



'IT IS NOT A PILL':

Uncertainties and promises in the entanglements of qualitative and quantitative medical research

by Doris Lydahl

Person-centered care seeks to improve health care by recognizing the individual patient's unique experience and by acknowledging the patient as an active and responsible participant in their own care. It is also conceptualized as a reaction to evidence-based medicine, opposing its alleged reductionist and exclusionary tendencies. Therefore, person-centered care is often conceived as different from evidence-based medicine, taking into account the combined biological, psychological and social identity of the patient which evidence-based medicine reduces to a set of signs and symptoms.

In this article, I analyze a paradoxical case in which a randomized controlled trial was used to evaluate person-centered care. Drawing on five interviews with researchers involved in this trial and on research documents and articles, I examine the entanglement of person-centered-care and evidence-based medicine from an STS perspective of standardization, uncertainties and promises. I first discuss the uncertainties and promises that emerge when trying to follow a research protocol. Second, the article illustrates the uncertainties and possibilities in knowing exactly what one measures. Finally, the article discusses the creation of a standard person. The article concludes that while the relation between person-centered care and evidence-based medicine is more complex than we might assume, the randomized controlled trial also transformed person-centered care in the process of evaluating it.

Keywords: Person-centred care, evidence-based medicine, standardization, uncertainty, promise

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*For the master's tools will never dismantle the master's house.
They may allow us temporarily to beat him at his own game,
but they will never enable us to bring about genuine change.*
(Lorde 1983: 27)

Introduction

Standardization in general and in clinical practice in particular has long been a subject for discussion and controversy in the social sciences. Evidence-based medicine is a movement of standardization in health care and medicine that has been especially controversial. While the phrase evidence-based medicine was first coined in the 1990's, it has been argued that it has a longer, and somewhat turbulent, history (Timmermans and Berg 2003). The methods of evidence-based medicine were already in use 70 years before it was coined and furthermore, some writers have argued that the 11th century physician Avicenna's approach to medicine resembles the principles and practice of evidence-based medicine (Shoja et al. 2011). Since the beginning of the 1990s when evidence-based medicine was established as a new paradigm, it has spread like 'wildfire' to every facet of the healthcare system of OECD countries, including the Nordic countries (Bohlin and Sager 2011: 13). Today, evidence is often seen as synonymous with evidence-based medicine. However, it has also long been a subject for discussion in the social sciences and humanities. Proponents of evidence-based medicine argue that it provides an unsurpassed way of integrating individual clinical experience with the best available evidence in making decisions about the care and treatment of patients. Opponents, on the other hand characterize evidence-based medicine as furthering a 'standard approach to health care problems advocated by the guidelines, in which every patient problem would be addressed generically, as one more instance of the same' (Timmermans and Berg 2003: 19). Moreover, evidence-based medicine has also been described as discriminatory towards women, by having medical procedures, instruments and samples being primarily of and for men (Epstein 2007).

Person-centered care is often depicted partly as a reaction to the rise of evidence-based medicine, opposing its allegedly reductionist and exclusionary tendencies. Although there is no universally agreed upon definition of person-centered care (Harding et al. 2015), it is commonly described as way of improving the health care system by recognizing the individual patient's unique experience, values and preferences while acknowledging the patient as a responsible participant in the development and evaluation of their own care (Hughes et al. 2008; International Alliance of Patients' Organizations 2007). Therefore, person-centered care is often conceived of as the antonym of evidence-based medicine; it takes into account the combined biological, psychological and social identity of the patient which evidence-based medicine reduces to a set of signs and symptoms (Mead and Bower 2000). For this

reason, evidence-based medicine and person-centered care have been described as belonging to separate worlds which are not easily brought together (Bensing 2000).

In this article, I analyze a paradoxical case in which a randomized controlled trial was used to evaluate person-centered care. While randomized controlled trials are sometimes used to evaluate person-centered care in the OECD and the Nordic Countries, the most common assessment method is surveys and interviews with patients and professionals and observations of clinical encounters (De Silva 2014; Skudal et al. 2012). In contrast, the case under study in this article used a randomized controlled trial to determine if the introduction of person-centered care in the management of patients with acute coronary syndrome – such as myocardial infarctions (also known as 'heart attacks') – would improve self-efficacy, reduce the duration of sick leave, decrease morbidity and increase activity compared to conventional care.

Person-centered care is commonly associated with a form of experiential qualitative medical knowledge rooted in clinical experience and worked out in everyday clinical practice, whereas evidence-based medicine draws on experimental quantitative knowledge generated in for example randomized controlled trials 'and worked out through the production of different kinds of clinical guidelines for practice' (May et al. 2006: 1022). Therefore, there is an interesting complexity to the case studied in this article. The randomized controlled trial analyzed in this article was set up because previous research on the benefits of person-centered care was conceived of as being too abstract and descriptive, and therefore not able to provide evidence of the potential benefits of person-centered care or how to implement it. The motivation for the randomized controlled trial was therefore to produce concrete and straightforward evidence for the benefits of person-centered care. Although person-centeredness can be argued to be a response to the proliferation of evidence-based medicine, the tools of evidence-based medicine were in this case used to test the benefits of person-centered care.

Drawing on interviews with researchers involved in conducting this trial and on research documents and articles, I examine how person-centered care and evidence-based medicine were interwoven and what uncertainties and potentials emerged. More specifically, I discuss how these uncertainties and promises were understood, reflected upon and handled in practice. How did



researchers combine an ambition to emphasize the uniqueness of the individual with the aim of extrapolating from knowledge about a few to produce guidelines for the many? Finally, I address

the consequences: what comes out of the mutual interference of evidence-based medicine and person-centered care, as they are examined and performed together?

Standards, uncertainties and promises in care and medicine

To understand the puzzling relationship between and the entanglement of standardization and person-centered care I draw on Science and Technology Studies (STS) theories of *standardization*, *uncertainties* and *promises* in research and medical practice.

STS researchers have suggested that the relationship between evidence-based standardization and person-centered care is more complex than suggested above. For example, van Loon and Zuiderent-Jerak (2012: 122) argue that person-centered reflexivity and standardization need not to be opposed, but can rather be intertwined. Zuiderent- Jerak (2007; 2015) has made a similar argument in his research on integrated care pathways. He argues that standards developed in practice that take into account local organizational complexities can actually further person-centered care. Lydahl (2019) has similarly argued that mundane standardization technologies can be integral components of person-centered care.

STS-scholars have further noticed that standards are ubiquitous in health care at large and argue that they are 'a fundamental prerequisite of scientific medical practice' (Berg 1997: 25; Bowker and Star 1999). Timmermans and Berg (2003; see also Timmermans and Epstein 2010) divide such standards into four ideal-types: design standards, terminological standards, performance standards and procedural standards. The first specify the desired properties of tools and systems. The second establish uniformity in the meaning of concepts. The third specify expected outcomes, and the fourth are used to govern the way different things should be done. This last type of standard has been especially important in modern medicine in the form of clinical guidelines.

Clinical guidelines are one of three main components of evidence-based medicine (Bohlin and Sager 2011). The first is the randomized controlled trial, also known as the 'gold standard' of modern medical research because it is regarded as superior to other means of assessing the results of an intervention (Timmermans and Berg 2003: 27; Timmermans and Berg 1997). Randomized controlled trials are experimental research for testing new treatments or interventions. The test subjects in a trial are randomly allocated either to a group receiving the intervention, or to a control group, not receiving the intervention. Often these trials are double blind, meaning that neither the test subjects nor the researchers know who is getting the intervention and who is not. Researchers use randomized controlled trials to evaluate both the effects and the effectiveness or efficacy of an intervention. Randomized controlled trials have become increasingly popular both in medicine and, for

behavioral studies, in social science (Deaton and Cartwright 2017). The second component of evidence-based medicine is the meta-analysis: a statistical technique used to combine the results of several randomized controlled trials. Advocates of meta-analyses claim that such analysis provides more accurate estimates of the effects of an intervention than an individual randomized controlled trial. Lastly, clinical guidelines translate the knowledge gained in randomized controlled trials and meta-analyses into protocols and checklists to be used in clinical practice (Bohlin and Sager 2011: 14).

In this article I build on Epstein's (2007) theories about diversity in medical research to understand how the researchers in the case I study combined the uniqueness of the individual with an aim to extrapolate from knowledge of a few to produce guidelines for the many. In relation to this, it is important to keep in mind the critiques of randomized controlled trials. One such critique is that randomized controlled trials build on a biased and exclusionary approach to knowledge making. In his study on changes in biomedical policy in the U.S, Epstein (2007) argues that politicians, activists and medical professionals in the 1980's joined forces to form an 'antistandardization resistance movement'. This movement accused biomedicine of generalizing results and constructing a non-representative standard human: a white middle-aged man. Biomedicine is one of the most notorious producers of standard humans as medical experiments imply that knowledge gained from limited groups of individuals can be considered generalizable to the human population as a whole. Even the limited groups of individuals participating in experimental arrangements like randomized controlled trials must be standardized if the results of different tests are to be accepted as comparable. Thus, if human subjects are to successfully serve medical research purposes they must be transformed into standardized 'working objects' (Epstein 2007: 33). To achieve this, Epstein argues that three ideal typical strategies are regularly used. Either researchers assume that possible variations are of little consequence for their purposes, or they use very specific inclusion criteria and only enroll individuals with a controlled set of characteristics. Finally, different subpopulations of humans can be subject to separate or comparable study – a strategy also known as niche standardization (Epstein 2007: 33).

Standard humans are however not only created in medical research. Standards in general always imply the idea of a uniform user (Epstein 2009). Feminist STS-scholars have also theorized about the consequences of standards. Notably, Star (1991) argues that as standards produce their own standard users, they will also produce their own 'monsters' or abnormalities – those who do not



fit the standard. These abnormal users are either otherized or they are silenced.

In her study on the *promises* of telecare technologies, Oudshoorn (2011) similarly shed light on those whose perspective are silenced or made the other. According to Oudshoorn, promises are important object of study because technologies – such as standardization tools – cannot exist without promises. Promises are performative because they can be considered enactments of a sought-after future (Oudshoorn 2011:36). In this article, I draw on Oudshoorn to analyze the promises that emerge from the entanglement of person-centered care and evidence-based medicine. In particular, Oudshoorn argues for the importance of a sensitivity concerning what problems a promise aims to solve, whose need and worries are addressed in a promise and whose perspective are taken into account. In every promise or expectation, she argues, 'some actors are foregrounded whereas the perspective of others receive less attention or are silenced' (Oudshoorn 2011:45).

Finally, I build on Singleton's (1998) theories about uncertainties and instabilities in medical research. In her groundbreaking work on the role of the laboratory in the cervical screening program in the UK, Singleton (1998) discuss the importance and potentiality

of instabilities and uncertainties. Rather than undermining the cervical screening program, Singleton argues that instabilities actually contributed to its continuity (see also Singleton and Michael 1993). Singleton contends that while a lot of uncertainties and instabilities characterized the laboratory practice of the cervical screening program, the laboratory continued to play its assigned role in the program. In other words, the laboratory continued 'to analyze samples and to make definitive diagnoses and recommendations' (Singleton 1998: 96). Moreover, she argues that the instabilities actually helped by creating flexibility and in making things doable. In addition, uncertainty is not necessary a sign of decreased validity, it can instead be interpreted as a commitment to the research and to the importance of discussing methodology. By redefining its role as complex rather than simple and straightforward, Singleton argues, 'the laboratory emerges as worthy of increased status and resources' (Singleton 1998: 98).

In what follows, I first outline my methods and materials. Thereafter I offer a description of a randomized controlled trial of a person-centered care intervention. In the subsequent sections, I discuss the uncertainties and promises emerging out of the combination of person-centered care and evidence-based medicine, as well as the consequences of such a combination.

Methods and materials

To study how person-centered care and evidence-based medicine were interwoven in a randomized controlled trial, I draw on a combination of document studies and semi-structured interviews. To understand the technicalities of the trial itself I rely on research protocols, research applications and articles published in the trial. I gathered this material through regional R&D databases and literature searches. I also build on materials used internally in the trial, which were subsequently published. This material consists of a fictive care plan used for educational purposes, and an assessment protocol used in interviews with patients.

In order to examine how the uncertainties and promises that emerged were handled in practice, I draw on interviews with five researchers engaged in the trial: one PhD student, one junior researcher, one senior researcher and two senior professors. The interviews were conducted as part of a larger research project on the definition, operationalization, barriers and facilitators to person-centered care in research and clinical practice (for more information see Britten et al 2017; Moore et al 2017; Naldemirci et al 2018). I initially approached the researchers via email. The interviews were then carried out between September 2012 and May 2016. Four of these were recorded and transcribed verbatim, while I held the fifth over the phone while taking notes. Most interviews took place at the interviewee's workplace out of respect for their tight schedules, but one interview was conducted at the Department of Sociology, University of Gothenburg. The

interviews generally lasted for about one hour (ranging from 20–78 minutes).

As the study does not include sensitive medical or personal information, ethical approval from the Regional Ethical Review Board was not deemed necessary. The study follows and utilizes the Swedish Research Council's ethical guidelines with its principles of information, consent, confidentiality and utilization (Vetenskapsrådet 202). To secure the anonymity of the participating researchers I have assigned each of them a pseudonym. Informed consent was received from all participants. The participants received written information before the interview which was discussed before the interview started. As this article is part of my PhD thesis, all researchers in the trial were invited to my public defense to discuss the results and analysis. However, no one chose to do so.

I used a purposive sampling strategy aimed at capturing several types of researchers, ranging from professors who were more or less only involved in the analysis of the material, to PhD students who were working more hands-on in the trial. The purpose of this sampling strategy was to get a broad view of the different kinds of uncertainties and consequences to be managed and negotiated. Still, it should be acknowledged that the interview material in this study is limited. When drawing on a small sample, it is not possible to make extensive generalizations. However, findings from the



analysis may be generalizable to theories that have a wider scope than the material presented here. Carrying out the interviews over a period of four years allowed me to gain insight to different phases in the trial. For example, I interviewed one researcher in May 2016 when the trial was finished. His account of the trial is therefore retrospective and reflective. In contrast, I interviewed another researcher during the first year of the trial. Her account is filled with hopes about the promises of the trial and of person-centered care at large.

For data analysis, I have made use of an abductive approach. Timmermans and Tavory define abductive analysis as a 'qualitative data analysis approach aimed at generating creative and novel theoretical insights through a dialectic of cultivated theoretical sensitivity and methodological heuristics' (2012: 180). As a form of reasoning, abduction depends on the interplay between observations and the researcher's theoretical disposition. Consequently, the researcher must begin with a familiarity with existing scholarship and theories while also having a willingness to abandon theories and think differently

(Tavory and Timmermans, 2014: 42). Abductive inferences may be strengthened by 'actively look[ing] for cases that may challenge both the possible hypotheses they [the researchers] came to the field with and the framework they began with' (Tavory and Timmermans, 2014: 75). In this vein, I initially analyzed the material using a coding framework inspired by Epstein's (2007) perspective on standardization in medical researchers. I began with codes such as *challenges*, *tensions* and *consequences* and with sub-codes such as *method-challenge*, *tensions in evidence* and *standard humans*. After this round of coding, I noticed that I needed theory to understand the promises visible in the material. These promises challenged my initial ideas concerning tensions and challenges. I also decided that I needed a deeper understanding of the tensions in the material. Therefore, I reread and coded the material against Singleton (1998) and Oudshoorn (2011), after which I merged the *challenge* and *tension* code into a single code called *uncertainty*, with sub-codes such as *do-ability*, *strengthening validity* and *weakening validity*. Additionally, I coded the material for *promises*, with sub-codes such as *perspectives* and *silences*.

A randomized controlled trial for person-centered care

In recent decades, there have been numerous calls for greater patient involvement in the planning and delivery of care and an emphasis on taking patients' experience, knowledge and preferences into account. These calls have both been patient initiated (Lydahl 2017), and institutionally driven (Gerteis 1993). To date there have been several concepts responding to these calls. Person-centered care (McCormack and McCance 2010), patient-centered care (Balint 1969) family-centered care (Platt 1959), and client-centered care (Rogers 1951) all favor increased patient involvement, partnership and an improved social, psychological, cultural and ethical sensitivity to patient-professional encounters (Hughes et al. 2008). There are also a variety of frameworks and models for the operationalization of these concepts.

In this article, I study one such model of person-centered care developed at a University Hospital in Sweden and the endeavors to produce evidence for this model. This model involved a particular approach to patient participation and shared decision-making coordinated through the three person-centered routines of narrative, partnership and documentation. It was argued that adopting these routines would facilitate and safeguard the transition from existing health care to person-centered care. In summary, the model took its starting point in the patient's personal account of her illness. Building on this narrative and other relevant clinical information, a partnership in the form of a care plan was to be established and agreed upon. Both narrative and partnership were to be secured through the practice of continuous documentation.

Researchers had already attempted to produce an evidence-base for the person-centered care model for some years before the

randomized controlled trial for person-centered care (from now on the PCC-RCT) was set up. This was done through a 'before and after design study' to investigate person-centered care in patients with chronic heart failure at five hospital wards. In this study, one group of patients received the 'usual' chronic heart failure care, and another group received care according to the person-centered care model in addition to usual guideline-based care procedures. Activities of daily living and health related quality of life were assessed when patients were enrolled in the study and when they were discharged from the hospital. The study found that person-centered care led to shorter hospital stays and better maintained levels of daily living activities. However, while this study pointed to the benefits of person-centered care, because it was not randomized, it did not live up to the gold standard of a randomized controlled trial.

It is commonly argued that randomization reduces bias, especially selection bias and confounding. Selection bias, i.e. when the research participant is not chosen at random, is argued to increase the risk of having a sample that is not representative of the population. Randomized controlled trials usually measures the association between two variables: the intervention and the outcome measure. Confounding refers to a third variable – one that is not tested in trial – that has an effect on the outcome measure. Therefore, studies aim to have a random distribution of confounders between the intervention group and the control group. In sum, randomization is thought to deal with the difficulties related to the fact that patients vary (Epstein 2007: 49).

Following the 'before and after design study', the researchers therefore decided to continue their research by undertaking a



randomized controlled trial design in order to implement and evaluate person-centered care.

Myocardial infarctions are one of the most common forms of acute illness in Sweden and one of the third most common causes of prolonged sick leave. Therefore, the researchers decided to design their randomized controlled trial for patients with acute coronary syndrome. This also enabled the testing of person-centered care over the complete care chain, i.e. not only in in-hospital care but also in outpatient and primary care.

The trial thus carried a lot of promises and expectations. It promised to solve the potential biases of the previous study and to provide an evidence-base for a newly developed model of person-centered care. Those whose needs and worries were primarily addressed in this promise were the researchers and the developers of the model of person-centered care. While the model itself promised to improve the situation for the patient, the perspectives of patients and healthcare professionals were less visible in the promise of the trial (For a discussion about the assumptions of this model see Naldemirci et al. 2018).

The trial hypothesized that the introduction of person-centered care in the management of patients with acute coronary syndromes would improve self-efficacy, reflected by reduced sick leave and morbidity and/or increased activity compared to conventional care. To test this hypothesis, 199 patients from two hospitals were randomly assigned either to an intervention group receiving person-centered care or to a control group receiving 'usual care'. In the following, I shall describe the intervention of the trial in more detail.

Intervention – implementing person-centered care

The PCC-RCT took its starting point in a structured process of narrative elicitation. According to the trial's research protocol, this was to take place at the hospital where a caregiver interviewed the patient. To organize narrative elicitation, an assessment protocol was developed for use in all patient interviews. The protocol began with four questions that aimed to define opportunities and problems in rehabilitation after acute coronary syndrome. Following these questions, patients were asked to judge their own medical condition and state of health using a variety of scales.

The narrative documented during these interviews formed the basis for an individualized care plan. According to the trial's research protocol, this plan should contain information regarding all follow-up actions, where these would take place, who the patient would meet and when, as well as what would happen – including the objectives about returning to a particular activity level. The protocol also emphasized that the care team and patient should both agree to the plan, which would then follow the patient and be updated and worked with throughout the care chain. It also emphasized that all caregivers needed to familiarize themselves with the care plan.

However, while the PCC-RCT aimed at implementing person-centered care over the whole care chain, it turned out to be quite a challenge to train all the hospital staff involved. Therefore, another approach was taken in practice:

Since the PCC-RCT mostly focused on primary care we said: 'Okay how much should we train the hospital staff?' (...) we [knew we] would have to make a big effort. Therefore, what we did was that the research nurse elicited the patient narratives and wrote the care plan which was later sent to primary care (...) Every primary care team had to meet with the patient at least once, and then they could decide if they wanted to meet on more occasions (Researcher 1)

Consequently, rather than having a 'person-centered approach' over the complete care chain, in practice the intervention became focused on two particular actions. First, an interview between the research nurse and the patient after which the care plan was formulated. Second, a meeting between the patient and the doctor or nurse at the primary care center in which the care plan was further refined. In other words, designing tools like assessment protocols and care plans and getting the intervention to work was prioritized over training hospital staff – who might then end up failing to perform person-centered care in accordance with the approach defined in the PCC-RCT.

This instability in the trial can be interpreted in two ways. On the one hand, one could argue that the researchers contributed to the instability digressing from the research protocol by focusing the intervention on the two specific meetings rather than having an overall person-centered approach over the complete care chain. From this perspective, it seems as if person-centered care was so different from what the design of the randomized controlled trial depicted, that it could not be imposed on standard medicine without issues.

On the other hand, I would also argue that what could be seen as a digression from person-centered care could also be interpreted as a commitment to person-centered care and to make the trial doable (Singleton 1998; see also Fujimura 1987). From this perspective, the temporary instability, and thereby the do-ability, was necessary in order to achieve stability for person-centered care in the longer run. In the hierarchy of evidence, meta-analysis of randomized controlled trials is given the highest grade (Greenhalgh 1997), while qualitative research does not even qualify for the hierarchy. To gain impact and to be listened to the researcher felt that they needed to produce evidence that qualifies and ranks high in the hierarchy of evidence. From this perspective, it makes perfect sense to prioritize the development of the technologies of person-centered care enabling the production of evidence.

This can also be interpreted as a promise of the PCC-RCT. Several researchers emphasized how if there was a standard for



person-centered care, such as a clinical guideline, dictating what person-centered care is and how it should be performed it would facilitate the uptake of person-centered care:

I think what would be valuable, would be some kind of a certification like the one you have with other quality standards. Because then people or wards or care centers could request to become certified and then someone else would find out if they are working according to person-centered standards and I think that not only would this speed the uptake of this but it would also help us doing research and applying for funding (Senior Professor).

This account imagines a desired future (Oudshoorn 2011) where the person-centered standard would act like an obligatory passage point (Callon 1984) for anyone doing research or funding research on person-centered care. The promise – that person-centered care organization and research would gain legitimacy – is chiefly reflective of the organizational and research perspectives. While this by extension includes patients and healthcare professionals, they were not clearly visible in this articulation of the promise of person-centered standards.

'It is not a pill' – on the problem of intervention variation

One of the main uncertainties in the PCC-RCT was in relation to variation, control and effect. One of the researchers very aptly described the problems that arise from using a method developed to test the effects of drugs on something that concerns relations and partnership:

...because person-centered care, it is not a pill. In other studies, like when you have studies on medication, so testing new medication, one will have like a sugar pill and one will have [an] active [substance]. Then you know that you have one group that will take this control sugar pill and the other one is eating the active substance. Then you will know when you are evaluating, 'okay, it must be the pill that is responsible for changing the blood pressure in a positive direction'. But person-centered care it's not a pill that you, like, swallow; it's more complicated, it's about philosophy (Researcher 2)

In other words, when testing person-centered care through a randomized controlled trial there was a problem of knowing exactly what it was that gave effect. Although the PCC-RCT was built as a proper randomized controlled trial with one control group and one group receiving the intervention, it turned out to be difficult to decipher which of the different, interwoven, relational and contextual components of the intervention produced an effect:

I still have no idea what it is in person-centered care that gives effect. Is it that we have structured the care path? Is it that a patient feels recognized? Is it that the professionals get to work more in accordance with their capabilities? I do not know. Moreover, because it is so complex – I have said that this is a

complex intervention. We have to evaluate it holistically; we cannot remove any parts. A biomedical randomized controlled trial does not want to see the whole picture, they just see the part that they are testing and if it has any effect. (Researcher 1)

This account nicely mirrors a tension present in research about person-centered care. This tension concerns the relation between the whole and the parts of person-centered care, for example between seeing person-centered care as an overarching holistic approach or something that can be operationalized. Several well-cited scholars in the health care sciences have argued that while person-centered care is widely used it is also poorly understood and ill-defined and have therefore called for a specification and/or operationalization of person-centered care (Stewart 2001; Mead and Bower 2000). Similarly, it has been claimed that person-centered care is a 'fuzzy concept' that is often recognized but 'difficult to operationalize in measurable elements' (Bensing 2000: 21).

Against this background, there has been a plethora of articles that attempt to pin down the core elements or indicators of person-centered care (Hughes et al. 2008). In the excerpt above, the researcher offered three potential explanations of what it was in person-centered care that gave effect. Perhaps it had to do with the continuity of care and the importance of having a structured care path. Another explanation was that it had to do with patients feeling recognized. Finally, it could be related to how the professionals work more according to their profession. All of these have been argued as important aspects in both the implementation and evaluation of person-centered care (Hughes et al. 2008; Gerteis 1993). At the same time, others argue that person-centered care is part a holistic paradigm best understood as 'complex phenomena, and multidimensional concepts, lacking single definitions' (Harding et al. 2015: 15). The researcher above was torn between wanting to identify discrete components of person-centered care and also wanting to keep the whole intact. Keeping the whole intact comes with the price of uncertainty – of not being able to specify what it was in the PCC-RCT that gave effect.

However, this uncertainty can also be put to use as an advantage. The researcher above distinguishes between what he called 'biomedical randomized controlled trials' and randomized controlled trials that take the whole into account. In this sense, he used the holistic perspective to criticize biomedicine. In other words, while the PCC-RCT made use of a biomedical method there was still an implied critique of biomedicine for not seeing the whole but only the parts. In saying 'We have to evaluate it holistically; we cannot remove any parts', the PCC-RCT is positioned as a non-biomedical trial. Not knowing what it was that had an effect was thus mobilized as advantage. Uncertainty is therefore not necessarily a problem; it can rather be seen as a confirmation of rejecting reduction and simplicity. Again, like in Singleton's study (1998), uncertainty can be seen as a commitment to validity and, more generally, as a commitment to the importance of discussing research design.



The standard person

There was significant ambivalence in the PCC-RCT between the demands posed by evidence-based medicine – in terms of who is eligible for an intervention – and the desire to value each patient as a unique person that is at the heart of person-centered care.

As argued by Epstein (2007) human subjects must be transformed to standardized working objects if they are to successfully adhere to the rules of medical research. Therefore, in accordance with the rules of evidence-based medicine, not all persons could be considered eligible for the PCC-RCT. To decide which persons to enroll in the trial a set of inclusion and exclusion criteria was formulated. Persons eligible for the study were men and women under 75 years of age hospitalized for acute coronary syndrome who have a diagnosis of acute myocardial infarction as defined by a set of medical criteria confirmed by a physician. Yet, to conform to these criteria was insufficient to ensure inclusion. A patient could also be excluded from the study if one or more of the following exclusion criteria applied:

- Not willing to participate
- No registered address
- Currently a patient in private primary care
- Severe disease with morbidity as expected outcome
- Severe disability like cognitive impairment or mental disability
- Abuse of alcohol or drugs
- Migration from the municipality
- Performed coronary bypass surgery during hospitalization

Following Epstein's theories, it is clear that the PCC-RCT created a standard person in this process of creating a working object through inclusion and exclusion-criteria. This imagined standard person was rather young (given that myocardial infarction is more common in patients over 75 years), had a home, did not have any substance abuse problems and did not suffer from any cognitive or mental disability such as dementia. To cope with the problem of having human subjects as working objects the PCC-RCT consequently made use of the second ideal type strategy identified by Epstein: only enrolling individuals with specific characteristics (Epstein 2007: 33). One of the researchers discussed the reason for insisting on specific criteria in the following way:

You need to have a homogenous group because otherwise you will compare apples and oranges. (Researcher 1)

If the control group and the intervention group were too different then comparison of the results would be difficult, if not impossible. This is a general principle in randomized controlled trials. While the randomization partially takes care of the problem of variation, strict inclusion and exclusion criteria are, according to Epstein, often mobilized to:

create a more standardized and homogenous research population for a study, based on the argument that the more researchers succeed in reducing the number of variables that might affect a study, the easier it will be to distinguish 'signal' from 'noise'. (Epstein 2007: 49)

By using strict inclusion and exclusion criteria the researcher hoped to be able to separate out the apples from the oranges. He thus returned to the idea of measuring the effects of person-centered care but this time he viewed uncertainty of knowing what gave effect as more negative than positive. Uncertainty thus seems to have a dual position in the PCC-RCT. Sometimes uncertainty was argued to be a rejection of simplicity, but at other times, it was seen as making the production of evidence more difficult.

Several issues can be raised in relation to the question of inclusion and exclusion. Following feminist science studies (Haraway 1988; Moser 2005; Oudshoorn 2011; Star 1991), we can ask: What bodies are made silent? Moreover, what are the spillover effects or consequences of constructing such a fitting person for person-centered care? I will address this topic below. First, however, I wish to highlight an additional issue.

As I have previously emphasized, person-centered care is often depicted as a response to the rise of evidence-based medicine, with its alleged reductionist and exclusionary tendencies. In an article on 'the separate worlds' of evidence-based medicine and person-centered care, Bensing (2000), a clinical psychologist, argues that randomized controlled trials by nature are not patient-centered since patient characteristics are often considered to be 'noise' that might disturb the results of a study:

Patients who are too old, too young, too illiterate, or suffer from comorbidity or concurrent psychiatric disturbances are excluded from the study, because the statistical power could be reduced by those characteristics. (...) Randomized clinical trials are performed on homogeneous patient groups, that are artificially constructed by banning many patients, while the consultation room is filled with patients that show a wide diversity in related symptom patterns and an even wider diversity in the way they evaluate and cope with these symptoms (Bensing, 2000: 19).

The critique that Bensing raises against evidence-based medicine could more or less be directly applied to the PCC-RCT. Patients who were too old, homeless or too disabled were excluded from the study. They were excluded precisely because it was much more difficult to get them to answer surveys and questionnaires, which could lead to problems when statistically analyzing the material.

We have to be pragmatic when it comes to homeless persons; it is so difficult to send questionnaires to them. Cognitive impairment is the same. Persons with cognitive impairment are usually excluded from controlled trials because they have so many difficulties in answering surveys (researcher 1)



Again, the do-ability of the trial was prioritized, which called for pragmatism in relation to the underlying principles of person-centered care. While this, again, can be interpreted as a digression from person-centered care, it can also be interpreted as a commitment to it.

Another example of the tension between do-ability and how person-centered care was envisioned relates to one of the core values of person-centered care – that all persons are capable¹:

I am totally convinced that it [person-centered care] works for all patients. In other words, the basic assumption is that all people are capable, including the small child and the elderly person – well, they need not to be elderly, the dementia patient is capable. People are capable of different things, but everyone is capable. (Project Coordinator)

However, in the PCC-RCT not everyone was deemed capable of participating in the randomized controlled trial, as both elderly patients and patients with dementia were excluded. In this way respecting the rigorous requirements of a randomized controlled trial and prioritizing do-ability, led to the partial suspension of core values and beliefs of person-centered care.

...and the 'abnormal'

Star describes – in a now classical essay on the standard hamburger eater – how standards create suffering and moments of friction for the people 'who must use the standard network, but who are also non-members of the community of practice' (Star 1991: 42). Similarly, Moser (2005; 2019) uses this argument when inquiring into the different modes of ordering disability. She argues that while standards create order for those inside the norm they also 'make trouble for, disable or exclude others with non-standardized bodies and subjectivities' (Moser 2005: 677). Standards, therefore, render standardized bodies invisible, letting them disappear into the background, while non-standardized bodies are performed as problematic and visible. Like Star, Moser points to the fringes of the standard convincingly arguing that '[t]he normal implies the abnormal, the deviant and lacking.

However, they not only build upon it, but also help produce and reproduce it' (Moser 2005: 678).

The PCC-RCT also produced its own abnormalities. This can be traced in relation to the inclusion and exclusion criteria. One of its consequences was, as previously mentioned, that persons who were too ill, too old, suffered from the wrong complaints, who were cognitively or mentally impaired, who had substance abuse issues or were homeless, were positioned as persons unfit for the PCC-RCT.

However, the standard person-centered care person and her others were not only produced through the study protocol, but also through the intervention and its tools. The standardized version of person-centered care performed a particular type of person:

Usually it's like you are listening to the health care professionals, to the nurses, to the doctors and they are, like the patients have a lot of respect, also, for the staff, and they are explaining and the patients are just passive, listening to what they are saying, what they are told to do [...] Person-centered care is more like we begin 'What do you think? What is your opinion? What do you believe? What can you, how can you'... the focus is shifting from the health care professionals to the patient, as a person (Researcher 2)

As seen in this account, 'usual care' produced docile and passive patients who were expected to respect and obey health care professionals. Person-centered care, on the other hand, invited the patient to offer their thoughts, beliefs and opinions. Pols (2005) connects these types of endeavors to a deliberative democratic view of the patient wherein the patient is enacted as having a 'perspective'. However, to have a perspective, Pols argues, one needs to have a language and therefore 'if a patient is not able to produce words, he or she is excluded from inquiries into the patient perspective' (Pols 2005: 206). Similarly, the PCC-RCT excluded persons without language, homeless persons, persons over 75, persons with substance abuse problems and persons with disabilities, thereby making them 'the other'.

Conclusions

While person-centered care and evidence-based medicine have been described as belonging to separate worlds (Bensing 2000), STS-scholars have argued that standardization and person-centered care can be intertwined (Lydahl 2019; van Loon and Zuiderent-Jerak 2012; Zuiderent-Jerak 2007; 2015). While building on a somewhat small empirical case study, this article adds to that discussion. By exploring an attempt to evaluate person-centered care with a randomized controlled trial this article shows that the entanglement of person-centered care

and evidence-based medicine gives rise to both uncertainties and promises.

The uncertainties related to the problem of following research protocols, with the fact that person-centered care is not a pill and that it therefore is difficult to know what the active ingredient in the intervention is. They also related to the problems of creating a standard person for a type of care that aims to value everyone as unique and capable. However, as argued by Singleton (1998: 101)

¹ For a more elaborate discussion on capability in person-centred care see Naldemirci et al 2018



uncertainties and instabilities do not necessarily lead to conflict or decreased legitimacy. Instead, exposure and discussion about uncertainties can be a sign of researchers', or in her case laboratory workers', commitment to the validity and the indispensability of the research in question. In addition, the uncertainties can be employed to increase do-ability. By putting some part of the person-centered care model in brackets, and thereby destabilizing person-centered care, the researchers succeeded in designing and performing the randomized controlled trial.

The promises related to hopes of creating unbiased evidence for a specific model of person-centered care and of creating a standard for person-centered. They also related to employing the uncertainty concerning what gave effect, seeing this as a proof of a holistic approach. In every promise however, some perspectives are foregrounded, and others are made silent (Oudshoorn 2011). In the PCC-RCT the needs and worries of the researches was visible, while

the perspective of patients and healthcare professionals was less so.

Importantly, the interference of evidence-based medicine and person-centered care has consequences. The methodological demands of evidence-based medicine have consequences for the description and definition of person-centered care. The person-centered care carried out in the PCC-RCT was different from the person-centered care described in the introduction of this article. It was not inclusive and anti-reductionist but instead – due to the efforts of increasing statistical power – had to be rather exclusionary. In other words, the randomized controlled trial transformed person-centered care in the process of evaluating it. If person-centered care implies a partial de-medicalization of care by emphasizing the patient narrative and partnership, randomized controlled trials for person-centered care risk medicalizing care anew. It does so by standardizing the person in person-centered care in order to better evidence the outcome of changes in care delivery.

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