T1 data 3. Multivariable regression analysis, controlled for possible confounders
Formative evaluation	Survey of patients Intervention cohort: n=500 patients	T1—follow-up: when discharged from the hospital	Interventional reach[22]	Use of the supporting measures	1. Descriptive statistics 2. Stratified subgroup analyses
	Survey of healthcare professionals *n*=approx. 240 employees	T1—after implementation	Interventional reach, dose and fidelity[22]	Use of the supporting measures No of training sessions Participation rates Evaluation of training sessions	1. Descriptive statistics 2. Stratified subgroup analyses
	Qualitative focus group interviews with healthcare professionals k=4 focus group interviews with n=4–8 participants	In the course of the implementation	Experiences with the training courses and the supporting measures; potential changes in communication about health information with patients; need for improvement of the intervention	Development of a semi-structured guideline based on the research question, a literature review and standards for the preparation of interview guidelines[24–27 41]	Transcription, qualitative structured content analysis[42 43] to break down the complexity of the material and identify categories

HL-COM, health literacy-sensitive communication; HLQ, Health Literacy Questionnaire.

The following sociodemographic data are collected as potential confounders: sex, age group, mother tongue, German language skills, languages which can be used to communicate with patients, highest educational attainment, employment situation, profession, work experience, percentage of working time spent caring for patients, clinical department, participation in training courses during the last year (with and without communication content).

Quality assurance during study execution is safeguarded by the standards of questionnaire development,[38 39] pretesting,[40] the total design method to increase response rates[30] and data processing with the Teleform software (V.16.5.1, Electric Paper Informationssysteme,

Lueneburg, Germany). When pretesting the study materials (questionnaires and other documents) care is taken that materials are tested with persons of different health literacy levels to prevent the exclusion of persons with low health literacy.

Healthcare professional focus group interviews

For formative evaluation, guideline-based focus group interviews are conducted. The focus group interviews will be led by two researchers according to a semistructured interview guideline and will last up to 90 min.[24–27] The interview guideline for focus group interviews is developed following the existing standards,[24 41] study objectives and research questions of the study. Topics are the evaluation of the communication training structure (frequency, duration, didactic realisation), the content of the communication training as well as the supporting measures.

Participation rates and evaluation of the communication training

As part of the formative evaluation, information is collected on the number of communication training sessions conducted and the number of training sessions each healthcare professionals attended. Additionally, every communication training session is evaluated by participants using a short questionnaire.

Data analysis

Patient survey

For the summative evaluation, collected patient survey data of the intervention cohort are compared with the control cohort by using multivariable regression analysis. Possible confounders (e.g., age, sex, diagnosis, comorbidity) are controlled for within the analyses. Collected survey data for the formative evaluation, which refer only to the patient intervention cohort, are analysed, with stratified analyses being conducted for subgroups of patients. Potential differences between the recruited cohorts at T0 will be analysed and adjusted for (e.g., propensity scores).

Healthcare Professional Survey

For summative evaluation, survey data from healthcare professionals prior to the implementation of the intervention are compared with data collected after the intervention using multivariable regression analysis, controlling for possible confounders (eg, profession, work experience). Since the individual survey participants before vs after the intervention are expected to differ to some extent (due to fluctuation, rotation and non-responders), the data are primarily treated as cross-sectional rather than longitudinal within the analysis.

All derived effects are calculated with 95% CIs and corrected for multiple testing. To handle missing data, multiple imputation is conducted.

Healthcare professional focus group interviews

Focus group interview data are analysed by structured qualitative content analysis according to Kuckartz.[42] Therefore, audiorecordings are first transcribed verbatim and pseudonymised according to transcription standards.[43] First, main categories derived a priori from the interview guideline are developed deductively. Transcripts are then coded and subcategories inductively formed during the coding process. The computer-aided coding of text segments into categories is performed using the programme MAXQDA Analytics Pro (V.2020, VERBI, Berlin, Germany). The entire coding process is conducted by two independent coders, followed by discussions to establish consensus.

Patient and public involvement

Our codesign approach is focused primarily on healthcare professionals since the intervention primarily addresses healthcare professionals and their experiences with patients. In addition, patients are consulted explicitly at different stages of the study. At the beginning of the study, patients as well as healthcare professionals are interviewed about factors that hinder or facilitate HL-COM as well as their needs for improving communication. The results serve as a basis for workshops that are held with healthcare professionals as well as at least one patient advocate in order to select communication training contents and to design supporting measures.

To ensure that the planned measures can be implemented, the hospital's education management, marketing communication as well as quality management areas are also included in the planning and facilitation process. To facilitate patient participation in the study, the division managers of the wards are also contacted and asked about optimal recruitment times and strategies.

ETHICS AND DISSEMINATION

Ethical considerations

The study is conducted in accordance with the Declaration of Helsinki in its current version (World Medical Association, 2013). A study protocol was approved by the Ethics Committee of the Medical Faculty of Oldenburg before the study started. All study participants are asked to provide written informed consent based on current data protection regulations. All study participants are informed that participation in the study is voluntary. All personal identifiers are pseudonymised. Data security has been approved by all institutions involved in data collection. The identifying data are stored separately from the research data.

Dissemination plan

Study results will be summarised in a final report. Moreover, the results will be disseminated in the international scientific community via publications and conference presentations. If the intervention turns out to be successful, the aim is to ensure widespread use of the communication training and to provide a selection of supporting measures to other hospitals. Since the communication concept is implemented in the cooperating clinical departments, patients will be directly affected by and hopefully benefit from some of the supporting measures

(eg, easily understandable information leaflets). With regard to study results, posters to be presented in the clinical departments and a press note will be released.

COVID-19-SPECIFIC ASPECTS

The coronavirus COVID-19 pandemic will influence the conduct and time schedule of the study. Some elements of data collection and possibly the intervention start will have to be postponed by a few months. An extension of the study duration and parallel planning of alternative ways for data collection (eg, using online tools) will ensure the achievement of the study aims. This may, however, result in an adaption of the concrete steps described in the original study protocol.

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Contributors LA, ALB and SL have contributed to the development of this protocol and applied for research funding. LA, ALB and SL developed the analytical strategy and overall methodology, and JSL, MV-B, RLDW, FG, DL, PCOV, JR, DS, GHS, L-AT-d-I-R and DW contributed to designing the study. JSL, MV-B, LA and ALB designed data collection tools and defined the sampling criteria. JSL and MV-B wrote the first andfinal drafts of the protocol. LA, ALB and SL revised all sections of the manuscript and are guarantors. JSL, MV-B, SL, RLDW, FG, DL, PCOV, JR, DS, GHS, L-AT-d-I-R, DW, LA and ALB have read, revisedand approved the final manuscript.

Funding The study is funded by the Federal Ministry of Health on the basis of a resolution of the German Bundestag (grant no. 2519FSB519).

Disclaimer The funder receives all reports but has no ultimate authority over any of these activities, securing good scientific practice and independence of the researchers.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES

1 Sørensen K, Pelikan JM, Röthlin F, *et al*. Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). *Eur J Public Health* 2015;25:1053–8.
2 Schaeffer D, Berens E-M, Vogt D. Health literacy in the German population. *Dtsch Arztebl Int* 2017;114:53–60.
3 Clouston SAP, Manganello JA, Richards M. A life course approach to health literacy: the role of gender, educational attainment and lifetime cognitive capability. *Age Ageing* 2017;46:493–9.
4 Heide vander I, Rademakers J, Schipper M. Health literacy of Dutch adults: a cross sectional survey. *Bmc Public Health* 2013;13:1–11.
5 Brand H, Naus T. Health literacy in Eu immigrants: a systematic review and integration of interventions for a comprehensive. *Eur J Public Health* 2016;26.
6 Berkman ND, Sheridan SL, Donahue KE, *et al*. Low health literacy and health outcomes: an updated systematic review. *Ann Intern Med* 2011;155:97–107.
7 Schaeffer D, Hurrelmann K, Bauer U, eds. *National Action Plan Health Literacy. Promoting Health Literacy in Germany*. Berlin: KomPart, 2018.
8 Ansmann L, Wirtz M, Kowalski C, *et al*. The impact of the hospital work environment on social support from physicians in breast cancer care. *Patient Educ Couns* 2014;96:352–60.
9 Kickbusch I, Wait S, Maag D. *Navigating health: the role of health literacy*. Alliance for Health and the Future, 2005.
10 Brach C, Keller D, Hernandez L, *et al*. Ten attributes of health literate health care organizations. *NAM Perspect* 2012;02.
11 Alexander JA, Hearld LR. The science of quality improvement implementation: developing capacity to make a difference. *Med Care* 2011;49 Suppl:S6–20.
12 Damschroder LJ, Aron DC, Keith RE, *et al*. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50.
13 Dawda PKA. Experience Based Co-design: a toolkit for Australia. In: *Prestantia health*. Canberra, 2017.
14 Jessup RL, Osborne RH, Buchbinder R, *et al*. Using co-design to develop interventions to address health literacy needs in a hospitalised population. *BMC Health Serv Res* 2018;18:989.
15 Baker R, Camosso-Stefinovic J, Gillies C, *et al*. Tailored interventions to address determinants of practice. *Cochrane Database Syst Rev* 2015;4:CD005470.
16 Schiersmann C. *Organisationsentwicklung.Prinzipien und Strategien von Veränderungsprozessen*. Wiesbaden: Springer VS, 2014.
17 Kaper MS, Sixsmith J, Koot JAR, *et al*. Developing and pilot testing a comprehensive health literacy communication training for health professionals in three European countries. *Patient Educ Couns* 2018;101:152–8.
18 Kaper MS, Winter AFde, Bevilacqua R, *et al*. Positive outcomes of a comprehensive health literacy communication training for health professionals in three European countries: a multi-centre pre-post intervention study. *Int J Environ Res Public Health* 2019;16. doi:10.3390/ijerph16203923. [Epub ahead of print: 15 Oct 2019].
19 Kaper MS, Reijneveld SA, van Es FD, *et al*. Effectiveness of a comprehensive health literacy consultation skills training for undergraduate medical students: a randomized controlled trial. *Int J Environ Res Public Health* 2019;17. doi:10.3390/ijerph17010081. [Epub ahead of print: 20 Dec 2019].
20 Welp A, Lippke S. Der gesundheitskompetente patient. *Pflege Z* 2020;73:34–7. doi:10.1007/s41906-020-0737-4
21 Bonaccorsi G, Romiti A, Ierardi F, *et al*. Health-Literate healthcare organizations and quality of care in hospitals: a cross-sectional study conducted in Tuscany. *Int J Environ Res Public Health* 2020;17. doi:10.3390/ijerph17072508. [Epub ahead of print: 06 Apr 2020].
22 Moore GF, Audrey S, Barker M, *et al*. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015;350:h1258.
23 Sanders EB-N, Stappers PJ. Co-Creation and the new landscapes of design. *CoDesign* 2008;4:5–18. doi:10.1080/15710880701875068
24 Morgan DL. *Focus groups as qualitative research*. 2nd edn. Thousand Oaks, Calif: Sage Publ, 2009.
25 Krueger RA, Casey MA. *Focus groups: a practical guide for applied research*. California: SAGE publications, Inc, 2009.

26 Flick U. *An introduction to qualitative research*. 5th edn. Los Angeles: Sage, 2014.
27 Helfferich C. *Die Qualität qualitativer Daten*. 4th edn. Wiesbaden: VS Verlag für Sozialwissenschaften / Springer Fachmedien Wiesbaden GmbH, Wiesbaden, 2011.
28 Feldman-Stewart D, Brundage MD, Tishelman C, *et al*. A conceptual framework for patient-professional communication: an application to the cancer context. *Psychooncology* 2005;14:801–9.
29 UMCG Groningen. *Impact Interim/Progress report 2018*. Groningen, NL, 2018.
30 Dillman DA. *Mail and telephone surveys: the total design method*. New York: Wiley, 1978.
31 Ernstmann N, Halbach S, Kowalski C, *et al*. Measuring attributes of health literate health care organizations from the patients' perspective: development and validation of a questionnaire to assess health literacy-sensitive communication (HL-COM). *Z Evid Fortbild Qual Gesundhwes* 2017;121:58–63.
32 Osborne RH, Batterham RW, Elsworth GR, *et al*. The grounded psychometric development and initial validation of the health literacy questionnaire (HLQ). *BMC Public Health* 2013;13:658.
33 Nolte S, Osborne RH, Dwinger S, *et al*. German translation, cultural adaptation, and validation of the health literacy questionnaire (HLQ). *PLoS One* 2017;12:e0172340.
34 Schaeffer D, Vogt D, Berens EM. *Gesundheitskompetenz Der Bevölkerung in Deutschland – Ergebnisbericht*. Bielefeld: Universität Bielefeld, 2016.
35 Christalle E, Zeh S, Hahlweg P, *et al*. Assessment of patient centredness through patient-reported experience measures (ASPIRED): protocol of a mixed-methods study. *BMJ Open* 2018;8:e025896.
36 Kowalski C, Lee S-YD, Schmidt A, *et al*. The health literate health care organization 10 item questionnaire (HLHO-10): development and validation. *BMC Health Serv Res* 2015;15:47.
37 Mackert M, Ball J, Lopez N. Health literacy awareness training for healthcare workers: improving knowledge and intentions to use clear communication techniques. *Patient Educ Couns* 2011;85:e225–8.
38 Groves RM. *Survey methodology*. 2nd edn. Wiley, 2009.
39 Bradburn NM, Sudman S, Wansink B. *Asking questions: the definitive guide to questionnaire design for market research, political polls, and social and health questionnaires*. Rev edn. San Francisco, Calif: Jossey-Bass, 2004.
40 Prüfer P, Rexroth M. Zwei Phasen-Pretesting. In: Kaase M, Mohler PP, Mohler PP, eds. *Querschnitt: Festschrift für max Kaase*. Mannheim: ZUMA, 2000.
41 Greenbaum TL. *The Handbook for focus group research*. 2nd edn. Thousand Oaks, Calif: Sage, 1998.
42 Kuckartz U. *Qualitative Inhaltsanalyse, Methoden, praxis, Computerunterstützung*. Weinheim/Basel: Beltz Verlag, 2016.
43 Fuß S, Karbach U. *Grundlagen Der Transkription: Eine praktische Einführung*. Opladen: Budrich, 2014.