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Krystallidou, D., Salaets, H., Wermuth, C., Pype, P. (2018)
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intervention for medical and interpreting students on empathic
communication in interpreter-mediated medical consultations. A study
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The International Journal of Educational Research

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EmpathicCare4All. Study protocol for the development of an educational intervention for medical and interpreting students on empathic communication in interpreter-mediated medical consultations. A study based on the Medical Research Council (MRC) framework phases 0-2.

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Abstract

Although empathy is associated with positive health outcomes, doctors do not often express empathy and they fail to sufficiently respond to patients' emotional statements. In linguistically diverse healthcare settings empathic communication is compromised even more. This has received little attention in medical education and even less in interpreter education. This project aims to develop an educational intervention for medical- and interpreting students on empathic communication in interpreter-mediated consultations. We rely on the Medical Research Council (MRC) framework for the development and evaluation of complex interventions (phases 0-2). The

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project will yield valuable insights into the communicative and interactional processes and resources doctors, patients and professional interpreters use in the expression and management of empathic communication in interpreter-mediated consultations.

Keywords

empathy, interprofessional relations, medical education, language barrier, interprofessional education, interpreters, MRC framework

1. Background

There are various definitions of empathy in the literature. In this study we adopt the conceptual definition of physician empathy by Feighny, Arnold, Monaco, Munro & Earl 1998, as cited in (Bylund & Makoul, 2005), namely “a physician’s cognitive capacity to understand a patient’s needs, an affective sensitivity to a patient’s feelings, and a behavioral ability to convey empathy to a patient”. We endorse the transactional communicative perspective that is attached to it, namely that the physician and patient influence each other in interaction and that the physician’s empathy is largely shaped by the empathic opportunities created by the patient, as well as by the characteristics of the physician and the context of the encounter (Bylund & Makoul, 2005).

The expression of empathy during medical consultations is important because it is associated with positive health outcomes and increased patient satisfaction (M. Hojat et al., 2011; Lelorain, Bredart, Dolbeault, & Sultan, 2012; Mercer, Neumann, Wirtz, Fitzpatrick, & Vojt, 2008; Neumann et al., 2009; Rakel et al., 2011). Therefore, it should be a priority in doctors’ professional development and professional behavior. However, research suggests that empathy among medical students might decrease during their training (M. Hojat et al., 2009), that clinicians express empathy infrequently and that they do not respond sufficiently to patients’ emotional statements (Butow, Brown, Cogar, Tattersall, & Dunn, 2002; Derksen, Bensing, & Lagro-Janssen, 2013; Easter & Beach, 2004; Morse, Edwardsen, & Gordon, 2008; Pollak et al., 2007), while responding to patients’ emotions is a way of being empathic. There is also evidence that empathy is compromised even more in cross-cultural and linguistically diverse healthcare settings (Schouten & Meeuwesen, 2006), which seem to become the norm in many parts of the world due to ever growing migration waves (Lwin et al., 2014). In these settings, when doctors and patients do not share a common language and cultural background,

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interpreters are called upon to help healthcare providers and patients overcome the language barrier and reach some common understanding. This results in medical consultations being interpreted (henceforth, interpreter-mediated consultations, IMCs). Due to the complexity of interpreter-mediated interaction (henceforth, IMI) (Angelelli, 2004; Wadensjö, 1998), research has provided findings that seem to suggest that the physician's empathic communication in IMCs might be compromised (Cirillo, 2010).

2. Significance

While empathy in monolingual settings has been studied both quantitatively and qualitatively, research on empathy in IMCs remains very scarce (Hsieh & Nicodemus, 2015) and mostly approaches empathy in an indirect way through the study of participants' perceptions (Kuay, Chopra, Kaplan, & Szwarc, 2015; Pugh & Vetere, 2009). Direct ways of studying empathy in IMCs would involve the study of the actual doctor-interpreter-patient interaction (as opposed to the study of their perceptions of empathy). Despite the invaluable insights this limited body of research offers, it fails to delve into the relational and transactional aspects of empathy that lie at the heart of it (Makoul, 1998). Research that investigates the ways in which empathy is being co-constructed in a relational way among participants during the actual interaction in interpreter-mediated healthcare settings remains scant.

At the training level, the development of empathy among medical students constitutes a key goal for medical trainers (Sulzer, Feinstein, & Wendland, 2016) and cultural competence curricula highlight the need for medical students to be trained in working effectively with interpreters (Kalet et al., 2005; Marion, Hildebrandt, Davis, Marin, & Crandall, 2008; Zabar et al., 2006). While methods to enhance empathy in medical education are emerging (Batt-Rawden, Chisolm, Anton, & Flickinger, 2013; Mohammadreza Hojat, 2016), the management of empathy, as co-constructed among doctors, patients and interpreters and expressed during a medical consultation (Hsieh & Nicodemus, 2015), has received insufficient attention in the interpreter education. Instead, the latter seems to have primarily focused on the interpreting students' ability to interpret accurately in an impartial manner – often seen as distant and disengaging (Merlini & Gatti, 2015) .

Poor implementation of available research and training initiatives, as outlined above, reflects a well-recognized problem in the field of implementation science, namely the translational gap between evidence and practice.

Against this backdrop and considering:

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- i) the urgent need to deliver doctors who are adept at communicating empathically in cross-cultural and cross-linguistic settings now more than ever (Hsieh, 2010) – often through interpreters,
- ii) that the combination of the doctors' medical expertise with the interpreters' linguistic expertise seems to be complementary (Hsieh, 2010) and, therefore, their collaboration is required (Hsieh, 2010; Krystallidou, 2014; Krystallidou; Salaets, 2016),
- iii) that empathic communication can be taught (Neumann et al., 2009), ideally in undergraduate medical education,
- iv) that it is necessary for interpreters to manage accurately the doctors' and patients' emotions and affective content to ensure successful doctor-patient interactions (Hsieh & Nicodemus, 2015),
- v) that interpreter education should pay more attention to the doctors' and patients' communicative goals in interaction – such as the expression of empathic communication (Hsieh, 2016; Krystallidou, 2014)

it becomes clear that medical students and interpreting students would benefit from training on the complexity of co-constructing (patients-interpreters-doctors), expressing (doctors–patients) and managing (interpreters) empathic communication in IMCs with a view to serving the patients' best interests in the provision of care in linguistically diverse healthcare settings, where medical consultations are held through interpreters.

Although the need for training both groups of students is obvious, the scientific development and implementation of a joint training that is underpinned by systematic and fundamental research for the above groups of students remains insufficiently addressed.

3. Intervention

This project aims to develop a research-based educational intervention for undergraduate medical- and interpreting students on empathic communication in IMCs. We opt for a joint training intervention as this is in line with the principles of interprofessional education (Macaulay, Spicer, Riches, & Lakhanpaul, 2016; O'Carroll, McSwiggan, & Campbell, 2016), which is strongly encouraged by the World Health Organization in relation to health professional training programmes (Yan, Gilbert, & Hoffman, 2007). Joint training would allow students from two different fields to learn to collaborate with each other to create the conditions for empathic communication in IMCs.

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To the best of our knowledge, both the development and evaluation of a joint training intervention, focused on empathic communication for medical students and interpreting students, is novel.

4. Research plan

4.1. Research objectives

- To identify and analyze all existing training interventions on collaborative training for medical students and students from different fields of study (such as dentistry, physiotherapy, pharmacology) on clinical communication and to review them as they appear in the literature.
- To gain practice-based insights into the interactional and communicative processes and resources (both verbal and non-verbal) doctors, patients and interpreters employ to co-construct, express (patients, doctors) and manage (interpreters) empathic communication in interpreter-mediated consultations.
- To develop a specific joint training intervention for medical and interpreting students that helps them express and manage empathic communication in IMCs by relying on knowledge acquired both from theory and practice.
- To study the feasibility and effectiveness of the developed joint training intervention in terms of increased competence and more specifically in terms of its three integrated pieces of knowledge, skills and attitudes (Lizzio & Wilson, 2004) .

4.2. Research questions

In order to meet the above objectives, we will provide a response to the following research questions:

- What interprofessional education initiatives exist in the literature, what works for whom and under what circumstances? (Objective 1)
- How is empathic communication co-constructed in IMCs? What interactional processes and communicative resources doctors, patients and interpreters employ when co-constructing, expressing and managing empathic communication? (Objective 2)
- Which components and underlying mechanisms should be incorporated in the design and development of a feasible and effective training intervention that address students' skills, knowledge and attitudes? (Objective 3)

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- How effective is the training intervention in shaping medical and interpreting students' skills, knowledge and attitudes in terms of empathic communication in IMCs? (Objective 4)

4.3. Design

For the development of our intervention, we will rely on the Medical Research Council (MRC) framework for the development and evaluation of complex interventions (Campbell et al., 2000; "Medical Research Council. (2006) Developing and evaluation complex interventions: new guidance.") (Figure 1).

Plz insert Figure 1 here

To display the interrelationships between the specific project activities and their intended outcomes, we provide an illustration of our outcome approach logic model *Logic Model Development Guide* 2004) (Figure 2).

Plz insert Figure 2 here.

4.4. Participants and sample

In phase 0 an a priori sample size of 20 to 30 consultations in gynecology, hepatology, pneumology (each consultation being held by a different doctor and featuring a different interpreter) has been defined. The sample (20-30 doctors, 20-30 patients, 20-30 interpreters) will be selected based on recommendations for and previous experience with qualitative studies of this nature (Krystallidou, 2013) and the anticipated complexity of and desired level of depth of analysis for our research questions. However, in keeping with the qualitative design, sample size will be determined throughout fieldwork by the use of saturation, which will be defined in terms of the non-emergence of new themes due to consensus across the behaviours shown and the views expressed (Turner, Barlow, & Ilbery, 2002). In other words saturation will be sought more across than within cases (Saunders et al., 2018).

The inclusion of the languages of the consultations will depend on the data (e.g. scheduled and confirmed IMCs) we will receive from the Social Work department of the University Hospital of Leuven, which processes the requests for IMCs. We know that the expression of empathy might be influenced by cultural norms and values (Chung & Bemak, 2002; Lorie, Reiner, Phillips, Zhang, & Riess, 2016). In order to ensure that our findings will be as representative as possible and as applicable to IMCs as

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possible, we purposefully chose to video record consultations in different languages with patients from different ethnic, linguistic and cultural backgrounds. In this way the cross-case comparison will allow for culture-specific resources and mechanisms to be “levelled out” and for generic dynamics in the expression of empathy in IMCs to be identified.

In phase II (exploratory phase) we will conduct a proof-of-concept study to determine whether the intervention has positive outcomes. Considering the relatively small number of students in the interpreting students group at our institution, we opted for a convenience sample including them all. The members of the study sample and the subsequent follow up study target population (MRC Phase III and IV) are homogeneous (all of them are interpreting and medical students at KU Leuven and have been exposed to the same curriculum) and as such it is anticipated that the same results would be obtained from another sub-sample (Etikan, Musa, & Alkassim, 2016).

We will recruit:

- 10 medical students who have already completed their Master's in Medicine at KU Leuven. We are opting in favour of Master's students, because according to the learning objectives of the Master's curriculum, Master's students receive specialized training on clinical communication skills (e.g. bad news delivery) and at the end of their training, they are expected to be able to communicate empathically. The reason we will recruit medical students who have received training on bad news delivery is because in a bad news delivery context, empathy would likely be seen as more important than it might be in other contexts (Lizzio & Wilson, 2004); what is more, students from that group are expected to be already competent enough to show empathy in monolingual consultations.
- 10 interpreting students from the Master's in Interpreting at KU Leuven. We have opted for Master's students because Interpreting forms part of the Master's curriculum and Master's students receive specialized interpreter training on a wide range of institutional settings. At the end of their training, they are expected to be able to prepare for, and perform, interpreting assignments in professional settings, such as healthcare.
- 10 simulated patients (native speakers of languages that will be among the working languages of the interpreting students). For the recruitment of the simulated patients, we will rely on the currently employed practices used at the Faculty of Medicine for the recruitment of professional actors enacting the roles of simulated patients. The simulated patients will be

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briefed on the symptoms and behaviour they will be required to display and will receive due compensation for this.

5. Outcome measures (MRC phase II)

5.1. Feasibility testing

Feasibility testing: We will convene a meeting with stakeholders (clinical communication skills- and interpreter trainers, clinicians, interpreters, students). We will concentrate our discussion on the following areas: Acceptability (to what extent is the envisaged intervention deemed suitable, satisfying or attractive to its deliverers and recipients?); Implementation (to what extent can the intervention be successfully delivered to intended participants?); Practicality (to what extent can the intervention be carried out with intended participants using existing resources?); Integration (to what extent can the intervention be integrated within the existing curriculum?); Limited efficacy (does the intervention show promise of being successful with the intended recipients?); Expansion (to what extent can this intervention be successful with a different population or in a different setting (Bowen et al., 2009); (expansion refers to a follow up study within the post-project trajectory).

Feasibility testing may identify not only what—if anything— needs changing in the protocol but also how changes might occur (Bowen et al., 2009).

5.2. Proof of concept: Pre-post tests

The participating medical- and interpreting students will be requested to participate in testing using appropriate validated tools. The students of each group will be requested to fill out questionnaires (each group will receive questionnaires tailored to their fields of study) that will be addressing aspects pertaining to attitudes, skills and competence (Lizzio & Wilson, 2004) as will have emerged at the preceding phases of our complex intervention development. Upon completion of the intervention the students from both groups will be asked to fill out the same structured questionnaire as they did in the pre-test phase (post-test).

The simulated patients will be requested to complete a questionnaire addressing aspects strongly associated with empathy, such as feeling understood, satisfaction [63], and others that will emerge during phase 0 of the intervention.

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The results of the pre-test stage will provide new insights into the necessary components of our intervention and will be incorporated into its development (phase III, post- project).

5.3. Success criteria

At this stage we are unable to define a set of criteria that have to be achieved in order to declare the proof-of-concept a success. This is because the measurable objectives (i.e. attitudes, skills, knowledge) are subject to the content of the training intervention that will be developed in phase I and will be largely informed by the insights that will emerge from the analyses in phase 0. As the measurable objectives are not known yet, we cannot define the degree of the measurement shift that is needed to declare the intervention a success. This depends on the shift needed to be clinically relevant and this is objective-dependent. A protocol of the proof-of-concept study with details on the criteria will become available upon completion of phase I.

6. Analysis plan

6.1. Phase 0: Theoretical phase

Review of the available scientific literature (Objective 1)

In this phase, we will assess existing knowledge on, and available evidence of, developed and evaluated complex interventions on clinical communication training that involves students from different disciplines as is to be found in the literature. An initial review of the literature suggests that this training is usually monolingual. However, given the interdisciplinary nature of our project, we will assess theory and evidence of cross-cultural and interlingual clinical communication training (e.g. using professional interpreters (Bansal, Swann, & Smithson, 2014; Berekyei et al., 2010; Jacobs, Diamond, & Stevak, 2010), bilingual medical students acting as interpreters (Diaz et al., 2016), as well.

For the complexity of emotion management in interpreter-mediated medical encounters, we will rely on a recent literature review (Hsieh & Nicodemus, 2015), which we will update at the beginning of the project.

More specifically: we will conduct two literature reviews: i) a realist review in order to determine the best evidence relating to interprofessional education (including cross-cultural and interlingual)

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between medical students and students from a different field of study; ii) a systematic literature review on the complexity of emotion management in interpreter-mediated encounters. The realist review will be carried out in accordance with the BEME Collaboration review procedures. The systematic literature review will be carried out in accordance with PRISMA guidelines and according to the methodology described in the *Cochrane Handbook for Systematic Reviews* (Higgins & Green, 2011).

We will develop a protocol for each literature review so that the reviews can be replicated by other researchers. The protocols and the results of each literature review will be published in scientific journals for further dissemination. The findings that will emerge from the literature reviews will be a key resource for the next phases in our methodology, as discussed below.

Assessing theory and evidence in the above areas will allow us to establish a theoretical basis for our educational intervention in terms of intervention components, the outcomes we expect and a theoretical understanding of the likely process of change. More specifically, this will allow us to identify the elements that our educational intervention should have and also the aspects and mechanisms that will shape the outcomes and ultimately help attain the envisaged objectives of our intervention.

Video recorded interpreter-mediated consultations (Objective 2)

We will identify and analyze interactional and communicative processes and resources (verbal and non-verbal), which doctors, patients and interpreters employ for initiating (patients/doctors), expressing (doctors) and managing (interpreters) (Hsieh & Nicodemus, 2015) empathic communication in interpreter-mediated consultations. We will do so by means of video-recorded authentic consultations, which we will code for empathic communication and analyse by drawing on multimodal interaction analysis, a framework in which the cognitive, psychological and bodily dimension of social actors are always linked to their physical and socio-cultural environment. (S. Norris, 2004; Sigrid Norris, 2012)

This will allow us to better understand and categorize processes and resources that either facilitate and promote, or hinder, the expression and management of empathic communication in IMCs.

Coding empathic communication

To identify interactional and communicative processes and resources that are used by the doctors, patients and interpreters, we will rely on the Empathic Communication Coding System (ECCS) [44]. This system is made up of two parts: one where patient-created empathic opportunities are identified and one where doctor responses to those empathic opportunities are coded (Bylund & Makoul, 2005). It

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distinguishes between different levels of empathy, starting from Level 0 – which stands for the doctor's denial of the patient's perspective – and moving up to Level 6, in which the doctor and the patient share a feeling or experience. This differentiation between levels of doctors' responses is particularly interesting for the purpose of our study as it allows us: i) to zoom in on the doctor's responses. Accordingly, it stops us from treating a simple acknowledgment of a patient's empathic opportunity (i.e. patient's explicit statement of emotion, such as "I'm really scared about the surgery") as confirmation (i.e. legitimization) (Bylund & Makoul, 2005); ii) to make a close and systematic observation of the doctors' responses, as rendered by the interpreter, by comparing the level of the doctor's empathy, as expressed by the doctor and as rendered by the interpreter.

This ECCS – although designed with monolingual communication in mind – has been adapted for interpreter-mediated doctor-patient communication (Krystallidou et al., 2017). We will use the adapted version of the ECCS which allows us to identify different levels of empathic communication and to flag up the interpreter's effect on the expression and management of empathy (by noticing shifts in the patients' empathic opportunities and the doctors' levels of empathy as a response to the latter).

Multimodal interaction analysis

Considering that empathic communication is a transactional process and patients and doctors use both verbal and non-verbal resources to this end, (Bylund & Makoul, 2005) we will approach interaction from the point of view of actions that carry communicative meaning (S. Norris, 2002) instead of taking only verbal interaction into account. Therefore, we will take an interactionist approach to the coded instances of empathic communication in order to identify doctors', patients' and interpreters' interactional processes and the communicative resources they employ when co-constructing, expressing and managing empathic communication. The previously coded instances of empathic communication will at this stage serve as units of analysis in which we will analyse the doctors', patients', and interpreters' actions (both verbal and non-verbal). In order to do so, we will rely on existing analytical tools, such as the A.R.T. framework and participation- and engagement frameworks (PEFs) (Krystallidou, 2014, 2016) especially tailored to IMCs, while scrutinizing the role of the doctors', patients' and interpreters' gaze, body orientation, gesture and facial expressions in the co-construction, expression and management of empathic communication. In this way, we will be able to investigate the ways in which gaze, body orientation, gestures and facial expressions are employed by doctors, patients and interpreters as semiotic resources in interaction, (Bavelas, Coates, & Johnson,

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2002; Bolden, 2003; Krystallidou, 2014, 2016) (e.g. complementing or contradicting the meaning of participants' verbal interaction, used in parallel with, or separately from, verbal interaction or replacing the latter, etc.). For the analysis of the above non-verbal semiotic resources, the units of analysis (i.e. instances of interaction previously coded as empathic) will be transcribed. Time-based transcripts will be realised with the linguistic annotator ELAN (<http://www.mpi.nl/corpus/html/elan/>) that will enable us to create, edit, visualize and search annotations for video and audio data. This type of multimodal analysis will allow us to gain further insights into how doctors, patients and interpreters co-construct (patients, doctors), express (doctors) and manage (interpreters) empathic communication.

Video stimulated recall interviews

In order to verify the results that will emerge from the ECCS coding and the multimodal interactional analysis, we will revisit our findings and try to gain a deeper understanding of them by using video-stimulated recall (VSR). We will invite the doctors, patients and interpreters featured in the video-recorded consultations to comment on their own and the others' behaviour during playback on the instances of interaction coded to the different levels of empathic communication within the framework of semi-structured interviews. This type of interviewing elicits more information about their behavior during the IMC (Paskins, McHugh, & Hassell, 2014). The stimulated recall methodology will consist of two steps: i) review of the video by the doctor/patient/interpreter and one member of the research team, and ii) discussion of instances of empathic communication evident in the video. Participants will be able to rewind or pause the video as needed. The discussion between the member of the research team (interviewer) and the interviewee will be organized around the ECCS coding and the multimodal interaction analysis of the video-recorded consultation. All stimulated recall interviews will be audio-recorded, transcribed verbatim and analysed by means of qualitative content analysis (Graneheim & Lundman, 2004)

Combining data derived from doctors', patients' and interpreters' accounts using VSR with the analysis of their interaction, as will be performed in the two preceding levels of analysis, will allow us to gain insights into the reasons why doctors, patients and interpreters acted in that particular manner when they were achieving the different levels of empathic communication.

6.2 Phase I: modelling phase

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During phase I the results of the analysis in phase 0 will be used to design the intervention for phase II. Phase I comprises no further analysis.

Although at this point it is impossible to state which components will definitely be incorporated, based on a scoping review of the literature we assume that theoretical underpinnings, reflection in practice, problem-based learning and experiential learning will be useful within the framework of interprofessional education [58], all aimed at increasing students' skills, knowledge and attitude.

To develop the protocol of the training intervention, we will hold expert consultation discussions at national and international level. More specifically, we will set up a multidisciplinary panel of experts (clinical communication- and interpreter trainers, educationalists, clinicians, interpreters, representatives of patient associations, as well as minority groups) to reflect and provide feedback in an iterative way on the findings that will emerge from phase 0 until general agreement is reached among the panel experts on all aspects of the training protocol.

6.3 Phase II: exploratory phase

The analysis of phase II is being described in detail in sections 5.1 and 5.2. of this manuscript.

7. Discussion

We have described the focus of our research agenda, which is to develop an educational intervention for medical and interpreting students on empathic communication in interpreter-mediated medical consultations. For this, we rely on the MRC framework phases 0-2 and we are employing a combination of qualitative methodologies, which, when combined, offer a novel approach to the processes to address the primary and secondary study objectives.

As far as we know, this is the first study on interprofessional training between medical and interpreting students that helps them to co-construct, express (medical students) and manage (interpreting students) empathic communication in interpreter-mediated consultations.

The transfer of the project findings into the curricula of the two faculties will pave the way for better trained doctors and interpreters who will be more likely to perform more effectively in linguistically and culturally diverse healthcare contexts. In so doing, they will be more likely to help improve the health and well-being of patients with linguistically and culturally diverse backgrounds. Professionals

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trained to perform in linguistically and culturally diverse settings will enhance the effectiveness and sustainability of hospitals in which they operate, contributing, in this way, to better social welfare and social cohesion. It is not only important from a human point of view that appropriate hospital-patient communication is ensured; there is also a significant economic return of investment. After all, communication that allows both doctors and patients to feel understood (including their emotions), means not only better care, but also less expensive care as it helps to improve patient compliance optimizing the therapeutic effect and to reduce costs for unnecessary interventions. Consequently, empathic interpreted patient-doctor communication will importantly contribute to a more rational use of financial and human resources in medical healthcare, as well as better quality of care for patients facing language barriers and requiring an interpreter. The inclusion of various stakeholders (e.g. representatives of patients, healthcare associations, educationalists) at the various stages of the research project will promote the concept of participatory research, fostering in this way KU Leuven's commitment with the public.

8. Personnel

Principal investigator

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9. Authors' contributions

Dr. Demi Krystallidou conceived, designed the study and wrote the study protocol.

Prof. dr. Peter Pype participated in designing the study and provided critical feedback on manuscript revisions.

Prof. dr. Heidi Salaets and Prof. dr. Cornelia Wermuth provided feedback on manuscript revisions.

All authors read and approved the final manuscript.

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10. Timeline

Workplan and timeline for the EmpathicCare4All project is presented below in Figure 3.

Plz insert Figure 3 here

11. Ethics

The study protocol and the informed consent forms have been approved by the Ethics Committee Research UZ/KULeuven (Belgian registration number: B322201835332). All ethical guidelines will be strictly followed. All participants (doctors, patients, interpreters, medical- and interpreting students, simulated patients) will be provided with an informed consent form in their native language.

12. Acknowledgments

We are grateful to Dr. J. Decaestecker, MD, Prof. dr. J. Flamaing, MD, Prof. dr. J. Menten, MD, Dr. Alexia Papageorgiou, Ms. Elke Lagae, Ms. Nele Vandingelen, Mr. Pascal Rillof, Prof. dr. Aline Remael, Ms. Beverley Costa for the support they lend to the project, as well as all patients, doctors, interpreters, students, simulated patients who participate in the project.

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