6 Geriatric trauma patients as research subjects in a technology-driven research project

A preliminary field report

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Abstract

This article highlights methodological and ethical challenges in research with adults of older and oldest age, by presenting field experiences of the current research project "Motion Monitoring of Geriatric Trauma Patients – Explorative Study on the Rehabilitation Process after Hip Fracture Using Sensor-based Data". Depiction of the survey situation, with regard to the subjects in particular, can serve as practical examples for designing future research projects.

The group of older adults is a rather large and growing group for which research is required, especially concerning their heterogeneity, their individual autonomy and quality of life. It is assumed, that research designs of studies on the target group must be specifically adjusted, in particular when considering the attribution of vulnerability of the group members. At the same time, it is not clear yet what exact specifics of the subjects and target group must be considered in research designs, as surprisingly little is known about the target group as subjects and corresponding theories have been insufficiently tested.

The exploratory long-term design of the research project presented in the second section of this chapter has a positive evaluation of an ethics committee. Still ethical challenges occurred in the field situation, that are illustrated in the third section of this chapter, by providing information on the patients, their role as research subjects, how they were recruited, how an informed consensus was reached, and in some cases how participation was rejected or abandoned. After a summary, the end of the paper is marked by recommendations on how to design future research projects.

Cumulatively it must always be expected that interaction between researchers and research subjects of this target group can become very intensive, what requires to follow clearly defined procedures and at the same time to be prepared to act flexibly.

6.1 Introduction

The geriatric environment is determined by caregivers and relatives, but also by care levels, cognitive impairments and, above all, by geriatric patients as well as the interplay between these groups and numerous social, healthcare and medical conditions. Geriatric patients belong to a heterogeneous group of very old people; therefore evidence-based research encounters various methodological challenges (Deutsche

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Akademie der Wissenschaften 2015). In addition, there are frequent prejudices and biased views of older people in society that influence caring processes and medical interventions (Trojan 2002) as well as geriatric research. Therefore, it seems reasonable, first, to further advance the development of research guiding hypotheses for geriatric research and, second, to do so in a morally informed approach in order to gain robust empirical knowledge about geriatric patients.

To begin with, a definition of geriatric patients and a brief overview of the terms to describe the feature "age" of these patients. A person of a so-called oldest age of 80 or more years of life can be a geriatric patient by definition. Actually, chronological age does not define a geriatric patient completely, but rather a health condition called multi-morbidity and an age above 65, in general from 70 years of age on (Sieber 2007). Persons in this age group are called "older persons" or "older people" or "persons/people of older age", according to suggestions of Avers et al. (2011), who criticise the use of the term "elderly". Multi-morbidity means that there are two or more health conditions, often chronical, that require treatment (Eckardt and Steinhagen-Thiessen 2012). A central goal in the treatment of geriatric patients is to preserve autonomy and quality of life, especially when it is at risk due to an increased vulnerability (Denkinger et al. 2018). Therefore, if an age-associated physical and cognitive decline emerges, as well as a growing state of vulnerability, a patient defines as geriatric too (Sieber 2007). This situation is called *frailty* which is a term that as yet lacks a precise definition (Denkinger et al. 2018). Statistics show that most industrialised countries, as well as many other, particularly developing, countries, are undergoing strong demographic change (Central Intelligence Agency 2018; The World Bank 2018). As a result, the number of older persons and adults of the oldest age is growing tremendously and at the same time the average life expectancy of these people is increasing. In other words, more of the older people live longer. It is very probable that this trend will be associated with an increase in geriatric diseases and multi-morbidity among the oldest agers (Hayward and Warner 2005). At the same time, there is hope that geriatric measures to improve health can maintain quality of life into old age ("healthy life expectancy"). To put it in the words of the World Health Organization (2012): "Good health adds life to years". In order to manage these changes and developments, medical and technical innovations are increasingly being sought to help to take care of older persons and oldest persons. The employment of technology in care will undoubtedly change the lives of patients and many other stakeholders as well as the work of caregivers (Abeles et al. 2017; Barth and Doblhammer 2017; Becker and Pfeiffer 2012; Claßen 2012; Normahani et al. 2015).

Therefore, it should be a research priority to closely examine the use of such technologies for geriatrics, whether in the form of pilot projects or laboratory experiments (Duh et al. 2006; Becker and Klenk 2010), in order to be able to make judgements about age-appropriate design of technology and to ensure that autonomy and quality of life of all stakeholders are preserved (Schulz et al. 2015).

It is to be expected that innovative technologies such as motion trackers or devices for the Internet of Things will be integrated into the lives of older people in the future (Schulz et al. 2015). Researching these technological innovations has become a high priority in geriatrics recently, mostly as pilot projects or under laboratory conditions; particularly, age-appropriate design and whether and how technology can sustain autonomy and quality of life of prospective users are examined. However, it is precisely in such research that methodological challenges arise. Among other things, the fact that assistive technologies are not yet widely disseminated (Becker and Klenk 2010; Weber 2017) makes research in actual care settings and under real conditions extremely challenging (Altenbuchner et al. 2019). Research in this area is also hampered by the fact that it is not always clear whether the results are essentially attributable to the technology used or to the patients or their personal traits. Another challenge is the vulnerability of patients with geriatric trauma, as there are many ethical aspects affecting research in these cases – this is true for laboratory research, but even more so for field studies.

It is the aim of the project described in this paper to explore physical motion of older and oldest persons as well as the measurement instrument, which is a customary motion tracker. Due to a research and knowledge gap concerning physical activity and behavior patterns in the actual living environments, it is necessary to conduct such studies. Thus, the following section will present preliminary results in order to shed light on the methodological challenges of research with older and oldest people in general and in connection with technology in particular. Although the research design of the project, which is described in the following section, was positively evaluated by an ethics committee of the University of Regensburg, it has to be noted that the handling of the project's target group poses multiple ethical challenges. In order to better illustrate these challenges, the third section provides detailed information on the patients, their role as research subjects, how they were recruited, how an informed consensus was reached, and in some cases how participation was rejected or abandoned. After a summary, the end of the paper is marked by recommendations on what needs to be considered in future research projects.

6.2 The research project: Motion monitoring of geriatric trauma patients – explorative study on the rehabilitation process after hip fracture using sensor-based data

In a nutshell, the aim of the project is to formulate assumptions and hypotheses about the mobility of geriatric trauma patients after a hip fracture. Although this is a rather large group, surprisingly, there is very little valid evidence on the mobility of geriatric patients, although mobilization is an essential part of treatment and an important therapeutic objective after a hip fracture (Hahn and Winker 2000; Rapp et al. 2012). Rapp et al. (2019) provide a systematic literature review on the epidemiology of hip

fractures. On the one hand, in western countries, 75 % of hip fracture patients are female. It is suspected that such injuries are typical for women, as they have a higher average life expectancy in Western countries, but older women at the same time often suffer from diseases such as osteoporosis. On the other hand, it is known that men in retirement and nursing homes fall more often and have a higher mortality risk six months after a hip fracture than women. A person who already suffered from a fracture has a higher risk of a secondary fracture. Current fall prevention programs and medication seem to be not sufficient to reduce the large number of hip fractures. Moreover, demographic change over the next three decades is expected to result in an increase in hip fractures (Lohmann et al. 2007). Only a few recent studies examined physical activity with body-worn sensors, and these have methodological limitations. Benzinger et al. (2014), who measured physical activity after hip fracture, used a pre-post-design at admission in a hospital and two weeks later. No continuous measurement was possible and therefore no variability in physical activity can be demonstrated. During the two days of monitoring, the time frame was only up to nine hours per day and patients of the geriatric rehabilitation centre had to perform different types of mobility assessments. Taraldsen et al. (2011) evaluated whether a body-worn sensor could be used to monitor mobility of persons suffering from neurological impairment. They found the sensor to be valid in measurement but mention the limitation that activities could not be tracked under everyday life conditions. Both studies recruited their patients on the ward and were ethically approved.

In the project described here, mobility is operationalized with the variables *steps* and *time*, which are measured with sensors that are built into a commercially available motion tracker. The study is designed as an explorative long-term study that does not include medical intervention. The methodological approach is descriptive and explorative and is performed in a geriatric trauma department in a hospital with patients living there while they are on the ward and undergoing initial rehabilitation as well as after they have returned home. Participation is voluntary and based on an informed consensus obtained by signing a consent form. Information about the project given to the patients emphasized the right to withdrawal without further consequences. Although no medical or physical treatment is part of the research design and wearing the device as well as follow up visits at home posed only a minimal risk to the patients, it has to be admitted that a greater then minimal risk occurs due to the continuous monitoring of vital data of the patients. During the study, the data collected is read once a month from the motion tracker. On this occasion, patients receive feedback on their mobility; they are told how many steps they have taken. Patients can see their individual achievements through time. The regular visits and the feedback might add value to the participation of the patients. For some of them those visits are a rare opportunity to have social contacts. In addition, the information about the level of activity can motivate patients to achieve even more. Both aspects would support the principle of beneficence because patients' well-being would be improved. However, it needs to be considered that this can also be a certain risk since

increased motivation can lead to overburdening activities; furthermore, the insight that a patient has achieved nothing or not much can also demotivate which can lead to even less physical activity. In both cases the principle of non-maleficence would be violated because patients could be harmed.

It should also be emphasized that the data collected in the project do not yet allow for medical and/or therapeutic interpretation; the purpose of the study is first to create an explorative database that can be used to derive research hypotheses and possible medical indicators. Furthermore, it should be noted that even a preliminary interpretation of the data communicated to patients may have effects that could lead to bias in further data collection or demotivate patients to the extent that it could cause harm to patients. For up to a year the motion tracker continuously collects data on how many steps have been taken. The opportunity of long-term recording and the low cost of the motion trackers used motivate the utilization of commercially available devices. The motion tracker is worn and looks like a wristwatch, which increases comfort. This helps to ensure that it is not forgotten and that data collection is not interrupted. With those motion trackers used in the study GPS location monitoring is impossible.

To reduce risk, data can only be read out by two project members knowing the necessary passwords and project e-mail accounts, that belong to the University of Applied Science Regensburg (OTH); the patients are not able to do this due to a lack of technical knowledge and access credentials. But even if they had this knowledge, they would not be able to access the data because most patients do not have computers, laptops or similar devices – but their mostly younger relatives have such devices. If a research subject would want to have digital access to the data, then it would be necessary that they had access to the Internet at home. Due to data protection regulations and requirements from the ethics review, patients would have to log in via the University, as the data can only be accessed there. This would therefore entail a considerable effort for the patients. However, to this day no research subject wanted access to the data, but were satisfied with oral feedback.

The credentials do not contain any personal information; they only refer to the motion tracker identifier. For example, the username as a pseudonym could look like this: “Mr. Tracker Twenty”. The personal data of the patients are stored exclusively on paper separately from the collected data, so that data protection is guaranteed. All statistical evaluations use only pseudonyms so no digital data linking with personal and health-related data is possible. As soon as the project is finished, all accounts will be deleted. To meet DFG (Deutsche Forschungsgemeinschaft) standards, raw data sets will be stored on University servers.

The continuous, individualized and objective measurement of motion data aims to discover clusters using explorative data analysis (EDA) and to develop predictors for the quality of treatment and therapy after a hip fracture. In addition, further hypotheses for research will be formulated, especially with regard to cognitively im-

paired patients (e. g. dementia or delirium), as these persons are often not considered in corresponding geriatric assessment tools.

Preliminary results on how to measure physical activity with a commercial motion tracker can be found in the text of Altenbuchner et al. (2018). The data collected so far show that after a very uniform period of time at the beginning of the measurement, patients begin to behave very differently. Cluster analysis shows three-cluster solutions with significant differences for the average amount of steps per patient during time. It is hoped that the long-term study will provide more data that can be used to examine the three-cluster solution. Possible hypotheses might be found with regard to predictors for rehabilitation; this might help to find out in what stage of rehabilitation the monitoring of physical activity could be used to predict the potential success of individually adapted rehabilitation (Altenbuchner et al. 2019).

6.3 The Patients

6.3.1 Geriatric trauma patients as research subjects

Patients involved in the study are on average 86 years old (± 7.1) and suffered a hip fracture. Treatment and therapy of such injuries with regard to the age group is complicated due to side conditions like dementia and special care needs. It is expected that these factors will increase up to 70 % in the next three decades and even 150 % for people over 80 years (Lohmann et al. 2007). Suffering an injury like a hip fracture increases the risk of a subsequent fracture (Kretschmer et al. 2017). Postoperative mobilization is essential in preventing muscular atrophy and contractures (Hahn and Winker 2000). Patients with dementia also benefit from physical activity therapy (Clare 2017; Bork 2017; McGilton et al. 2013). A continuous measurement and therefore observation of mobility would allow the development of complex and personalized interventions (McGilton et al. 2013). Geriatric mobility valid assessment tools and tests exist but due to everyday variability, individual conditions, time aspects or cognitive status they often cannot be employed. Furthermore, they only provide information about mobility and physical ability with regard to a particular moment in time. Thus, the question of how to adequately measure physical activity with regard to geriatric patients and persons of the age group to a large extent remains unanswered (Altenbuchner et al. 2018).

The design of the project described here does not include medical intervention or physiological treatment, but oral and written feedback on the data collected. Patients get to see how many steps they took on average week by week; differences in comparison to the last month and a graph showing the development since the first day of measurement are also provided. The feedback is provided as a slide show presentation on a tablet PC in order to allow the patients to slide back and forth and zoom in easily. Additionally, they get a printed version to keep and to show their relatives. It

is quite likely that the feedback motivates patients to be more active and to take more steps as they would without the feedback, which poses a methodological problem. However, the feedback is necessary from an ethical point of view for not providing it would violate the principle of beneficence since the feedback might improve the quality of life of patients.

Irrespective of such details, the fundamental question is whether such vulnerable patients (Wild 2014) should participate in a long-term study of this kind at all. Patzig (1986) argues that participation is morally expected, as it could contribute to the common good. Patients who are treated in university hospitals or general hospitals where research is carried out expect the best possible treatment based on state-of-the-art of research and science. Therefore, these patients in particular would be obliged to participate in research projects, even if they did not benefit from them themselves. Even older people who could no longer benefit from positive results and findings of such studies would have a moral obligation to society of the future (Laslett 1995). The common good is often used as an argument in the human sciences and medicine with reference to public health (Osieka 2006).

There are specific moral guidelines for research with cognitively impaired patients; the decision to participate in studies and research projects should not be taken easily by legal guardians or caregivers (Patzig 1986). The German Ethical Council also emphasises this with regard to patients with dementia (Deutscher Ethikrat 2012) whose right to self-determination (Freier 2014) has to be taken into account. In the best interest of the patient this right can also be exercised on behalf of the patient by a legal guardian, but nobody should be urged into participation, even if this would mean that research progress is slowed down (Patzig 1986).

Within the project, those patients who did not wish to participate in the project always informed the project staff directly and confidentially. In some cases, however, it may be assumed that the consent of some patients to participate was given far too thoughtlessly. In one case, a relative said not to be caring whether a patient would participate or not, so the decision was ultimately up to the project staff. From a moral point of view, this is of course unacceptable, as the right to self-determination would be so disregarded. Either the patients have to decide for themselves or those persons who have to decide on their behalf but not the project members. For that reason, the patient was excluded from the sample. Some patients said that they would participate as long as there was no effort for them. These experiences suggest that the idea of informed consent is an ideal that is not always fully realized.

A patient suffering from a physical impairment requested detailed information about the project, but a relative refused to accept to take the information and therefore the patient did not receive it. Although the aim was to involve all new patients admitted to the ward in the project, another patient in the hospital was not informed that there was an opportunity to participate in the project because the patient suffers from a psychiatric condition that leads to delusions (as a relative informed us). The relative still wanted the patient to take part in the study. However, a situation where

strangers visit at home in order to get data from the motion tracker can be horrifying and does not meet the principle of non-maleficence that demands the reduction of suffering (Osieka 2006). Thus following Freier (2014) sometimes autonomy – in this case autonomy to take care in the study – has to be restricted by the researcher, if circumstances show that the situation caused by a previous decision can be overwhelming for the patient, even if the caregiver would agree anyway. Due to the occurrence of a flu wave, some other patients who were in poor health and therefore had to be considered particularly vulnerable could also not be included in the study. This shows that participation in research must ultimately be decided on a case-by-case basis (cf. Wild 2014).

6.3.2 Recruitment

The recruitment of the patients took place in the geriatric trauma ward of the cooperating hospital. Before the study began, meetings were organized on the ward and in the department. With the help of letters containing photos, telephone numbers and e-mail addresses, the project members introduced themselves to the nursing staff, physiotherapists and ergotherapists. It was important to build trust so that the project staff could move freely around the ward. A good relationship with the healthcare professionals was essential for the project, as they were responsible for encouraging patients to participate. They were the first to ask the patients whether they would agree on whether the project members would be allowed to inform them about the study. Some patients also asked nurses or doctors if they thought that patients should participate. Since the aim of the project was to carry out a full survey all patients or their guardians had to be contacted. The full survey should also include patients with cognitive impairments, as this group of patients can also benefit from physical therapy (Clare 2017; Füsgen 2008; Huxhold 2012). To date, only two patients could not be invited to participate because they had to be isolated due to health reasons. In general, it was important to always remember that patients were recovering from a fall resulting in a hip fracture and subsequent surgery which meant they were in a difficult situation.

During recruitment, patients are usually visited in their hospital rooms, as these are the only rooms where a certain level of privacy can be provided. However, this privacy is limited because it is very likely that another patient will be in the room as well nurses, visitors or other patients might enter. Many patients know the project staff and the project because they have already met them in the lounge and heard about the project. All in all, it can be said that the conditions under which patients can be recruited are very far from the ideal of existing moral guidelines or other regulations. However, it is hardly possible to create better conditions in everyday clinical practice. Further elaborating Patzig's (1986) argument that patients have a certain duty to participate in research if they are treated in university hospitals it might be assumed that

it may be common knowledge that usually research is going on there and that social conditions are far from being optimal.

Recruitment followed a standardised and binding procedure for the project staff, which included a salutation, the question of current well-being and a brief introduction. Patients also are given an explanatory text, printed in large font, containing telephone numbers and photos of the project staff. This personal contact between the patient and the project member is very important as the patients are invited to participate in a long-term study that includes home visits. In order to be able to take the personal circumstances of the patients into account, all agreements with the patients require the willingness to work outside normal office hours. During recruitment, patients are also given the opportunity to get to know and try out the motion tracker. Although this procedure is standardized, flexibility in implementation is necessary if certain preconditions exist on the part of the patients:

- visual and hearing impairments
- poor health conditions
- ongoing nursing and medical procedures
- uncertainty and mistrust
- fatigue
- concurrent involvement in other studies
- visits of relatives or other persons.

6.3.3 Process of obtaining informed consent

Attaining informed consent usually takes up to a week, as patients want to talk to their relatives or even expect them to make the decision even though patients do not have a legal guardian, but find it difficult to make their own decisions. In such cases, appointments must be made with relatives. Some patients and/or relatives may want to talk to the senior ward physician who knows the study first; some also address ward nurses. Some relatives would like an oral explanation of the above-mentioned written statement in a private conversation or they would like to see the motion tracker. Although this process is time-consuming, it can help to protect the autonomy of the patient and/or the person making the decision (Osieka 2006), as the individual's decision is actually placed at the center of recruitment (Scorna et al. 2017). If the patients then wish to participate, the last step is to let them sign an agreement in order to document informed consent. This agreement was drafted in collaboration with the hospital's legal department. Finally, the motion tracker is attached to the patient's wrist and data collection can begin. It must be emphasized again that the study does not include any medical intervention.

Although very extensive verbal and written information is offered, it remains to be stated that some patients do not know exactly whether the project team members belong to the OTH Regensburg or are employed in the hospital, as is the case for ex-

ample for the nurses, social workers or medical students. At least that is an impression that arises because some patients still address the team members after three days as "nurses". This uncertainty or misunderstanding is amplified by other scientists on the station accomplishing research for their medical graduation or other purposes. Some patients are very sure that they have agreed to participate in a particular study, even though they have actually given their consent for another study. Other patients basically do not want to know details about the project but still want to participate. Fava and Guidi (2007) have already described this behavior and concluded from their observations that too much (medical) information would put patients under too much stress. Wearing a motion tracker is not information in the strict sense, but the many explanations about its purpose seem to be too stressful for some patients. Again, this situation is far from being optimal when it comes to informed consent and participation in studies and research projects. From a moral point of view, the circumstances described above appear to be deficient; ultimately, one has to conclude that the implementation of moral ideas must always be striven for, but can usually not be fully achieved.

6.3.4 Rejection and cancellation of participation

Although it should be a matter of course, it must be stressed that patients who did not want to participate in the study were treated with particular consideration and sympathy. As described above, recruitment takes place in a situation of limited privacy. Sometimes this leads to family members requesting further information even though a rejection has already been expressed. While recruitment must therefore take place under suboptimal conditions, on the whole patients and their relatives seem to be able to deal with this inconvenient situation.

During the previous recruitment process, in 28 cases it was possible to document the reasons for a refusal to participate. Fifty percent expressed a lack of interest and respectively did not want an explanation about the study at all, which can be counted as a kind of disinterest. Fear of excessive effort on the part of the patient, especially after the spill that led to the fracture, was expressed in 18 % of the cases of refusal. Eleven percent expressed the feeling of "bad timing" because the situation with regard to the time after the discharge from hospital had not yet been clarified. Another person said that the time spent on home visits was too great an investment. Two patients did not want to take part due to their health conditions. One patient did not want to "be controlled". One patient deceased during recruitment and one patient was discharged before recruitment was finished.

During the ongoing study four patients deceased; one patient migrated to another locality. Another person dropped out after she had been wearing the motion tracker at home and then ended up in the emergency room a second time. The motion tracker was reported lost and relatives did not want the patient to take part in the study any

longer with a new motion tracker. A dependent of another patient called in to cancel the participation providing the information that the patient had constantly forgotten the motion tracker and therefore did not wear it on a regular basis – however, the recorded data shows that the tracker was used regularly. The relatives of some patients justified the withdrawal of participation with the fact that the future situation of the patients concerned was not clear and they therefore no longer wanted to participate.

Without additional information, the figures just mentioned are difficult to put into perspective. Schulc et al. (2016) reported that in their study on preventive home visits for people over 70 years of age only 9 % of those contacted with a letter answered at all. Recruitment therefore had to be supported by gatekeepers and word of mouth. As reasons for these problems, the authors state that, on the one hand, the purpose of the intervention for the target group was unclear and, on the other hand, the target persons were afraid of losing autonomy if the need for assistance was determined. Further reasons for non-participation can be found in a paper on pulmonary rehabilitation by Taylor et al. (2007): almost one-third of the non-participants did not understand either the purpose or the approach of the study. About a quarter feared that their health would be negatively affected by the study, although this contradicted the intervention. Interestingly, more than half of the non-participants only wanted to participate in a study that did not use rehabilitation measures but administered medication to improve their own health. Although not all of the reasons just described apply to the study documented here some similarities can actually be identified: lack of knowledge, incomprehension, aversion to certain types of treatment as well as fear of loss of autonomy and the fear of great effort.

6.4 Summary

Demographic change is taking place in many countries, making many people living longer. However, since the risk of disease or injury usually increases with age, it is important from both a medical and a care perspective to be prepared for the treatment of these diseases and injuries. This is the only way to ensure that age does not generally have to be equated with the loss of quality of life. It is therefore all the more surprising that in many areas of interest there is a lack of knowledge about older and oldest age adults. This applies in particular to people with cognitive impairments. In addition, if technology is to be used to improve the life and quality of life of this target group, studies on the effectiveness of the use of technology must be carried out. Many methodological and moral challenges have to be overcome, some of which have been described above.

In order to ensure the participation of as many people as possible in such studies, it is necessary to examine the reasons for refusing to participate in order to develop policies and practices that will help to increase the willingness of older people to participate in such studies. It can already be said that the living conditions of many older

people make it difficult for them to participate in research; therefore, the respective study design must take such difficulties into account. However, participation in studies or research and development projects must always be voluntary. In addition, it can be said that the design of technology to support older people in their lives or to contribute to therapy should increasingly involve participatory approaches. The acceptance of such technology will depend on the participation of prospective users in the design of this technology (Altenbuchner et al. 2019). This applies in particular to the consideration of moral entitlements not only of prospective users but of all stakeholders. There are already several methods for incorporating such factors into technology development, like MEESTAR (Weber and Wackerbarth 2015). Although there are already many development projects concerning age-appropriate assistance systems, specific geriatric requirements are rarely taken into account, so there is a particular lack of research in this area (Barth and Doblhammer 2017). Better and more profound knowledge of the target group of older and oldest age people, as research subjects as well as potential users of technology, could support the necessary research.

These last paragraphs mentioned older and oldest adults as a group of future challenges and research interest. Obviously, the individual patient as a subject in human research has to be taking into account too.

Increased attention should therefore be paid to answering the following questions: what conditions need to be established to make patients more willing to participate in studies? To this end, it would probably be useful to bring in the debate on nudging (e. g. Sunstein 2014, 2015; Thaler and Sunstein 2009; for an overview see Barton and Grüne-Yanoff 2015). It will also be necessary to ask what information must be provided to be able to speak of informed consent, and what information may do more harm than good. It will be even more difficult to answer the question about the role of researchers who visit patients at home as part of a long-term study. Methodological questions of influencing the results, but certainly also many moral challenges, arise here. Finally, without any doubt it should be noted that this list is not complete, but that it will be indispensable to clarify this issue, because demographic change is a fact that poses new challenges to societies as well as to science.

6.5 Lessons learned for future research

The project just described is designed as a long-term study with exploratory character in which an attempt was made to include all patients during the duration of the project in order to gain a broad data basis. Although the design of the study was successfully ethically assessed, normative problems were identified that cannot always be avoided, but can nevertheless be solved.

In cases of quantitative studies, researchers seem to be uninvolved because they collect data using standardised methods. There is a great distance to research subjects and interactions between researchers and research subjects do not seem to take

place. Of course, this is a false perception. Yet it is most obvious that interactions between researchers and research subjects are usually much more extensive and intense when qualitative methods are used. With regard to oldest adults who are most often at risk of losing autonomy and quality of life due to reduced mobility, unfavourable environmental conditions or an aging body with its physical and psychological handicaps, it must always be expected that interaction between researchers and research subjects can become very intensive and that predefined processes must be deviated from. In such cases, it is not enough to use light language or large fonts on documents; instead, means need to be found to shape the relationship between researchers and research subjects. Often, not only patients but also their relatives demand special attention and care. This starts with the help, for example, if a patient has lost his glasses and ends, in extreme cases, with the death of a patient. However, special consideration of such vicissitudes of life can massively influence the results of a research project. For some patients, the monthly visit of a researcher becomes a welcome and important event, not because feedback is given on their own physical activity, but because this visit offers the opportunity for a chat; sometimes the freshly brewed coffee is already on the table. For the researcher, this is a psychologically and morally challenging situation, as there is a potential conflict between objectivity on the one and care on the other hand, and between the mission of research on the one and beneficence as well as nonmaleficence on the other side.

Situations such as those just described require very precise field descriptions, which can later help to interpret the results obtained. The research design of studies on older and oldest people must be specifically adjusted for the target group. At the same time, it must be kept in mind that there is still too little empirical knowledge about this age group and that corresponding theories have therefore been insufficiently tested. In order to counteract the blurring of research on the one hand and social interaction with research subjects on the other, it is mandatory to define precise processes that are adhered to. Simultaneously, measures must be taken to address the particular vulnerability of the target group.

In short: in the context of qualitative research projects on oldest adults, researchers need to consider a life situation that is generally not (yet) their own. To do this with the greatest care is a fundamental moral requirement of such projects. Although it may seem self-evident for qualitative field research, it is essential that researchers have social skills to deal with situations such as those outlined above. Those who work with oldest adults must expect to be directly confronted with suffering, grief and sometimes even death. Again, it is helpful to follow clearly defined procedures and at the same time be prepared to act flexibly.

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