The debate about the «right» designs for nursing research is on-going. According to international surveys, studies on the effectiveness and safety of nursing interventions are rare. Thus one could assume that nurses frequently expose patients in hospitals and nursing homes to unproven therapeutic and preventive nursing interventions. Nursing interventions are predominately of a complex nature, consisting of several components depending on and interacting with each other and their complex contextual factors. Thus, evaluation studies are often challenging and need careful development, ambitious designs and systematic evaluations. The UK Medical Research Council (MRC) has proposed a framework, where qualitative and quantitative research rely on and cross-fertilize each other in order to develop theory-based complex interventions, prepare and conduct their optimal delivery, explain how and why the interventions work and which conditions contributed in case they did not work. The present essay outlines the points where qualitative research contributes towards the development and evaluation of complex interventions. Firstly, the UK MRC framework is introduced, and secondly it is illustrated where qualitative research should be located by using examples from a handful of qualitative studies.

Future clinically meaningful and implementable nursing interventions should best be developed by research groups with both excellent qualitative and quantitative research skills.

**Keywords:** Clinical nursing research, evaluation studies, qualitative research
The debate about the «right» approach for nursing research is ongoing (e.g. Richards & Hamers, 2009, Rolfe, 2009). Qualitative and quantitative research is still compared and contrasted (Liamputtong, 2010). Nursing scientists doing research in the field of clinical epidemiology are sometimes profoundly challenged by nursing scientists committed to qualitative research (e.g. Moers, Schaeffer, & Schnepf, 2011).

International analyses of publications in nursing journals suggest that nursing research is predominately non-experimental and descriptive (Mantzoukas, 2009; Polit & Beck, 2009b). Only a few studies report on the evaluation of nursing interventions. This is astonishing since nursing practice deals with a bulk of interventions and nurses make daily decisions on interventions. Ostensibly, nurses often expose hospital patients and nursing home residents to unproven therapeutic and preventive nursing interventions.

In this essay we will discuss the meaning of qualitative research in the stepwise development of nursing interventions. We assume that integration of qualitatively derived findings increases the soundness of a complex intervention and results in better outcomes. This essay hopefully contributes to bridging futile boundaries between quantitative and qualitative research traditions, resulting in benefits and wellbeing for patients and their relatives.

**Background**

Nursing interventions are predominately of a complex nature, consisting of several components depending on and interacting with each other and their contextual factors. Typical examples of complex nursing interventions are programmes to increase hospital hygiene, prevention of falls or pressure sores, just to mention a few. There is no distinct boundary between simple and complex interventions (Craig et al., 2008a) and few interventions are truly simple. A medication could be judged as a simple intervention after it has passed all phases of drug evaluation, has been approved by the regulatory authorities and is available as standardized product in pharmacies (Mühlhauser, Lenz, & Meyer, 2011). The application context of that simple medical intervention, however, might appear complex.

Complex interventions do not only comprise several interacting components. The number and variability of outcomes could also contribute to the complexity as could the number of groups or organisational levels targeted by the intervention. The flexibility or tailoring of the intervention which is often permitted or the number and difficulty of behaviours and attitudes required by those delivering or receiving the intervention contribute further to the complexity (Craig et al., 2008a, 2008b).

The context nursing interventions are embedded in is characterized by high turnover of environmental and organizational conditions. Thus, evaluation stud-
ies are often challenging and need especially careful development, ambitious designs and systematic evaluations.

A randomised controlled trial (RCT) is considered a most reliable study design for efficacy and effectiveness testing because spurious causality and the influence of potential confounders are largely reduced. Unfortunately, many RCTs dealing with complex interventions obviously do not consider a stepwise developmental process covering the theory fundament and piloting before experimental implementation (Möhler, Richter, Köpke, & Meyer, 2011). Sometimes, failure to succeed in improved clinical outcomes cannot be explained. Often no process evaluation has been performed alongside the trial in order to explain barriers and facilitators. Thus, the conclusion on the evaluation of a complex intervention could sometimes turn out like in the discussion section of a paper published in the highly respected journal Lancet:

> Introduction of such a system [Medical Emergence Team (MET)] did not significantly reduce the incidence of our study outcomes. Possible explanations for our findings are that the MET system is an ineffective intervention; the MET is potentially effective but was inadequately implemented in our study; we studied the wrong outcomes; control hospitals were contaminated as a result of being in the study; the hospitals we studied were unrepresentative; or our study did not have adequate statistical power to detect important treatment effects. (Hillman et al., 2005, p. 2094).

Clearly, such a conclusion must be prevented, both from an ethical and economical point of view, since the knowledge at the end of the clinical study is similar to that at the beginning of the trial. The United Kingdom (UK) MRC framework for the development and evaluation of complex interventions (Craig et al., 2008a, Craig et al., 2008b) facilitates the systematic and careful development and evaluation of complex nursing interventions. Some recent nursing studies have used this framework, e.g. the study by Kirkevold and colleagues (Kirkevold, Bronken, Martinsen, & Kvigne, 2012) on an intervention promoting psychosocial well-being following a stroke or a study investigating a guideline-based intervention programme aimed to reduce physical restraints in nursing homes (Köpke et al., 2012).

Qualitative and quantitative research rely on and enhance each other in order to develop theory-based complex interventions, prepare and conduct their optimal delivery, explain how the interventions work and which conditions contributed in case they did not work. However, the framework does not precisely outline when which qualitative method should be used.

Thus, the aim of this essay is to outline how qualitative research indispensably contributes to complex intervention development and evaluation. First we will introduce the UK MRC framework and then we will delineate some main notions of qualitative research and the meaning of knowledge in this research tradition. Following that and
using examples from a handful of qualitative studies, we will illustrate how and where in the intervention process cycle qualitative research contributes to complex interventions. We will conclude by stressing the combination of different research approaches in doing complex interventions and the need for quantitative and qualitative researchers to collaborate in order to achieve success in the development of clinically meaningful and theory-based complex interventions.

UK MRC framework of complex intervention development

The first UK MRC framework was published more than a decade ago (Campbell et al., 2000). It comprised five phases on a continuum of increasing evidence of intervention development and evaluation. The framework was highly influential. However, it was also profoundly criticized for linearity of increasing evidence, lack of methodological guidance, and neglect of social, political and geographical contexts in which complex interventions are implemented (Craig et al., 2008b, Möhler, Bartoszek, Köpke, & Meyer, 2012). In 2008, an update of the UK MRC framework was published aiming to address the limitations of the first approach (Craig et al., 2008a, 2008b). The revised version comprises four phases and suggestions for evaluation methods; and it reflects the circularity of the intervention development processes (Figure 1). In preparing all four phases, thorough evidence including available qualitative derived findings are needed. Various methodologies and methods available for qualitative research may be suitable for a number of questions to be answered in the course of designing and evaluating the MRC framework. As an introduction to each step of developing and evaluating complex interventions, the nature and particular merits of qualitative research will be briefly introduced.

Main notions of qualitative research

Qualitative research is a generic term for studies that are built up on «soft» data and is recognized as a science of words (Denzin, 2008) compared to quantitative research as a science of numbers strictly measuring «hard» data (Liamputtong, 2010). Qualitative research:

1. describes the form or nature of what exists (contextual)
2. examines the reasons for or associations between what exists (explanatory)
3. appraises the effectiveness of what exists (evaluative) and
4. develops theories, strategies or actions (generative) (Ritchie, 2003)

Qualitative research covers a wide variety of data sources, including observations, in-depth interviews, records, charts, and other types of physical evidence (e.g. photographs, diaries, letters). Ethnographic studies, for example, can help to facilitate understanding of people’s behaviour affecting health and illness episodes (Polit & Beck,
2009a). In phenomenology the researcher investigates the nature or meaning of something, trying to get a grip on the essence of what is often expressed as people’s «lived experience» (van Manen, 1990). Main data sources are in-depth conversations with researchers and informants. Similarly, hermeneutics uses lived experiences as a tool for better understanding of the social, cultural, political or historical context in which these experiences occur. Grounded theory focuses on the manner in which people make sense of social interactions and the interpretation they attach to social symbols (e.g. language) (Polit & Beck, 2009a).

Data collected through qualitative research help researchers to go behind people’s (professionals’, patients’, etc.) preconceptions and frameworks. The results, typically organised into quotes, incidents or stories are concrete and meaningful, providing diverse insights about phenomena (Miles & Huberman, 1984; Munhall, 2007). Thus, qualitative research provides different knowledge than quantitative studies. Knowledge here builds on holistic, deep understanding or comprehensive description of certain events, relationships or conditions and is presented as hypothesis, themes, concepts, categories or theories.

Qualitative research from singular empirical studies is often referred to as first level research or primary studies. However, the findings in these qualitative studies may involve small numbers of participants, be scattered, conflicting or in need of systematizing (Lee & Sandelowski, 2012). Qualitative metasynthesis is secondary level research that interprets available primary qualitative studies within a field of inquiry by bringing together and breaking down the findings, elucidating the key features, and combining the findings from primary studies into a transformed whole, i.e. to a single description of the findings (Zimmer, 2006; Sandelowski & Barroso, 2007).

**Qualitative research in the context of the MRC framework**

Qualitative research is likely to contribute to each phase of the development and evaluation process due to its specific epistemological merits.

**Qualitative research in the developmental phase of the MRC framework**

The first phase of MRC framework (Figure 1, box Development) covers the identification of external evidence, theory development or theory identification, modelling of the MRC components, development of hypotheses on how the components might work, as well as modelling of appropriate outcome parameters. In this pre-clinical phase of the intervention qualitative research is well suited when trying to understand the problem. It is essential in this phase to know the patients’ and caregivers’ experiences and beliefs about for instance lifestyle to be able to model the intervention accordingly. Secondary level qualitative research may be useful at this stage, either as a synthesis of qualitative research exclusively based on qualitative data or as mixed methods – mixed research syn-
thesis (Sandelowski, Leeman, Knafl, & Crandell, 2012) integrating qualitative and quantitative primary studies.

In developing a critical care discharge information pack, for instance, the researchers (Bench, Day, & Griffiths, 2012) used various qualitative findings including qualitative metasynthesis of the user perspective of critical care discharge (Bench & Day, 2010). Similarly, in planning for introducing developmental care in a neonatal unit, Aagaard and Hall (2008) performed a qualitative metasynthesis of mothers’ experiences of having a preterm infant in a neonatal intensive care unit. Likewise Kirkevold and colleagues (Kirkevold et al., 2012) performed a qualitative synthesis of the major characteristics of the trajectory of stroke rehabilitation and recovery; the authors qualitatively examined theories to illuminate possible effective mechanisms and actions aimed at promoting psychosocial well-being. Metasynthesis is well suited to the development phase of the MRC framework because its results are ideally part of the evidence and integrated into the modelling of the intervention.

Qualitative research in the feasibility phase of the MRC framework

The second phase (Figure 1, box Feasibility/piloting) covers feasibility testing and piloting, in particular the stability of the intervention, its context components and different implementation conditions. In this phase the controlled study is prepared, i.e. a hypothesis about the effect size is generated, sample size calculation is planned and control intervention defined. The main issue in this phase is that trials of the intervention should be preceded by in-depth piloting to clarify critical components and establish feasibility and acceptability (Craig et al., 2008a, 2008b). A pilot study does not need to be a scale model of the planned evaluation but should examine key uncertainties that have been identified during development (Craig et al., 2008b). In this process, eliciting views and identifying barriers in patients or professionals with regard to the interventions are effectively reached through qualitative studies. For example participant observations of patients, relatives and professionals in their natural settings, combined with informal dialogues and formal qualitative interviews, would inform and help clarify feasibility and acceptability. One example is a complex fall prevention intervention that in phase 1 was modelled using qualitative testing in focus groups and through the completion of Delphi surveys by independent specialists. In the feasibility and piloting phase, the feasibility of the intervention and evaluation was discussed in focus groups of participants and instructors (Faes, Reelick, Esselink, & Rikkert 2010). Another example is a pilot study describing barriers among healthcare professionals towards implementation of evidence-based recommendations for stroke rehabilitation. Barriers thus identified were then targeted in the consecutive RCT (Bayley et al., 2012). Comparably, in a mental health care intervention researchers used interview findings to elicit carers’ and mental healthcare profes-
sionals’ views of psychosocial treatment (Mairs, Lovell & Keeley, 2012).

Metasynthesis may be ill-suited to the feasibility phase. Here the newly developed intervention is to be tested in a new healthcare setting with new stakeholders (e.g. new population, new types of professionals etc.) and new organisations. Therefore primary qualitative studies exploring current stakeholders’ views and experiences may be appropriate at this stage and likewise at the evaluation and implementation phases.

Qualitative research in the evaluation phase of the MRC framework

The third step (Figure 1, box Evaluation) comprises the evaluation of benefits and harms of the complex intervention, preferably within a RCT. The change process can be made understandable through a careful process evaluation. Qualitative findings are likewise well suited to help shed light on the pathways through which an intervention generate its effects, i.e. why a successful intervention works and how it can be optimized. Qualitative methods can also explain why an intervention fails unexpectedly, has unanticipated consequences or why the intervention works differently in different centres. They allow for critical reflections on the transferability of the complex intervention (Cresswell et al., 2012).

One example is a qualitative inquiry that helped researchers to understand organizational matters in a trial on medicine management in primary care. Through interviews, diaries and notes researchers explored key stakeholders’ accounts of acceptability, and their likely impact and strategies for the optimizing and rolling-out of the intervention (Cresswell et al., 2012). Another example is the ongoing OPERA trial which investigates the effects of a physical activity intervention to address depression amongst older people living in nursing and residential homes (Ellard, Taylor, Parsons, & Thorogood 2011). Follow-up interviews are conducted in the control group and the intervention group aimed to explore perceptions about the home and its levels of activity and, in intervention homes, perceptions of the activity programme and its impact. Non-participant and participant observations focus on the home environment, levels of activity, and staff/resident interactions (Ellard, Taylor, Parsons, & Thorogood 2011).

Qualitative research in the long-term implementation phase of the MRC framework

The fourth step (Figure 1, box Implementation) is dedicated to long-term implementation after the effectiveness and the absence of harm have been proven. Dissemination and long-term follow-up data collection, surveillance and monitoring techniques belong to the fourth step. When disseminating the results, quotes from qualitative research may help explaining statistical results and add another perspective to the findings.

In exploring the long-term effect of an intervention and possibilities for further implementation, qualitative re-
search results are effective in conveying the participants’ subjective meaning. They disclose new insights because:

No matter how many so-called experts are involved in program development, the individuals for whom the intervention is intended can best convey the subjective meaning of the health problem and its antecedents. The people who will deliver the program can best convey the realities of the program setting. (Bartholomew, Parcel, Kok, & Gottlieb, 2006, p.28)

When determining whether others can reliably replicate the intervention and its results in uncontrolled long-term settings similar research questions and qualitative research methods as exemplified in the evaluation phase above are suitable (Blackwood, 2006). Focus groups with for example staff/patients or managers will provide qualitative data with regard to peoples’ perception of the intervention after some years of running. Also semi-structured interviews and participant and non-participant observations may support this process. In a RCT of maintenance of cognitive stimulation therapy in practice focus groups and semi-structured interviews with staff and managers will be conducted in order to obtain qualitative data with regard to peoples’ perception of running groups and outreach support (Streater et. al., 2012). Another example is a mixed-methods study of the Change4Life convenience store programme around two years after initial implementation. Ten qualitative interviews with a purposive sample of retailers and other professionals explored experiences of the intervention and thus provided further insight into the quantitative results (Adams et.al. 2012).

Figure 1: The development-evaluation-implementation process suggested by the UK MRC (Craig et al., 2008b; reprint permission granted by the BMJ)
Concluding remarks

In this essay we have illustrated how qualitative research contributes to complex intervention development and evaluation. Qualitative studies are able to produce a deeper understanding of contextual factors and participant perspectives, explain blurred and complex situations and give new insights into the intervention trajectory.

A convincing conclusion of a recent successful complex intervention study would likely not have been possible without employing qualitative approaches.

This embedded qualitative inquiry has helped to understand the complex organizational and social environment in which the trial was undertaken and the ... intervention was delivered. The longitudinal element has given insight into the dynamic changes and developments over time. ... The transferability of the ... intervention approach, both in relation to other prescribing errors and to other practices, is likely to be high. (Cresswell et al., 2012).

Interventions are, so to speak, daily bread in nursing and therefore it is about time to give clinical nursing sound evidence-based interventions to work from. Evidence in clinical healthcare is neither exclusively generally abstract and mathematical nor narrative and particular. Instead, research evidence is a mediation of various knowledge modes (Upshur, 2001; Berg et al., 2008). Findings from qualitative research present an epistemology quite different from quantitative research. The two research traditions complement each other. For the sake of scientifically robust knowledge we need a wealth of research based on carefully chosen methods that fit the phenomenon being studied. In establishing a complex intervention programme, groups of researchers specialized in either qualitative or quantitative research methods have to form alliances.

The authors of this essay have established a mixed skills multinational research group, called PRANSIT. The name stands for research in the field of patients’ experiences of transition after transfer to another ward or care setting. In a first step, the group prepares second level research dealing with patient transition topics in different health care contexts (e.g. critical care, adolescent care, neonatal care) as part of the UK MRC framework phase of identifying the evidence-base. In a next step primary studies and preparation of intervention studies might be the choice.

In 2010, the European REFL-ECTION Network (http://www.reflection-network.eu) was launched for supplying nursing research and research education according to the UK MRC framework. The network aims to overcome the current fragmented and mainly descriptive research in favour of systematically developed programmatic research generating clinically meaningful evidence (Richards & Borglin, 2011).

It is very likely that researchers feel more or less attracted by either qualita-
tive or quantitative research. Therefore, future research groups in the field of nursing intervention development would benefit from consisting of researchers with excellent qualitative or quantitative research skills. Commitment, willingness to collaborate and a big portion of understanding of epistemological and methodological challenges are key issues in developing clinically meaningful complex interventions.

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