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EVIDENCE FOR PERSON-CENTEREDNESS IN TELEHEALTH RESEARCH

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Abstract

This paper describes person-centred care and distinguishes it from person-centred medicine and patient-centred care. Three characteristics of person-centeredness are drawn from human subjects research principles: respect, benefit and justice. Using reports of telehealth research involving people with diabetes, an exploratory assessment of the methods was done to look for descriptors and processes that would contribute to evidence for the identified characteristics of person-centeredness. Reports from fourteen studies were explored. The study methods and results had great variability; four of the 14 studies used a descriptive design and five studies used a design that included randomization. From a person-centred perspective, respect of study participants could be seen in their willingness to aid, when asked, in the development of intervention approaches and they were grateful for personal attention. Benefit could be seen in that participants responded positively to the offer of improved diabetic self-management and overall better health. As evidence of justice or fairness, telehealth researchers described using various and wide-ranging methods for inviting people comprising populations to become research participants. The triad of concepts may provide guidance for the improvement of research involving people with diabetes.

Keywords: telehealth; diabetes; research design, human subjects' research.

Introduction

eHealth is the use of information and communication technologies (ICT) for health. Examples include treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health.[1] As eHealth increases in scope and impact across multiple settings and environments, it presents opportunities for improved health on an impressive scale. Telehealth provides health information and services over distances, mediated by ICT. Countless specialties are using telehealth technologies and applications today. Given that distance is characteristic of telehealth care and research, an emphasis on retaining the person-hood of all telehealth care recipients and research subjects seems especially warranted.

The United Nations Educational, Scientific and Cultural Organization published the Universal Declaration on Bioethics and Human Rights in 2005.[2] The Declaration includes fifteen principles that are to be respected by all involved in medicine, life sciences and associated technologies. The Helsinki Declaration,[3] most recently approved by the World Medical Association in 2008 and under revision in 2013,[4] describes principles for medical research and medical care. The Belmont Report,[5] published in 1979 by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, reflects the tenets of the Helsinki Declaration and mirrors the UNESCO Declaration while specifically identifying three ethical principles that should underlie the conduct of biomedical and behavioural research involving human subjects. The three principles identified were respect for persons, beneficence and justice. Since the principles were articulated to underlie research involving people, we suggest that they serve as principles for person-centeredness in research as well as person-centred care.

By respect we mean that all who are involved in health care should value and demonstrate respect for human dignity and for every individual's interests, beliefs and values, culture and socioeconomic status. Beneficence means that persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making

efforts to secure their well-being. Justice is used here in the sense of fairness in distribution or receipt of what is deserved.

Person-Centred Care

The concept of person-centred care is different from person-centred medicine and patient-centred care. Person-centred medicine has recently had a re-invigoration, with substantive philosophical and theoretical arguments for returning to a medicine of, for, by and with the person in an empowering manner through a partnership of patient, family and clinicians.[6,7] Person-centred medicine is a model of care for physicians who apply advances in biomedicine and technology within a humanistic framework while being attentive to each person's bio-psychosocial and physical needs.[7]

Patient-centred care is primarily focused on diagnosis and treatment of illness or injury during episodes of care. Patient and family engagement is another concept that is similar to, if not synonymous with, patient-centred care.[8] Patient-centred care is an evolving concept with learned competencies on the parts of patients, physicians and other providers, and health care systems.[9]

Person-centred care, in which the health care provider and recipient are in collaborative partnership, includes health-related care rendered before, during or after direct care episodes. For example, teaching communities about malaria prevention techniques would be a disease prevention strategy and it would take place before the occurrence of illness that requires treatment. Or, the provider who visits the new mother to support her in the breast feeding of her child would constitute provision of a health promotion strategy after the labour and delivery care episode. Person-centeredness in telehealth research might include emphasis on the consideration of whole communities as the population for a study. Or, the researchers might broaden their interactions with new mothers to include education and support approaches beyond just those that are specific to the study design.

While person-centred care includes diagnosis and treatment episodes, it also allows for the provision of advice or reassurance or engaged listening; none of these interventions of themselves make the person a patient. Receiving both care and, when necessary, treatment or cure, should benefit the recipient by

optimally meeting health-related needs. Care delivery should be designed to ensure the recipients' readiness to learn and participate, while prioritizing and integrating their goals for health and coping with illness in a plan of care.[10] For example, in an effort to move patients with advanced cancer toward person-centred care, nurses used out-reach phone calls as well as calls or communications from patients and family to meet the need for high levels of collaboration between providers across acute, palliative and primary care settings.[11] Said one clinical researcher for this study, "I think the patients liked having someone within the hospital who 'knew their story' and who was interested in them as individuals as well."[11]

We propose that recipients of person-centred care and the participants in research that is person-centred, which may be individuals, groups or communities, are fully considered throughout every interaction. Providers, in the context of their own discipline, consider care recipients' mental and physical health, beliefs and values, cultures and socio-economic realities, while also integrating the science and clinical expertise relevant for the anticipated or actual needs, risks or problems. Similarly, researchers committed to person-centeredness could be expected to consider the participants' health, beliefs and values, cultures and socio-economic realities in addition to the participants' responses to research interventions. Essentially, the biography of the person/recipient is respectfully and fairly considered, whether the interaction consists of care delivery or research in the areas of health promotion, disease prevention, health information, emotional support, risk assessment and intervention, or illness or injury diagnosis and treatment.

Person-centred care providers represent any number of disciplines, and they are capable and qualified to render health care services based on their knowledge, skills and scope of practice. Providers and researchers who use telehealth technology must be technically competent and also adherent to the appropriate standards of practice and care. Assured competence and adherence to standards is gaining importance with the increased use of eHealth and mHealth. For example, nurses or community workers are able to bring health care to people in the community who do not have access (or reasonable access) to physicians or tertiary care facilities. In keeping with the aim of universal coverage or fairness,[12] the health-related needs of people can be

more equitably met because their personal context is the foundation of the provider's assessment and mutually developed plan for care.

Purpose

Considering the constantly increasing application of telehealth, and with the rapidly growing body of telehealth research, the purpose of this paper is to describe an exploratory assessment of whether and how the principles of respect, benefit and justice or fairness are applied in telehealth research when people are the subjects. The larger goals of this assessment are to (1) develop a framework by which a more extensive body of telehealth research can be analyzed for person-centeredness, and (2) disseminate the populated framework for consideration by researchers as they design and execute telehealth studies.

Methods

This exploratory assessment used a convenience sample of 14 studies that met the criteria of telehealth research involving people with diabetes and published 2011-2013. The 14 studies resulted in 16 papers for review, with two studies generating different analyses of the same subject group. The sample was drawn from research involving people with diabetes because diabetes is a worldwide problem. In year 2000, about 171 million people had diabetes and estimates are that by 2030 that number will more than double.[13] In an effort to look at the people in the study sample as closely as possible, no review papers or studies using retrospective data were used since their content would be, by definition, somewhat removed from the participants themselves. The papers were assessed, first, for subject recruitment and data collection methods, and, second, for textual descriptions considered to represent evidence of respect, benefit and justice or fairness for the subjects.

Results

Four of the 14 studies used a descriptive design.[14-17] Other designs used included a variety of randomized trials including randomized control clinical trial,[18] exploratory randomized comparison,[19] randomized practical effectiveness trial,[20] pilot randomized control trial,[21] and translational randomized trial.[22] The remaining designs were descriptive with controls,[23-25] convenience and matched sample,[26] and mixed methods design.[27] Nine of the studies used control groups which were often described as receiving 'usual care.'[18-26]

Six studies noted approval of the institutional review board[14,16-19,25] with two more studies documenting obtaining informed consent.[20,27] Three studies reported a theory-based development of their methods, with two using Bandera's Self-Efficacy theory[14,21] and one using Bandera's Social-Cognitive and Self-Efficacy theory.[20]

Study populations were also quite varied. Sources of subjects included veterans (former military personnel),[18,19] diabetic clinics,[16,25,26] diabetic nurse or diabetic educator clients,[14] phone consults,[15] diabetics at home,[21] diabetics in the community,[23] rural diabetics,[24] diabetics who were not eligible for automated phone system management,[17] primary care database,[20] primary care plus home care databases,[27] and members of a health care workers union.[22]

Evidence of Respect, Benefit and Justice (Fairness)

Respect of people asked to participate in research could be inferred in several ways. Examples of involvement of the actual or potential subjects in the development of the study included asking for input about the process, content and format of the web-based education[14] or the messaging intervention that was to be tested.[25] Subjects were asked to participate in the development of the self-management program[21] or were asked to create their own self-management plan and to set their own goals.[20] Participants reported that the personalized aspect of using email to communicate about their state of health and how they were feeling meant a lot to them.[27] Some reports labelled the subjects 'participants' rather than patients.[24,25] One study reported coaches 'gently querying' the participants.[24] Another study noted that participants in the intervention group were given prompt and 'warm care' on the phone.[26]

Benefit accrued by people participating in research was less detectable. One study reported improved quality of life and decreased fear of hypoglycaemia as a study result even though it was not statistically significant.[16] Another benefit was that better communication and participation in discussions about care supported both patients and families.[21] Subjects

were said to 'eagerly anticipate' the weekly reports that summarized their weight, activity, calories and that gave motivational comments.[23] No studies reported a financial remuneration or other kind of benefit not related to diabetic care *per se*.

Justice or fairness was estimated in terms of the likelihood of being asked to participate in a study. Letters mailed to all with clinic visit appointments[18] or an advertisement in a regional paper[23] or phone calls to all members of a particular labour union[22] cast a fairly wide net and allowed potential participants to make their own decisions about entering the different studies. Other groups were drawn from a more narrow population and could have been construed as the remainders of a larger population, for example, those people not eligible for a different study were invited into another one[17] or those people who might not be able to complete an in-person diabetic management program were invited into another one.[22] A number of studies reported that both or all groups of participants received diabetic education.[14,19,26]

Discussion

In spite of the inability in human subjects research to control all extraneous variables and ensure all interventions are consistent, researchers apparently consider randomized controlled trials, or some variation including randomization, as the best research design. In proposing a framework for person-centred health research, Buetow[28] developed a hierarchy of person-centred study designs. With participant as a person as the y axis and researcher as person as the x axis, intervention studies were at the lowest, least applicable, end of both axes. Auto-ethnography, case and single subject designs and phenomenology and grounded theory were at the highest place on the two axes. The studies described in this paper that used descriptive designs come closest to this ideal taxonomy.

More than half of the studies had control groups, where the participants received usual care or a non-telehealth intervention. From a person-centred view, it may be useful to add a qualitative research design component to telehealth studies, especially when control groups are used as part of a randomized design. This would help to ensure that all of the people participating in the studies have the opportunity to relate their experiences and to consider themselves as contributing and valued partners in the research process. It could also support knowledge development that would lead to improved care and outcomes.

While about half the reports indicated ethics review, we might assume that all studies were reviewed for human subjects' protection, given the prevalence of ethics review boards and the concern for litigation if people/patients/subjects/participants are not reasonably well-treated in research.

Table 1. Proposed framework for person-centered research.

RESPECT	BENEFIT	FAIRNESS
Use 'participants' rather than 'subjects' or 'patients'	Consider assessing QOL and designing interventions to improve QOL	Offer participation to whole population, eg, community
Include participants in design of interventions	Assess and, if needed, decrease participants' fears	Have interested persons make the initial contact with the researcher
Include participants in design of web-based materials, eg, messaging	Include families in discussions with participants	Avoid implying that participants are remainders or in a second-choice group
Have participants set own goals	Give participants feedback during and after study	Educate all participant groups (if any receive it)
Have participants design own self-management plans	Include communications intended to motivate participants	Avoid having a 'usual care' group
Include 2-way email communications		
Use 'gentle' communications		

Considering the wide diversity of this small set of studies discovering descriptions representing respect, benefit and fairness with subjects was difficult. The researchers did not know their reports would be analyzed for person-centeredness using the concepts of, respect, benefit and justice or fairness. However, the beginnings of a framework for assessing person-centeredness in telehealth research can be articulated. (Table 1)

Respect descriptors can be seen in the involvement of research participants or a matched group in the development and pre-study review of instruments that will be used in the study interventions. When possible, participants' own goals, self-management or self-care approaches can be used as a way of making the research process more person-centred. Researchers can focus on positive and personalized communications and interactions with participants so that participants experience a sense of value received for their time and effort and perhaps a greater motivation for their own health care promotion and disease prevention.

Participants' perceptions of the benefits of research participation can be enhanced by highlighting health improvements and ensuring holistic support of the participants and their families and significant others. People with diabetes seem willing to participate in studies that will help them and others to deal with this chronic, non-communicable disease. Justice or fairness could be seen in research subject accrual methods, generally with the potential participants arising from a large population being able to come forward or take the initiative to respond positively to an invitation to participate in a research study. None of the studies gave any evidence of coercion or other excessively strong encouragement to enrol in the study.

Conclusions and Recommendations

The abundance of published research that uses telehealth applications with people with diabetes is slowly contributing to the body of knowledge about diabetes care. For the most part, however, the studies have small samples or are unique without replication, or both. Increased emphasis on person-centeredness in diabetes research, with qualitative research methods used to learn from those people with diabetes what they need to have and know in order to cope with their diabetes, may be a useful avenue for continued research. This could mean a decreased emphasis on randomized controlled trials which, given the variability of interventions and measured outcomes across research groups, do not lend themselves to meta-analysis for building knowledge. Integrating the triad of respect, benefit and justice with research conceptualization and methodology could improve the participants' experience by making them feel more valued and thus strengthening the reliability and validity of the study findings.

The next phase of this work will use the findings of this study, in terms of descriptors of respect, benefit and justice or fairness, as the basis for analysis of a larger set of diabetes telehealth research. Studies will be analyzed for evidence of the three concepts. Studies using similar designs and methods will also be compared for evidence of person-centeredness together with study outcomes so assess whether outcomes are related to person-centeredness.

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