Department of Industrial Engineering and Management

Building Evidence for Cost-effectiveness of Self-management Interventions in Chronic Care

Acknowledging Context and Mechanisms

Iiris Riippa

Aalto University

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Building Evidence for Cost-effectiveness of Self-management Interventions in Chronic Care

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Iiris Riippa

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Abstract

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Abstract

Involving the chronically ill in the management of their own health is proposed to improve the cost-effectiveness of chronic care by improving health outcomes and diminishing the need and demand for care provided by professionals. Despite high expectations, empirical evidence of the cost-effectiveness of self-management remains scant. This may be due to the methodological challenges posed by the often complex nature of the self-management interventions and difficulty in operationalizing their outcomes.

In this study, two empirical evaluations with distinct designs were applied to gain understanding of the methodological considerations related to the cost-effectiveness evaluation of chronic care self-management interventions. Realist evaluation approach was applied to acknowledge the contextual factors and the mechanisms that induce the economic and health outcomes of a self-management intervention.

The findings of a retrospective cohort analysis with interviews showed that the present administrative and clinical data that is routinely collected in primary care does not reflect the mechanism of self-management interventions, that is, the improvement in patients' ability to manage their condition. A Finnish translation of Patient Activation Measure (PAM), a viable instrument for assessing the effectiveness of self-management interventions, was validated and used as a measure for effectiveness in the second part of this study.

A quasi-experiment on the effectiveness and economic outcomes of a novel self-management intervention, an electronic patient portal, showed that providing chronically ill patients with access to their own health records and secured messaging with the care provider may increase patient activation at an acceptable cost to the health care provider, and therefore be cost-effective. More research is needed to validate the acceptable thresholds for investments in patient activation. The benefits of an electronic patient portal are dependent on the mechanisms that its functionalities generate, and on the contextual factors such as the characteristics of the patients and the health care professionals using it, the health care system that it is adopted in, and its implementation in the organization. The empirical evidence from the two studies showed that realist evaluation can complement the traditional outcome trials in the pursuit of accumulating knowledge on cost-effectiveness of complex health care interventions, such as self-management interventions.

Keywords self-management, chronic illness, cost-effectiveness, patient activation, electronic patient portal

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Tiivistelmä

Pitkäaikaissairaiden potilaiden aktiivisen omahoidon on ehdotettu parantavan potilaan terveyttä ja vähentävän terveydenhuollon ammattilaisten antaman hoidon tarvetta ja kysyntää. Suurista odotuksista huolimatta, empiirinen näyttö omahoidon kustannusvaikuttavuudesta on vähäistä. Tämä saattaa johtua tutkimusmenetelmällisistä haasteista, joita omahoitointerventioiden kompleksisuus ja tyypillisesti viiveellä havaittavat vaikutukset aiheuttavat.

Tässä tutkimuksessa omahoitointerventioiden vaikuttavuutta ja taloudellisuutta arvioitiin kahdessa erilaisessa tutkimusasetelmassa. Kustannusvaikuttavuuden kannalta keskeisten mekanismien ja kontekstitekijöiden ymmärtämiseksi tutkimuksessa hyödynnettiin realistisen arvioinnin lähestymistapaa.

Haastatteluilla täydennetty retrospektiivisen kohorttitutkimus suomalaisessa perusterveydenhuollossa osoitti, että nykyiset rutiininomaisesti kerättävät hoitotiedot eivät kuvasta omahoitointerventioiden toimintamekanismia, eli potilaan parantunutta kykyä hallita omaa sairauttaan. Tutkimuksen toisessa empiirisessä osassa omahoitointervention vaikuttavuutta arvioitiin potilaan aktiivisuus -mittarilla (Patient Activation Measure, PAM), joka mittaa potilaan tietoja, taitoja ja itsevarmuutta oman sairautensa hoidossa. Suomenkielinen käännös PAM-kyselyinstrumentista validoitiin tutkimuksessa.

Näennäiskoe ajankohtaisen omahoitointervention, sähköisen potilasportaalin, vaikuttavuudesta ja taloudellisuudesta osoitti, että potilaan mahdollisuus tarkastella omia hoitotietojaan ja viestiä sähköisesti ammattilaisten kanssa voivat parantaa potilaan aktiivisuutta kohtuullisin kustannuksin. Pääsy verrattain yksinkertaiseen sähköiseen potilasportaaliin voi täten parantaa hoidon kustannusvaikuttavuutta. Jotta potilasta aktivoivien investointien hyväksyttävyyttä voidaan arvioida tarkasti, tarvitaan lisää tutkimusta potilaan aktiivisuuden pitkäaikaisista vaikutuksista ja aktiivisuuteen liittyvistä maksuhalukkuuden kynnysarvoista.

Potilasportaalin hyödyt syntyvät vaikutusmekanismeista, joita portaalin toiminnallisuudet saavat aikaan yhdessä kontekstitekijöiden kanssa. Potilasportaalin kannalta keskeisiä kontekstitekijöitä ovat portaalin käyttäjien ominaisuudet, ympäröivän terveydenhuoltojärjestelmän rakenteet sekä portaalin jalkauttaminen organisaatiossa. Tämä tutkimus osoittaa, että realistinen arviointi voi täydentää perinteisiä koetutkimuksia kompleksisten terveydenhuollon interventioiden kustannusvaikuttavuuden arvioinnissa.

Avainsanat omahoito, pitkäaikaissairaus, kustannusvaikuttavuus, potilaan aktiivisuus, sähköinen potilasportaali

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CONTENTS

LIST OF PUBLICATIONS

This doctoral dissertation consists of a summary and of the following papers:

I Riippa, Iiris; Kahilakoski, Olli-Pekka; Linna, Miika; Hietala, Minni. 2014. Can complex health interventions be evaluated using routine clinical and administrative data? –a realist evaluation approach. *Journal of Evaluation in Clinical Practice*, 20(6), 1129–36. ISSN: 1365-2753. DOI: 10.1111/jep.12175

II Riippa, Iiris; Linna, Miika; Rönkkö, Ilona. 2014. The Effect of a Patient Portal With Electronic Messaging on Patient Activation Among Chronically Ill Patients: Controlled Before-and-After Study. *Journal of Medical Internet Research*, 16(11), [Online journal, 12 pages]. DOI: 10.2196/jmir.3462. ISSN 1438-8871.

III Riippa, Iiris; Linna, Miika; Rönkkö, Ilona; Kröger, Virpi. 2014. Use of an Electronic Patient Portal Among the Chronically Ill: An Observational Study. *Journal of Medical Internet Research*, 16(12) [Online journal, 10 pages]. DOI: 10.2196/jmir.3722. ISSN 1438-8871.

IV Riippa, Iiris; Linna, Miika; Rönkkö, Ilona. 2015. The Cost-effectiveness of a Patient Portal with Electronic Messaging: Controlled Before and After Study. *Submitted manuscript, 21 pages.*

Author's Contribution

Paper I: *Can complex health interventions be evaluated using routine clinical and administrative data? –a realist evaluation approach*

Riippa is the primary author. She was responsible for the design of the theoretical and the empirical parts of the study. She participated to the collection and analysis of the data, and to the interpretation of the results. Riippa drafted the paper. Kahilakoski conducted the statistical analyses for the study and participated to the interpretation of the results. Linna participated in the design of the study and to the interpretation of the results. Linna revised the paper often during drafting. Hietala performed the interviews for the study and participated to the interpretation of their findings.

Paper II: *The Effect of a Patient Portal With Electronic Messaging on Patient Activation Among Chronically Ill Patients: Controlled Before-and-After Study*

Riippa is the primary author. She was responsible for the design and the execution of the study, participated to the collection of the data, statistically analyzed it, and interpreted the results. Riippa drafted the paper. Linna participated in the design of the study and in the interpretation of the results. Linna revised the paper often during drafting. Rönkkö participated in the collection of the data and provided insight into the implementation of the intervention, and to the collection of the data in the target organization.

Paper III: *Use of an Electronic Patient Portal Among the Chronically Ill: An Observational Study*

Riippa is the primary author. She was responsible for the design and the execution of the study, participated to the collection of the data, statistically analyzed it, and interpreted the results. Riippa drafted the paper. Linna participated in the design of the study and in the interpretation of the results. Linna revised the paper often during drafting. Rönkkö participated in the collection of the data and provided insight into the implementation of the intervention, and to the collection of the data in the target organization. Kröger provided medical expert comments.

Paper IV: *The Cost-effectiveness of a Patient Portal with Electronic Messaging: Controlled Before and After Study*

Riippa is the primary author. She was responsible for the design and the execution of the study, participated to the collection of the data, statistically analyzed it, and interpreted the results. Riippa drafted the paper. Linna participated in the design of the study and in the interpretation of the results. Linna revised the paper often during drafting. Rönkkö participated in the collection of the data and provided insight into the implementation of the intervention, and to the collection of the data in the target organization.

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Abbreviations

ACIC	Assessment of Chronic Illness Care
ANCOVA	Analysis of Covariance
APR	Ambulatory and Primary Care Related Patient Group
BMI	Body Mass Index
CCI	Charlson Comorbidity Index
CEA	Cost-effectiveness Analysis
CEAC	Cost-effectiveness Acceptability Curves
CCM	Chronic Care Model
CMO	Context-Mechanism-Outcome
DRG	Diagnosis Related Group
EBM	Evidence-based Medicine
EHR	Electronic Health Record
HbA1c	Glycated Hemoglobin
HSD	Honestly Significant Difference
HTA	Health Technology Assessment
ICD-10	International Classification of Diseases, 10th revision
ICER	Incremental Cost-effectiveness Ratio
ICPC-2	International Classification of Primary Care, second edition
LDL	Low-density Lipoprotein
PAM	Patient Activation Measure
PAS	Patient Administration System
QALY	Quality-adjusted Life Years
RCT	Randomized Clinical Trial
VPN	Virtual Private Network
WTP	Willingness to Pay

1 INTRODUCTION

Around 40% of the population in Europe and the United States suffer from at least one chronic disease, and this number is expected to grow (Bodenheimer et al., 2009). Such conditions currently account for between 70% and 80% of health care costs in these regions. Economic pressure, along with efforts to prevent the progress of the chronic conditions and their comorbidities in the population, has led to a priority shift in chronic care management from handling acute care needs to striving for longitudinal and holistic management of patients' health. In academic literature, this shift is led by models for organizing chronic care in a cost-effective way. In the prominent Chronic Care Model (CCM), Edward Wagner and colleagues (2001) compile the empirical evidence on "enhancements to the [health care] organization and its practices that contribute to productive interactions between providers and patients" (E. H. Wagner et al., 2001). These productive interactions "consistently provide the assessments, support for self-management, optimization of therapy, and follow-up associated with good [disease control] outcomes" (E. H. Wagner et al., 2001, p. 68).

As a part of the greater paradigm shift toward longitudinal care of chronic patients, a broad range of attempts to engage the most underutilized asset in health care, the patient, in the care process have been made in research and practice. Self-management support has the potential to improve health outcomes through improved control of the disease, and also to decrease the cost of chronic care by 1) preventing deterioration of the disease and further need for medical care, and 2) by transferring some of the tasks previously performed by the health care professionals to the patients themselves (Bodenheimer, Lorig, et al., 2002; Lorig & Holman, 2003).

Despite high expectations for active patient participation in the management of their condition, little evidence on their cost-effectiveness has been shown (Coulter & Ellins, 2007). Further, little is known about how, for whom, and in what circumstances chronic care self-management interventions are or may be cost-effective. A plausible reason for this may be in the scant recognition of the context and mechanisms of the self-management interventions in the previous research.

This study set out to evaluate the health and economic effects, specifically the cost-effectiveness, of chronic care self-management interventions in the clinical primary care environment, using appropriate methodology. To accomplish this, methodological challenges related to the complexity of self-management interventions and operationalization of their outcomes had to be overcome. The results of two empirical studies fulfilling this purpose are reported in four papers.

This summary presents the relevant literature, the methodological underpinnings of the dissertation, and the methods, results, and contributions of the papers.

In the following chapter (Chapter 2), the relevant literature on the cost-effectiveness evaluation of self-management interventions is reviewed. Chapter 3 specifies the purpose of this dissertation. Chapter 4 synthesizes the current evidence on the economic and health effects of a specific self-management intervention examined in this study, namely an electronic patient portal. Chapter 5 describes the research approach and Chapter 6 the research design and methods. Chapter 7 contains the findings. The contribution of the results is discussed in chapter 8, and chapter 9 concludes the dissertation.

2 LITERATURE REVIEW

2.1 SELF-MANAGEMENT IN CHRONIC CARE

Clark and colleagues (1991) define self-management generally as the "day-to-day tasks an individual must undertake to control or reduce the impact of disease on physical health status" (Clark et al., 1991, p. 5). More recently, attention has been paid to the patient's need to deal with cognitive, behavioral, and emotional responses related to the consequences of their disease (Barlow et al., 2002). Self-management is, therefore, more than simple adherence to treatment guidelines (Bodenheimer, Lorig, et al., 2002; Newman, Steed, & Mulligan, 2004). Further, recent literature suggests that in addition to maintaining physical health status, self-management and self-management support should eventually aim at improving the patient's perceived quality of life (Barlow et al., 2002; Trappenburg et al., 2013). Accordingly, successful self-management support improves the outcomes and quality of care. Supporting patients' self-management is also posited to decrease the cost of chronic care by 1) preventing deterioration of the disease and further need for medical care, and 2) transferring some of the tasks previously performed by the health care professionals to the patients themselves (Bodenheimer, Lorig, et al., 2002; Lorig & Holman, 2003). Self-management support therefore has the potential to diminish both the need and the demand for care (Fries et al., 1998).

The design and mechanisms of self-management interventions are often disease-specific (Newman et al., 2004). Different diseases require varying levels and types of lifestyle changes, monitoring physiological states, and taking medication. Nevertheless, general self-management skills needed in the management of any disease can be identified. Regardless of the diagnosis, core self-management skills include problem solving, decision making, effective resource utilization, forming of a patient–provider relationship, and taking action (Lorig & Holman, 2003). Adopting these skills requires cognitive and emotional capabilities, and therefore, self-management interventions often draw on behavioral theories such as Albert Bandura's (1977, 1982) self-efficacy theory.

In an attempt to operationalize patients' active participation in the management of their health and health care, Judith Hibbard and colleagues (2004; 2005) developed the concept and a measure for patient activation. The concept draws on psychological theories of health locus of control (Wallston, Stein, & Smith, 1994), self-efficacy in self-managing behaviors (Lorig et al., 2001), and readiness to change health-related behaviors (DiClemente et al., 1991), but it also incorporates competency elements specifically related to the self-management of a chronic illness (Hibbard et al., 2004). The questionnaire for the Patient Activation Measure (PAM) assesses a patient's knowledge of their diseases, skills to self-manage their disease, and self-confidence in their abilities to manage their

disease (Hibbard et al., 2005). Validated by several empirical studies (Hibbard & Cunningham, 2008; Hibbard et al., 2007; Mosen et al., 2007), patient activation reflects one's predilection to take on self-management behaviors (Mittler et al., 2013) and can therefore be used as an intermediate outcome measure for self-management interventions (Hibbard & Greene, 2013).

Despite high expectations and a tremendous amount of empirical research, the evidence on the effects of self-management interventions has remained heterogeneous. Multiple components and complex dynamics of self-management interventions complicate the accumulation of knowledge on how, for whom, and in what circumstances a self-management intervention works (Trappenburg et al., 2013). Several literature reviews note that it is often difficult to identify which component of a self-management intervention caused the observed effect (Chodosh et al., 2005; Coster & Norman, 2009; Coulter & Ellins, 2007; Ditewig et al., 2010; Panagioti et al., 2014). Further, Lawn and Schoo (2010) emphasize the organizational factors and patient needs and preferences that contribute to the dynamics and the eventual effects of self-management support. Literature reviews encourage more precise description of self-management interventions, their theoretical backgrounds, and the context in which the study was performed (Coulter & Ellins, 2007; Lawn & Schoo, 2010; Newman et al., 2004). Further, investigation of long-term effects (Coulter & Ellins, 2007), impact on cost-effectiveness (Coulter & Ellins, 2007), and the intervention effects in different subgroups of patients (Newman et al., 2004; Trappenburg et al., 2013) are suggested.

2.2 Intervention evaluation in health care

The primary purpose of evaluation research is to provide information to decision makers. Health intervention evaluations serve multiple decision makers, such as clinicians, health care managers, and politicians. The viewpoint taken determines what type of evidence is considered useful and relied on in the decision making. Although not always explicitly specified, evaluation studies typically follow a paradigm of a certain discipline, such as medicine, public health, or management. Drummond and colleagues (2008) distinguish essentially between evidence-based medicine (EBM) used in clinical decision making and health technology assessment (HTA) primarily applied in policy decision making. Whereas EBM is primarily interested in the clinical effectiveness of a treatment, HTA considers also the economic and societal impacts of a medical technology, which may be a drug, a device, a procedure, a diagnostic, or a treatment strategy. Typically, the question addressed in HTA studies is whether the technology is worth the resources it consumes and the possible negative effects it may have (Drummond et al., 2008).

Although in principle HTA is an interdisciplinary stream of research and "explores all elements of value of a technology, not just those that can be demonstrated in randomized clinical trials (RCTs)" (Drummond et al., 2008, p. 245),

an RCT is considered to provide the strongest evidence for intervention effects. Recent literature has criticized HTA studies for appraising study designs that assume false stability of the intervention and the environment (Douma et al., 2007). The difficulty of replicating an intervention and the context is especially true for behavior change interventions (Michie et al., 2009) and accordingly public health interventions (Armstrong et al., 2008) that are aimed to "promote or protect health or prevent ill health in communities or populations" (Rychetnik et al., 2002, p. 119). In the evaluation of complex interventions, the "key concerns are to unpack the 'black box' of the intervention and to make clear assessments about the external validity of the study" (Armstrong et al., 2008, p. 104). To better acknowledge these concerns, alternative research approaches that account for the contextual factors and the sociodynamic processes ignited by the complex health interventions have been suggested (Douma et al., 2007; May, 2006; Victora, Habicht, & Bryce, 2004). Further, as RCTs are often arduous to conduct, a broader range of validated evaluation methods and approaches is also encouraged to improve research efficiency and to speed up the accumulation of knowledge on different health interventions (Ammerman, Smith, & Calancie, 2014; Spine, 2010; Tunis, Stryer, & Clancy, 2003).

Researchers have also expressed concerns about the slow translation of health intervention research into practice (Kessler & Glasgow, 2011; Neta et al., 2015). In their recent article, Neta and colleagues (2015) suggest a framework for enhancing the value of research for the dissemination and implementation of public health interventions. They emphasize the importance of transparent reporting on different phases of the intervention: planning, delivery, evaluation, and long-term outcomes. They encourage reporting on economic effects, on the implementation strategy and adoption of the intervention, context, sustainability, and the evolution of the intervention. Regarding the philosophy of science, Kessler and Glasgow (2011) suggest contextualist or realist perspectives to speed the translation of health care research into practice, instead of the mechanistic, reductionist view on philosophy of science currently dominant in medical research.

2.3 Cost-effectiveness evaluation of health interventions

As each decision to implement an intervention in a health care organization is a decision to reject other alternative uses of the resources to improve health and well-being, assessment of economic effects should be included in all evaluation of health care interventions (Moatti, 1999). In Weinstein and Stason's (1977, p. 716) words, "Limits on health-care resources mandate that resource-allocation decisions be guided by considerations of cost in relation to expected benefits." A general method used to evaluate health outcomes and costs of health interventions is cost-effectiveness analysis (CEA) (Russell et al., 1996). CEA describes an intervention in terms of the ratio of incremental costs per unit of incremental health effect (Garber & Phelps, 1997). Typically, the health output of a medical intervention is translated into a common denominator, such as quality-adjusted

life years (QALY) (Weinstein et al., 1996). Choosing a common measure for health outcome facilitates the ranking of different interventions based on their cost-effectiveness ratio, and allows the decision maker to implement the interventions that produce the greatest health outcome with the restricted financial resources available (Russell et al., 1996). Ideally, the incremental costs include costs of the intervention accrued to all relevant parties, such as the care provider, patient, and society as a whole (Weinstein et al., 1996). Recommendations for cost-effectiveness analyses are subject to the "rule of reason", that is, an author may decide to depart from them for practical reasons or if necessary for the goal of the specific analysis (Weinstein et al., 1996).

Previous research on health care costs and effectiveness has efficiently managed to utilize the data that is routinely recorded in health care organizations. In the Finnish PERFormance, Effectiveness and Cost of Treatment Episodes project (PERFECT), the costs and outcomes of disease-specific care were compared between care providers and regions using administrative and clinical data (Peltola et al., 2011). Similarly, Kiivet and colleagues (2013) used person-level administrative and clinical data in their case study conducted under the EuroREACH project to identify differences in diabetes care costs, care quality, and consequent health outcomes in three different countries. Although in these studies the focus was on the costs and effectiveness of an entire disease-specific treatment chain, routinely collected administrative and clinical data has also been proven useful in the evaluation of single health care interventions (Kiivet et al., 2013).

Whereas cost-effectiveness evaluations have become a standard in the evaluations of narrowly defined clinical interventions, such as drugs and medical procedures, economic evaluations of public health interventions remain few (Kelly et al., 2005; Oliver, Mossialos, & Robinson, 2004; Weatherly et al., 2009). Weatherly and colleagues (2009) identify four methodological challenges faced in the economic evaluation of public health interventions that may have led to this. First, undertaking a RCT may be relatively difficult, as the impacts of a public health intervention on health outcomes typically accrue over a long period of time. Second, the benefits and costs of public health interventions concern multiple stakeholders that should be taken into consideration. Third, given their broad nature, the traditional approaches to valuing health outcomes, such as QALYs, may be inadequate. Finally, public health interventions are often concerned with health inequalities. As the standard economic evaluation methods focus on maximization of health gain, specific attention should be paid to equity considerations when assessing public health interventions (Weatherly et al., 2009).

2.4 Research gap

Empirical evidence on the cost-effectiveness of chronic care self-management interventions remains scant. The preceding literature review suggests that the methodological challenges related to the cost-effectiveness evaluation of chronic

care self-management interventions arise from the multiple components and complex dynamics of these interventions. Further, the impacts of the self-management interventions on the traditional effectiveness measures, such as on the patient's state of health, typically accrue over a long period of time, which complicates the observation of the outcomes.

Approaches that acknowledge the mechanisms and the contextual factors of the interventions, and the use of different methods are proposed to speed up the accumulation of knowledge on self-management interventions, and their translation into practice. To date, these methodological practices are limitedly used in the empirical evaluations of self-management interventions. Further, routinely collected register data is suggested as a viable source for cost-effectiveness evaluation but its feasibility in the evaluation of self-management interventions remains unclear.

3 PURPOSE OF THE DISSERTATION

This study set out to evaluate the cost-effectiveness of chronic care self-management interventions in a clinical environment using appropriate methodology.

To accomplish this, the following general objectives for self-management intervention evaluation emerge as important:

1. *To investigate how the cost-effectiveness of chronic care self-management interventions can be evaluated.*

2. *To evaluate how, and in what context a self-management intervention improves the cost-effectiveness of chronic care.*

To achieve these objectives, two empirical evaluations of effectiveness and economic effects of complex chronic care self-management interventions were conducted. The studies contribute to the cost-effectiveness evaluation literature by investigating effects of the interventions on both components of cost-effectiveness, that is 1) the effects on clinical or intermediary health outcomes that reflect effectiveness of the intervention, and 2) the effects on resource use that reflect the cost of the intervention.

Following the first objective, two different study designs with two different interventions were chosen to gain understanding on the methodological considerations related to the cost-effectiveness evaluation of chronic care self-management interventions. In the first study a retrospective cohort analysis with interviews was conducted to assess the economic and health outcomes of a complex chronic care intervention, namely Chronic Care Model (CCM), which aims at supporting patient self-management. In this study, administrative and clinical data from the health care provider's electronic health record was used to assess the feasibility of the present routinely collected data in the cost-effectiveness evaluation of chronic care self-management interventions. The second empirical study was a quasi-experiment on the cost-effectiveness of a novel self-management intervention, namely an electronic patient portal.

To achieve the second objective, specific attention in both empirical studies was paid on the mechanisms and the context of the interventions. As a part of the CCM study a context-mechanism-outcome (CMO) analysis of the CCM was conducted. In the patient portal study, the suggested effect mechanism of the patient portal, namely the improvement in patients' knowledge, skills, and self-confidence related to the management of their condition, was assessed with the PAM instrument. Further, additional observational analyses from the patient portal quasi-experiment were conducted to add insight to the contextual factors essential in evaluating patient portal cost-effectiveness.

The findings of the two empirical studies are reported in four papers. Paper I reports the findings of the CCM study. Paper II assesses contextual factors that may dilute or promote the effect of a patient portal on patient activation. Paper III investigates factors that may affect the use and consequently the potential cost-effectiveness of the portal. Finally, paper IV reports the cost-effectiveness analysis combining the economic and health outcomes of the patient portal.

The research questions of this dissertation are:

- *What methodological aspects should be considered when studying the cost-effectiveness of chronic care self-management interventions in natural and experimental settings?*

- *Can the present routinely collected administrative and clinical data be used in the cost-effectiveness evaluation of self-management interventions?*

- *How, for whom, and in what circumstances may an electronic patient portal be a cost-effective self-management tool?*

4 PREVIOUS EVALUATIONS OF ELECTRONIC PATIENT PORTALS

Along with the recent progress in information technology, new electronic channels for self-management support have emerged. Web-based solutions, such as electronic patient portals, enable health care providers to efficiently offer information to and interact with their patients. An electronic patient portal (also known as patient portal, patient web portal, patient online portal, or patient internet portal) typically includes patients' own health records, drawn from the care provider's electronic health records (EHR), and the possibility of interacting with the provider through secure messaging in non-acute matters and to request repeat prescriptions (Ammenwerth, Schnell-Inderst, & Hoerbst, 2012). More advanced portals may also offer personally tailored health information or education, as well as social functionalities that enable peer support from other patients (Ahern et al., 2011).

Adoption of an electronic patient portal is purported to benefit both the patient and the health care provider, thanks to more convenient and efficient provision of health care services (Osborn, 2010). The potential benefits of patient portals include the empowerment and activation of patients in the management of their own health (Nagykaldi et al., 2012; Solomon et al., 2012) through increased access to related information and communication with the health care professionals (Ahern et al., 2011; Berikai et al., 2007; Ross & Lin, 2003). In addition, interaction through a patient portal may improve the efficiency of care by replacing some of the service contacts previously performed in person or via phone calls that are bound to time and often to place (Zhou et al., 2010). Patient portals are suggested as being especially beneficial in the care of the chronically ill, whose health maintenance and the restoration of functioning require repeated interaction with the care provider and patient engagement in the management of their own condition (Agarwal et al., 2013).

Despite the expectations, present empirical evidence does not uniformly support these potential benefits. In their meta-analysis, Ammenwerth and colleagues (2012) identify six types of outcomes and processes that patient portals are suggested to affect and which have been empirically investigated. These are clinical outcomes, health resource consumption, patient adherence, patient–physician communication, patient empowerment, and patient satisfaction. The authors conclude that the present empirical evidence does not support the assumptions on patient portal benefits and question whether the appropriate measures to operationalize the benefits have been used.

In addition to the choice of outcome measures, the components of the portal and contextual factors may affect the results of a patient portal evaluation. Like other

self-management interventions (Trappenburg et al., 2013), patient portals may contain a variety of components, in terms of functionalities included, generating different benefits to different patient groups. This complexity, combined with contextual factors, such as the implementation of the patient portal to the service processes in the target organization (Lawn & Schoo, 2010), complicates the replication of the empirical setting and the results.

In an attempt to explain differences in portal outcomes, Otte-Trojel and colleagues (2014) apply the realist review method and study how patient portals are proposed to improve the clinical outcomes, patient behavior, and experiences. They find that these improvements in effectiveness of care are yielded by four different mechanisms related to electronic patient portals. These mechanisms are patient insight into personal health information, activation of information, interpersonal continuity of care, and service convenience. Patient insight into their personal health information is proposed to "enable and motivate patients and their caregivers to be involved in the application of [the information] and in ensuring its accuracy and comprehensiveness" (Otte-Trojel et al. 2014). Activation of information in terms of decision-support tools and reminders sent to patients improves patient adherence. Improved interpersonal continuity of care, i.e. "the easier and improved access for patients to contact their providers" (Otte-Trojel et al. 2014), is suggested to improve clinical outcomes and patient satisfaction. Service convenience in acquiring medical information and navigating the health care system may improve patient satisfaction by saving patients' time.

Previous research has also stated some concerns over the potential adverse effects of electronic patient portals. These concerns are related to the possible inequality between patients in access to patient portals and to the effects of substituting face-to-face visits with electronic communication between the patient and the health care professional. The benefits of electronic patient portals may not be equally distributed among patients, owing to differing interest in, access to, or ability to use the service (Goel et al., 2011; Morrison et al., 2014; Sarkar et al., 2011). Previous studies have reported disparities in patient use of health information technology, mostly differentiated by sociodemographic factors (Or & Karsh, 2009). Concerns have also been expressed about the loss of personal relationships between the patient and the caregiver and the possible worry that the patient may suffer on seeing his or her medical information (Wakefield et al., 2010).

5 RESEARCH APPROACH

5.1 CRITICAL REALISM

The philosophical research approach applied in this dissertation is critical realism. Epistemologically, realism is situated between the traditional poles of positivism and relativism (Pawson & Tilley 1997). Realism shares the views of positivism, 1) that there is a reality separate from our description of it, and 2) that social and natural sciences should apply a similar approach to data collection and explanation (Bryman & Bell, 2011). However, unlike positivists, critical realists perceive that the terms they use to describe and understand the reality are distinct from the objects of their enquiry (Bryman & Bell, 2011). In Bhaskar's (1979, p. 2) words: "science is the systematic attempt to express in thought the structures and ways of acting of things that exist and act independently of thought." As opposed to the other form of realism, empirical realism, critical realism focuses on recognizing the underlying generative mechanisms that bring about the observable phenomena (Bryman & Bell, 2011). Pawson and Tilley (1997) state that "[critical realism's] key feature is its stress on the mechanics of explanation, and its attempt to show that the usage of such explanatory strategies can lead to a progressive body of scientific knowledge" (Pawson & Tilley, 1997, p. 55-56).

In this dissertation, a specific evaluation approach applying critical realism, namely realist evaluation (Pawson & Tilley, 1997), is applied. Instead of merely assessing whether or not the interventions cause the predetermined effects in the given empirical settings, this dissertation seeks to accumulate knowledge on how, for whom, and in what circumstances (Pawson & Tilley, 1997) the chronic care self-management interventions may be cost-effective.

5.2 REALIST EVALUATION

Realist evaluation was originally developed for social program evaluation. The originators of the approach, Ray Pawson and Nick Tilley (1997), suggested realist evaluation as an alternative to the traditional empiricist approach then prevalent in social experiments. They claimed that the traditional empiricist approach puts too much focus on predetermined outcomes in an evaluation setting where the intervention is social by nature. The claim is based on the tendency of social interventions to operate differently in different contexts. They argue that, in order to accumulate knowledge on these kinds of interventions, the questions how, for whom, and in which circumstances the intervention works should be addressed. It is suggested that the focus on this context–mechanism–outcome configuration provides insight into the generative mechanisms of interventions and

thence helps to build and refine theories that can be generalized in different contexts (Pawson & Tilley, 1997).

The realist evaluation approach affords an opportunity to add to extant theory even in a situation where an experiment fails to show an expected effect. Pawson and Tilley (1997) suggest that inspection of the context, mechanism, and outcome may explain why an intervention did not lead to outcomes suggested in prior studies and thus prompt an additional hypothesis to the theory at hand. An alleged bias toward publishing studies with greater and statistically significant effect sizes may be at the expense of the possibility of refining theories.

According to Pawson and Tilley (1997), realist evaluation is not constrained to certain methods of scientific enquiry, but rather employs "the full panoply of research techniques and strategies". Neither does a researcher need to explicitly define a study as realist evaluation for it to represent the guiding themes of the approach. Pawson and Tilley (1997) describe realist studies as follows:

"1 They increase specificity of our understanding of the mechanisms through which [an intervention] accomplishes change.
2 They increase specificity of our understanding of the contextual conditions necessary for triggering [intervention] mechanisms.
3 They increase specificity of outcome pattern predictions according to context and mechanism triggered." (Pawson & Tilley, 1997, p. 114)

Recently, evaluation researchers have suggested that the aims of realist evaluation— that is, stressing understanding of what works, for whom, and under what circumstances—should be examined within randomized trials (Berwick, 2008; Blackwood et al., 2010; Bonell et al., 2012; Olmen et al., 2013). From another point of view, it is recommended that application of the experimental methods that can provide strong evidence of the causalities proposed by theory be further extended to health care interventions that are more complex than single treatments (Blackwood et al., 2010; Bonell et al., 2012; Cohen et al., 2014). Following these notions, in this dissertation, the realist approach is not considered contradictory to the experimental method for empirical enquiry; rather, the experimental setting and realist approach to evaluation are considered mutually complementary.

5.3 Application of realist evaluation in the empirical studies

In this dissertation, realist evaluation is applied in two distinct ways. In the case study, CMO-configuration was applied as a tool to assess the feasibility of EHR data in the evaluation of a self-management intervention. In the quasi-experimental study, realist evaluation was applied implicitly, as the themes of the approach guided the setting of the statistically tested propositions and therefore the choice of measures and analyses used in the study. In order to increase understanding of the mechanisms through which an electronic patient portal may im-

pact cost-effectiveness of care, an intermediary outcome measure for self-management interventions, namely Patient Activation Measure, was used as the primary outcome measure. Further, to increase understanding of the contextual conditions relevant in triggering intervention mechanisms, contextual factors suggested essential by previous patient portal literature were examined. First, patient activation at baseline may have an impact on self-management intervention outcomes, especially when the intervention requires some level of patient participation. Therefore, the main and interaction effects of patient activation at baseline were assessed. Second, as being diagnosed with a severe illness may affect a patient's interest in managing their health (Hörnsten et al., 2004), the main and interaction effects of temporal proximity of a severe diagnosis were examined. Last, as concerns related to the inequality in patient portal adoption have been expressed (Goel et al., 2011; Morrison et al., 2014; Sarkar et al., 2011), the association between patient characteristics (age, gender, state of health, and previous care received) and portal adoption was studied.

6 RESEARCH DESIGNS AND METHODS

The designs for empirical enquiry were distinct in the two empirical studies discussed in this dissertation. Chapter 6.1 describes the research design and the methods for the case study on EHR data applicability in self-management intervention evaluation. Chapter 6.2 discusses the research design and methods for the controlled before and after study with observational analyses, in which the cost-effectiveness of an electronic patient portal was evaluated.

6.1 A NON-EXPERIMENTAL EVALUATION OF A COMPLEX SELF-MANAGEMENT INTERVENTION

6.1.1 The setting and the intervention

The self-management support efforts assessed in paper I were a part of a broader best-practice model for providing chronic care, the Chronic Care Model (CCM) (E. H. Wagner, Austin, & von Korff, 1996), implemented in the public primary care of a Finnish town, Espoo. The CCM was built on the evidence of effective system changes that improve clinical (Bodenheimer, Wagner, & Grumbach, 2002; Musacchio et al., 2011) and patient-reported (Battersby et al., 2010) health outcomes, and reduce the cost of chronic care (Bodenheimer, Lorig, et al., 2002). Wagner and colleagues (2001) refined the model to counterbalance the emphasis on acute care by focusing on longitudinal and patient-centered care for the chronically ill (E. H. Wagner et al., 2001). Self-management support is one of the six components on which the CCM suggests the organization of chronic care should be based (E. H. Wagner et al., 2001, 2005).

The case study consisted of two empirical parts. In the first part, routine data was used to compare changes in health outcomes and resource use between CCM patients and usual care patients. In the second part, interviews with health care professionals were conducted to examine retrospectively the implementation of the CCM in the case organization. Finally, in order to evaluate the feasibility of the data used in the evaluation of the intervention effects, the CMO-configuration from the realist evaluation approach (Pawson & Tilley, 1997) was used.

6.1.2 Data and analyses

In order to retrospectively compare the health outcomes and resource use between the intervention group exposed to the CCM and the control group in usual care, routinely recorded administrative and clinical data from 2007 to 2011 on all patients with type 2 diabetes treated in the city of Espoo (population c. 250 000) was retrieved. The CCM had been implemented in the case organization in

2007. The nurses and doctors had been encouraged to include all type 2 diabetic patients to the CCM and draw a care plan together with the patient. By the end of year 2011 6672 type 2 diabetic patients had a care plan in their visit related records and were therefore included in the intervention group. 2606 patients did not have a care plan and were therefore included in the control group.

The best available indicators for effectiveness and cost of care, namely levels of glycosylated hemoglobin (HbA1c) and number of nurse and doctor visits, were used as dependent variables in Bayesian linear mixed models to analyze nurse and doctor use. Bayesian linear mixed models were used to control confounding in this natural setting where no randomization was made to assign the patients to the research arms. Mixed models were used to include patient and observation-level varying intercepts, and Bayesian priors for model parameters were used to control for the probability of the participants with eventual improved outcomes to having been ended up in the intervention instead of the control group. Observation-level variables included in the models were age, gender, comorbid cardiovascular disease, onset of CCM, patient group, observation year, health center that the patient used most, and concomitant personal health record intervention. The effect of the CCM was computed as the difference in predictions of the model between the two values of the CCM indicator variable, averaged over the case group. The statistical analyses for this study were done in collaboration with a biostatistician using the statistical software R (www.r-project.com).

To assess the implementation of the intervention in the target organization, 5 physicians and 6 nurses working in 5 of the 11 health centers of the target organization were interviewed. Interviews were based on the Assessment of Chronic Illness Care (ACIC) questionnaire, which is a tool for evaluating the realization of the six dimensions of the CCM in a health care organization (Bonomi et al. 2002). Interviews were recorded, and a content analysis was conducted.

6.2 THE COST-EFFECTIVENESS EVALUATION OF AN ELECTRONIC PATIENT PORTAL

6.2.1 Study setting, participants, and the intervention

The controlled before and after study was conducted among chronically ill patients in public primary care in Hämeenlinna, a medium-sized town in Finland (approximately 68,000 citizens). Patients visiting one of the 10 health centers in the town of Hämeenlinna during the recruitment phase from October 2011 to March 2012 were considered as potential participants for the study. As the benefits of a patient portal apply to all regular primary care customers (Agarwal et al., 2013), the participation was not restricted on the basis of specific diagnoses, but instead on a professional's perception of the chronic, but treatable, nature of a patient's condition. The eligibility criteria for the participants were: 1) age 18

or older, 2) has at least two treatable health conditions assessed by a health professional, 3) has bank identifiers for electronic identification and access to the internet, 4) is willing and able, both according to themself and to a health care professional, to use the portal.

The eligible patients were approached during their visit to primary health care facilities. Once a patient had shown interest in taking part in the study, they were allocated either to the intervention or control group, based on their date of birth. Patients born on uneven dates were assigned to the intervention group and patients born on even dates were assigned to the control group. The intervention group received immediate access to the patient portal and the control group would receive delayed portal access, after 6 months. Ethical approval for the study was granted by the ethical board of the local authority (Pirkanmaa Hospital District). Patients who returned the informed consent to participate were included in the study (Figure 1).

Once a patient was enrolled in the study, they drew up a care plan together with a health care professional. The plan was tailored to each patient individually in order to care for the patient's health holistically and to involve the patient in the planning of their own health care. Although a care plan was drawn up for each of the study participants, only the patients in the intervention group got access to their care plan online through the portal. Other features of the patient portal were access to 1) the customer's own patient record with diagnoses of chronic illnesses and long-term medication prescriptions, 2) laboratory results with commentary from a health care professional, 3) vaccination history, and 4) electronic messaging with a health care professional. The names of diagnoses, medicines, and laboratory results were linked to relevant additional information in the online medical information service "Terveyskirjasto", administered by the Finnish Medical Society Duodecim (www.terveyskirjasto.fi). Users could visit the portal through the care provider's web pages. For secure identification, the patients used their bank identifiers to sign in. Whenever the patient received a message or a comment on a laboratory test result through the portal, a text message reminder was sent to their mobile phone. A reminder was also sent if there were changes made in their next follow-up appointment.

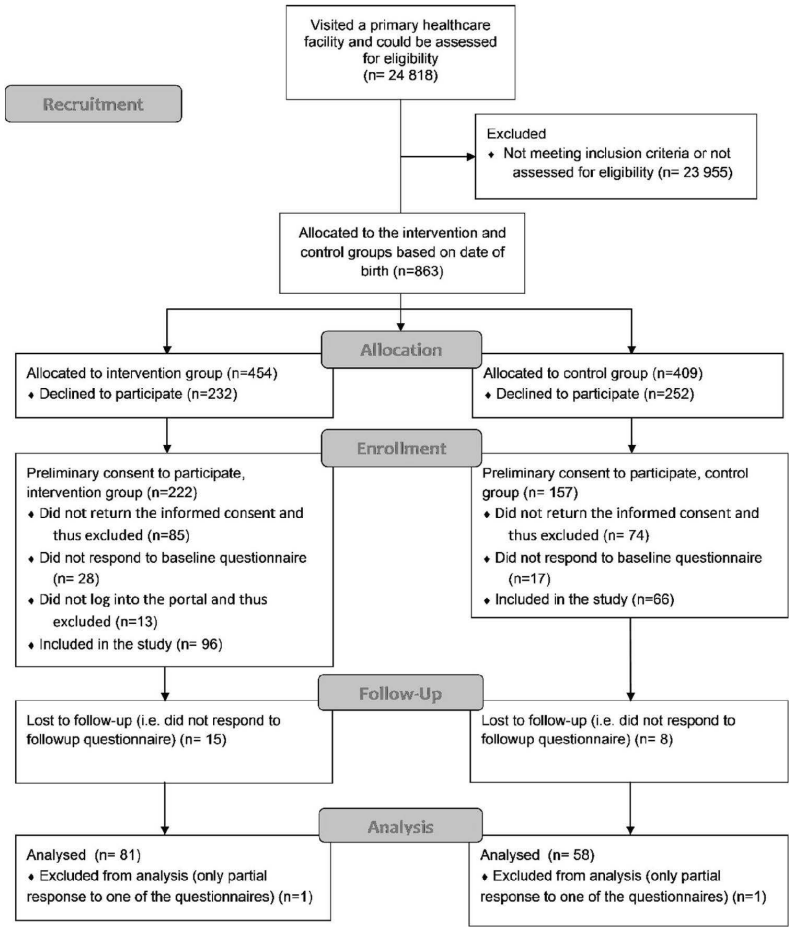

Figure 1. Participant flow of the quasi-experiment.

6.2.2 Data

The data was obtained from the health care provider's EHR and through surveys. To assess patients' activation and self-reported state of health before and after the intervention, responses to validated instruments were collected by an online link sent to the participants by email at the baseline and at 6 months follow-up.

Patient activation

To measure patient activation, the short form of Patient Activation Measure (PAM13) created by Judith Hibbard and colleagues (2005) was used. The measure has been developed using Rasch analysis and has been validated through several studies (e.g. Hibbard & Cunningham, 2008; Hibbard et al., 2007; Mosen

et al., 2007). PAM13 assesses patient knowledge, skill, and confidence for self-management (Hibbard et al., 2005). Increases in the patient activation score have been shown to be followed by improved health behaviors (Harvey et al., 2012; Hibbard et al., 2007); thus, the measure can be used as an intermediate outcome measure for self-management interventions (Hibbard & Greene, 2013).

As a Finnish translation of the short form of Patient Activation Measure (PAM13) had not been used in previous studies, the translation was conducted in collaboration with an expert panel of three researchers with expertise in health service research. The translation process and statistical tests for the validity of the translated Finnish PAM13 instrument are reported in paper II.

Patient activation was used as the main outcome measure in the study. In the cost-effectiveness analysis (Paper IV), it was used as a measure for intervention effectiveness along with patient-reported health. As the level of patient activation at baseline may affect portal adoption and the magnitude of the increase in activation, it was treated as a potential contextual factor in papers II and III.

Cost of care

The Ambulatory and Primary Care Related Patient Groups (APR) system (Honkasalo et al., 2014), equivalent to diagnosis related groups (DRG) used in hospital care, was used to estimate the cost for the primary health care contacts of the patients. The patient-level data extracted from the health care provider's patient administration system and fed to the APR grouper included contact types (such as visits, phone calls, or electronic messaging), the patient's age, the diagnoses (ICD-10), the reason for the encounter (ICPC-2), and the employee category of the health care professional in the contact.

In the cost-effectiveness analysis of an electronic patient portal, the additional costs of the intervention were compared with standard care from the health care provider's perspective. Here, both the change in the cost of primary health care contacts and the cost of the intervention itself were acknowledged. The cost of providing access to the patient portal was estimated based on a five- year depreciation plan of the cost of the portal deployment, on the expected average number of users during this period, and on the yearly maintenance cost. The deployment and maintenance costs were received from the health care provider's financial records and were based on the purchases from the portal vendor, and on the labor cost of the health care providers' own personnel. The portal was provided by the present EHR vendor and integrated to the existing EHR. The portal deployment costs included the license of the portal, integration to the present EHR, training for nurses and doctors, and two training sessions provided for interested patients in the intervention group. The maintenance cost of the portal included the administration by the portal vendor, cost of the virtual private network connection (VPN) and the cost of sending the text message reminders to the patients' mobile phones. The cost the portal was estimated to be 6 euros per year per patient.

Previous care received
Service contacts and the physiological outcomes measurement in the year preceding access to the portal were retrieved from the care provider's EHR databases. Service contacts included doctor and nurse visits and calls in primary care and referrals to specialized care. To assess the monitoring of the essential physiological measures among the chronically ill, measurements of the patients' relevant physiological health outcomes (HbA1c, BMI, LDL, and blood pressure) were collected. The association between electronic patient portal adoption and previous care received by the patient was assessed in paper III.

Health status
The indicators for patients' state of health were patients' medical conditions and physiological health outcomes recorded in the health care provider's EHR, and health as reported by the patients through the second version of the short-form health survey SF-36. SF-36 is a broadly used instrument that generates functionality-based scores for mental and physical health and wellness (McHorney et al., 1994; McHorney, Ware, & Raczek, 1993; Ware & Sherbourne, 1992). In the cost-effectiveness analysis, patient-reported health was used as a secondary measure for effectiveness.

Owing to the diagnostic heterogeneity of the study group, three different types of diagnosis indicators were gathered to represent the comorbidity of the patients. First, diagnoses for the most common chronic illnesses in the study group, namely type 1 or 2 diabetes, hypertension, and hypercholesterolemia, were identified through the International Classification of Diseases (ICD-10) codes. Second, the Charlson Comorbidity Index (CCI) was used to assess the comorbidity of the patients. The CCI is a widely used system for characterizing patient comorbidities, drawing on ICD-10 recordings of 17 common chronic medical conditions (Charlson et al., 1987). Third, the total number of diseases identified as chronic by a health care professional were collected from patients' EHR.

Values of the physiological measures glycated hemoglobin (HbA1c), low-density lipoprotein (LDL), Body Mass Index (BMI), and blood pressure were collected to assess the patients' state of physiological health. These measures were chosen because of their relevance in the management of the most common diseases in the participant group.

Temporal proximity of a severe diagnosis
Diagnoses of the participants from five years before the intervention were gathered from the EHR of the service provider. A list of common severe chronic diagnoses was formed by using CCI. In paper II, the effect of temporal proximity of a severe diagnosis as a contextual factor was assessed.

6.2.3 Statistical methods

The controlled before and after setting was utilized to assess the effect of the electronic patient portal on patient activation and on cost-effectiveness of care.

In addition, the data obtained allowed for observational analyses on contextual factors that may promote or diminish the impact of a patient portal on cost-effectiveness of care.

To examine the similarity of the intervention and control groups at baseline, differences in age, gender, number of chronic diseases, prevalence of the most common chronic conditions in the sample (diabetes, hypercholesterolemia, and hypertension), doctor and nurse visits one year before the intervention, cost of care one year before intervention, physical and mental health, and patient activation at baseline were tested for. Independent sample t-tests for continuous variables and chi-square tests for categorical variables were used.

In paper II, an analysis of covariance (ANCOVA) with patient activation score at baseline as a covariate was used to assess the effect of patient portal access on patient activation score at 6-month follow-up. Paper IV reports the cost-effectiveness evaluation of the portal. Patient activation was used as the preliminary measure for effectiveness and patient-reported state of health as the secondary outcome measure. Owing to the plausible attrition bias acknowledged in paper II, in paper IV propensity score matching (Rosenbaum & Rubin, 1985) was used to adjust for the baseline differences between the intervention and control groups in the variables that may affect the outcomes of interest (Brookhart et al., 2006). Nearest available matching (Rosenbaum & Rubin, 1985) was used to pair each participant in the control group with a participant in the intervention group, based on the propensity score similarities. As suggested by Austin (2008), the balance achieved between the matched groups was tested with standardized differences for each covariate at baseline. A standardized difference of less than 20% is considered to indicate an adequate balance and therefore good comparability between groups (Rosenbaum & Rubin, 1985).

For both the matched and non-matched samples, non-parametric bootstrapping was used to simulate 1000 incremental cost-effectiveness ratios (ICERs). ICERs were plotted on a cost-effectiveness plane to assess the uncertainty related to the result. This method is widely used in health economics evaluations (Korthals-de Bos et al., 2003; van Spijker et al., 2012) to evaluate the health effects of an intervention in relation to the costs of care induced by the intervention (Briggs & Fenn, 1998). In this study, ICER was the ratio between the incremental cost and the incremental effectiveness, which consisted of changes in patient activation or in health status. Each bootstrapped ICER falls into one of the four quadrants of the cost-effectiveness plane, where differences in average effectiveness are displayed on the x-axis and differences in average costs on the y-axis. The quadrants represent four possible situations in relation to the incremental cost and incremental effectiveness of the intervention in comparison with care as usual. The proportion of bootstrapped ICERs that falls into a quadrant indicates the likelihood of the outcome represented by the quadrant. In addition to the cost-effectiveness plane, the cost-effectiveness acceptability curves (CEAC) for patient portal cost-effectiveness were calculated (Löthgren & Zethraeus, 2000). The CEAC indicates the probability of cost-effectiveness of the intervention at different levels of willingness to pay for the additional health outcome (van Hout

et al., 1994). CEAC is a non-cumulative distribution function and is therefore not necessarily an increasing function of willingness to pay (Fenwick et al. 2004).

The observational analyses of contextual factors that may promote or diminish the impact of a patient portal are reported in papers II and III. To examine the main effect of (1) patient activation level at baseline and (2) severe diagnosis proximity on the change in activation score, post hoc tests for group comparisons were used. In the post hoc tests, the Tukey honestly significant difference (HSD) method was employed to compare the change in patient activation between groups at different times since severe diagnosis (0-1, 1-2, >2, severe diagnosis during the intervention, and no severe diagnoses), and between groups with different levels of patient activation at baseline (1-2, 3, and 4). To test the moderating effect of 1) patient activation level at baseline and 2) severe diagnosis proximity on intervention outcome, linear regression modeling was used (Paper II).

To analyze the predictors of patient portal use, participants were divided into three groups (non-users, viewers, and interactive users), based on their portal use during the 6 months after gaining access to the portal. Non-users did not log in to the portal during the follow-up period. Viewers logged in at least once, but did not use either of the interactional functionalities, namely messaging with the care team or prescription renewal. Interactive users logged in to the portal and used one of the interactional functionalities at least once. For categorical variables, chi-square tests for overall differences among the three groups were used. To further identify such differences, pairwise comparisons using chi-square tests were conducted. Owing to the non-normality of the distributions for continuous variables, the non-parametric Kruskal-Wallis test was used to analyze overall differences among the three groups and the Wilcoxon-Mann-Whitney test for pairwise comparisons. (Paper III)

All statistical analyses for this study were performed using Stata version 13 (StataCorp LP, College Station, TX).

7 FINDINGS

7.1 THE FEASIBILITY OF THE PRESENT EHR DATA IN A NON-EXPERIMENTAL EVALUATION

In paper I, an attempt to evaluate the effect of the CCM on outcomes and cost of care using administrative and clinical data was demonstrated. The results of the "state-of-the-art" statistical analyses of the EHR data indicated that the CCM decreased type 2 diabetic patients' HbA1c levels by an average of 1.4 mmol mol−1 (1.2–1.7) during the first year in the care model. This decrease was gained through a small increase in resource use: an increase of 1.8 nurse visits (1.7–1.9) and 0.7 doctor visits (0.6–0.7) during the first year in the CCM. Although these results would imply that the CCM model may be moderately cost-effective, it remained unclear whether the results of the statistical analysis can be attributed to the intervention and whether the intervention could be replicated in another setting. The interviews with the health care professionals working in the target organization showed issues in the implementation and maintenance of the intervention. Despite initial comprehensive plans and instructions for CCM adoption, systematic guidelines, support for the model's long-term use, and development in daily care were perceived as insufficient. Further, self-management support, which was considered a key issue in the implementation phase, had not become a working practice in the organization.

With the CMO-configuration of the CCM, the relevant parameters needed to assess the causal effects of the intervention could be identified. These parameters were then compared with the available data in the service provider's EHR to identify the gaps in the present available data.

The analysis showed that the six components of the CCM trigger two distinct mechanisms that may improve patient's health outcomes: 1) improved clinical care, including, for example, adjustments in medications and procedures to follow care guidelines to the patient, and 2) self-management support to the patient. Operationalization of these mechanisms requires distinct parameters for contextual and outcome parameters. For example, improvements in clinical care are mostly contingent on the care professionals' skills, capabilities, and available tools, while successful self-management support also depends on patient characteristics, such as motivation.

Regarding outcomes, both clinical care and self-management support are expected to have a positive effect on clinical outcomes, such as HbA1c in the care of the diabetic patients. However, concerning self-management support, a longer time lag is expected for the clinical effects to be realized (Weatherly et al., 2009). Psychosocial changes and/or changes in the patient's knowledge base are needed to trigger lifestyle changes, which, in turn, can affect the patient's clinical health

status. To operationalize this lengthy process in a natural setting, measures of patients' health behavior and/or psychosocial measures assessing changes in patients' knowledge, skills, and confidence in managing their own health are needed.

Configuration of the mechanisms, relevant contextual factors, and the necessary outcome parameters showed that the administrative and clinical data available at present is not adequate for operationalizing the self-management support. Whereas relevant measures for evaluating improvements in clinical care were available, relevant contextual factors and outcome measures for evaluating self-management support were not recorded at all or were recorded too unsystematically to facilitate valid analysis.

7.2 THE EFFECTS OF ELECTRONIC PATIENT PORTAL ON COST-EFFECTIVENESS OF CHRONIC CARE

A total of 24 818 unique patients visited the health care facilities during the recruitment phase and could be assessed for eligibility. Of the assessed patients, 863 met the inclusion criteria and were allocated to intervention and control groups. In the end, informed consent and responses to baseline and follow-up questionnaires were obtained from 80 patients in the intervention group and 57 patients in the control group; thus, 137 patients in total were included in the final analysis (Table 1).

There were no significant differences in the baseline characteristics between the intervention and control groups (Table 1). A slightly greater proportion of the patients in the intervention group were women (56.2%, 45/80) than in the control group (45.6%, 26/57), and more patients in the control group had diagnosed hypertension (36.8%, 21/57) than patients in the intervention group (27.5%, 22/80). The mean cost of care during the year before the intervention was somewhat higher for the intervention group (935 euros) in comparison to the control group (756 euros). The mean age, patient-reported physical and mental health, and patient activation at baseline were similar in both groups, as were the proportions of patients with diabetes and hypercholesterolemia (Table 1).

Table 1. Descriptive characteristics of quasi-experiment study participants.

	Portal access (n=80)	Control (n=57)	t_{135}	χ^2(df)	*P*-value
Age (years), mean (SD)	61 (9)	63 (10)	−0.8		0.40
Female, n (%)	45 (56.2)	26 (45.6)		1.5 (1)	0.22
Number of chronic diagnoses[a] , mean (SD)	1.3 (1.3)	1.4 (1.4)	−0.6		0.53
Diagnosis, n (%)					
Type 1 or 2 diabetes[ab]	32 (40.0)	22 (38.6)		0.0 (1)	0.87
Hypertension[ac]	22 (27.5)	21 (36.8)		1.3 (1)	0.25
Hypercholesterolemia[ad]	37 (46.3)	24 (42.1)		0.2 (1)	0.63
Doctor visits[e], mean (SD)	3.8 (3.3)	3.0 (3.1)	1.4		0.18
Nurse visits[e], mean (SD)	3.5 (2.6)	4.1 (2.5)	−1.3		0.18
Cost of care[e] (euros), mean (SD)	935 (767)	756 (528)	1.5		0.13
Patient activation, mean (SD)	63.7 (15.4)	63.4 (14.5)	0.1		0.89
SF36 Physical Health, mean (SD)	65.9 (19.3)	63.8 (20.6)	0.6		0.55
SF36 Mental Health, mean (SD)	72.8 (21.1)	73.5 (19.6)	−0.2		0.85

a From the time before the beginning of the intervention
b ICD10 codes E10-E14 or ICPC codes T89-T90
c ICD10 codes I10-I15 or ICPC codes K85-K87
d ICD10 codes E78 or ICPC T93
e During the year before the intervention

This study was the first to use a Finnish translation of the short-form PAM. In paper II, the psychometric properties of the translated instrument, internal consistency, and item-rest correlations were examined at both baseline and follow-up. The results supported the reliability of the measure, and replicated to a great extent the findings from the previous Danish (Maindal, Sokolowski, & Vedsted, 2009) and Dutch (Rademakers et al., 2012) versions.

During the 6-month follow-up, the patients in the intervention group accessed the portal 10.8 times, viewed their care plan 3.2 times, sent 1.5 messages to their care team, and viewed their vaccination record 1.3 times on average. While the

prescription renewal functionality was offered in the portal, its use was not promoted, owing to the lack of a national prescriber–pharmacist interface at the time of the study. The functionality was only used 0.3 times, on average.

The analysis of variance with patient activation score at baseline as a covariate showed no significant effect of access to patient portal on patient activation ($F1,133= 1.87$, $P= 0.17$,$\eta2= 0.01$). The difference between the intervention and control group at follow-up adjusted for baseline activation score was 2.77 (95% CI: –1.24 to 6.79). As the difference of 4 to 5 points in patient activation is considered meaningful in terms of patients' health behavior (Fowles et al., 2009; Hibbard et al., 2008), the adjusted difference is minor.

The results of the cost-effectiveness analysis show that the effect of the intervention on cost of care, and therefore on the likelihood for cost-effectiveness of the intervention, was sensitive to the propensity score matching. In the adjusted sample, the incremental change in costs due to the intervention was 45 euros (95% CI: −94 to 183), whereas in the unadjusted sample the incremental change in costs changed sign, being −94 euros (95% CI: −253 to 65). The effect on patient activation was less sensitive to the matching. The mean change in patients' activation score was 2.8 points (95% CI: −2.2-7.8) higher in the intervention group, compared to the control group in the adjusted sample, and 2.6 points (95% CI: −1.8-7.1) higher in the intervention group, compared to the control group in the unadjusted sample. The cost-effectiveness plane (Figure 2) further shows that the likelihood for cost-effectiveness was higher in the unadjusted sample, compared to the adjusted sample.

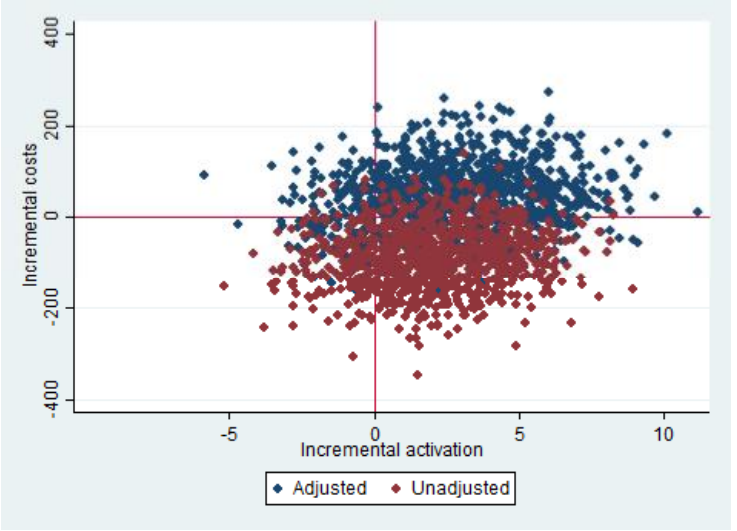

Figure 2. Distribution of bootstrapped incremental costs and activation with and without propensity score matching adjustment.

In the unadjusted sample, 71.9 % of the simulated ICERs fall into the southeast quadrant, indicating that increased activation was generated with less cost by the intervention in comparison with care as usual (dominance), whereas in the adjusted sample, 67.4% of the bootstrapped ICER fall into the northeast quadrant, indicating increased activation at an incremental cost.

The incremental cost-effectiveness acceptability curve (Figure 3) for the matched sample shows that, at willingness to pay 18 euros per one-point increase in patient activation, there is a 50% probability that the intervention is cost-effective. At willingness to pay 40 euros per one-point increase, the probability is 70%. In the unadjusted sample, at no willingness to pay for incremental patient activation points, the probability of intervention cost-effectiveness is 89%.

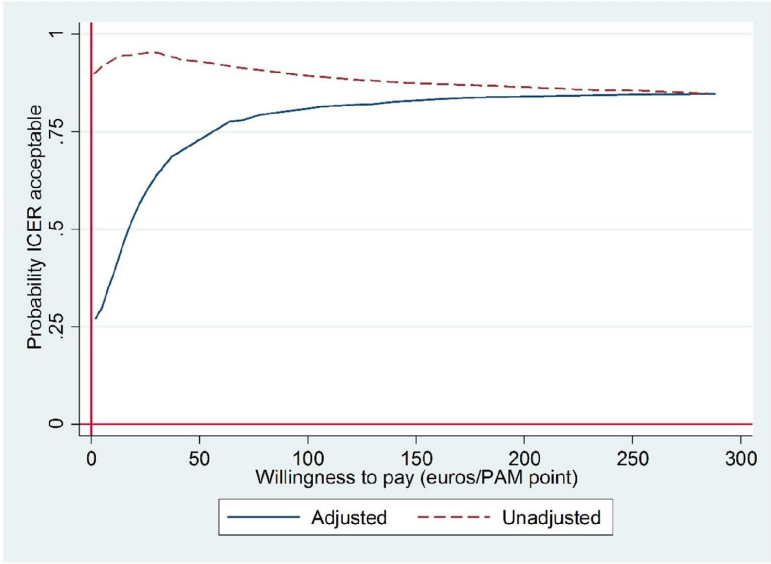

Figure 3. ICER acceptability curve based on willingness to pay for clinically significant change in patient activation gained.

The cost-effectiveness analysis for the proportion of clinically significant change in patient activation (≥5 point increase) was also performed. The results were parallel with the analysis for a one-point increase in patient activation. In the adjusted sample, a majority (61.1%) of the bootstrapped ICERs fall into the northeast quadrant, indicating increased activation at an incremental cost. In the unadjusted sample, 57.7 % of the simulated ICERs fall into the southeast quadrant, indicating that increased activation was generated for less cost by the intervention, in comparison with care as usual. The incremental cost-effectiveness acceptability curve (Paper IV, Appendix 3) for the adjusted sample shows that, at willingness to pay 700 euros per clinically significant change in patient activation, there is over 50% probability that the intervention is cost-effective. At willingness to pay 2100 euros per clinically significant change in patient activation, the probability of cost-effectiveness rises to 70% in the adjusted sample. In

the unadjusted sample, the probability of cost-effectiveness is 89% at a willingness to pay 0 euros per clinically significant change in patient activation. At willingness to pay 2000 euros per clinically significant change in PAM, the acceptability was still as high as 82% in the unadjusted sample.

7.3 Contextual factors that may affect patient portal cost-effectiveness

The 1-way ANOVA showed a significant difference in mean change in patient activation score across the three groups starting from different levels of patient activation ($F_{2,137}= 17.90$, $P< 0.001$, $\eta 2= 0.21$). Patients starting at low levels of patient activation (1–2) demonstrated greater positive change (mean change 8.5, SD 12.3) in activation score than patients starting at level 3 (mean change 0.7, SD 11.7) and 4 (mean change –6.1, SD 11.3; Figure 4). Pairwise post hoc comparisons using the

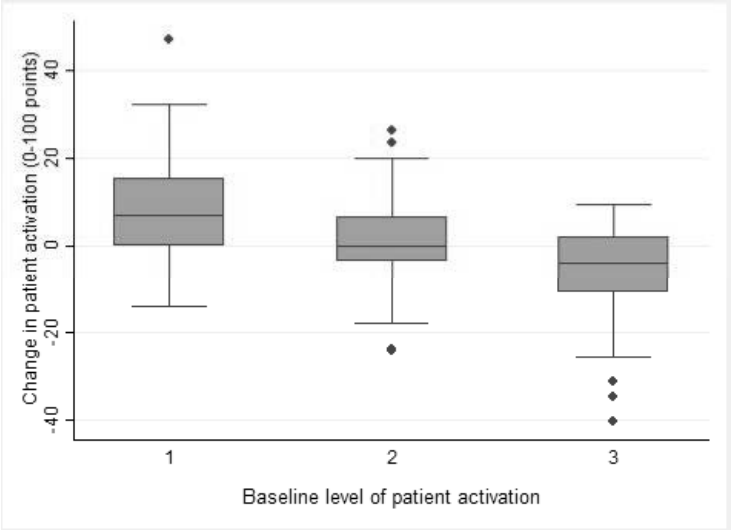

Figure 4. Changes in patient activation scores within groups starting at different levels of patient activation (n= 137).

Tukey HSD test further supported the statistical significance of the differences. Patients starting at the combined level 1–2 had significantly greater mean change scores than patients starting at level 3 (mean difference in change 7.8, $P= 0.01$) and level 4 (mean difference in change 14.6, $P< 0.001$). Furthermore, patients starting at level 3 showed a significantly greater mean change in patient activation than patients starting at level 4 (mean difference in change 6.8, $P= 0.01$). The difference of 4 to 5 points in patient activation is considered meaningful in terms of patients' health behavior (Fowles et al., 2009; Hibbard et al., 2008); thus, the differences between groups are considerable.

The 1-way ANOVA also showed a significant difference in mean change in patient activation scores across the 5 groups with different temporal proximity of a severe diagnosis (F^2,137= 17.90, P< 0.001, $\eta 2$= 0.21). Patients who received a severe diagnosis during the intervention showed greatest positive change in patient activation (mean change 5.4, SD 8.4). In addition, patients diagnosed 1–2 years ago (mean change 2.3, SD 15.7) and patients with no severe diagnoses (mean change 1.6, SD 13.1) showed a positive change in patient activation. The greatest decrease in patient activation change was observed for patients with a severe diagnosis made more than 2 years before the intervention (mean change –7.1, SD 12.3), and the change was also negative for patients diagnosed less than 1 year before the intervention (mean change –3.0, SD 11.5) (Figure 5). Pairwise post hoc comparisons using the Tukey HSD test showed a significant difference between patients diagnosed with a severe condition more than 2 years before the intervention and patients diagnosed during the intervention (mean difference in change 12.4, P= 0.02). The differences between the other groups were not statistically significant.

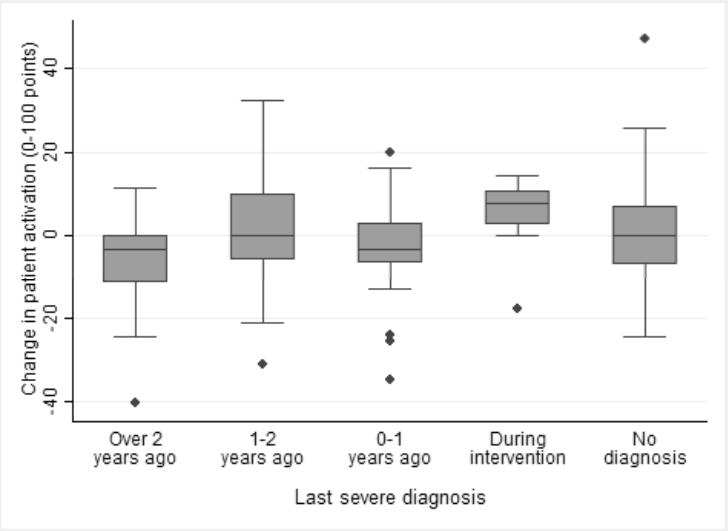

Figure 5. Changes in patient activation scores by time since last severe diagnosis (n= 137).

No significant interaction effects of portal access with baseline level of PAM or time since last severe diagnosis were detected. The most notable difference between the intervention and control groups was among patients starting from the highest level of patient activation (Difference= 4.82, P= 0.13) and among patients diagnosed within a year after the intervention (Difference= 7.65, P= 0.12).

The significant differences (P< 0.05) detected in health status and previous care received between non-users, viewers, and interactive users of the portal are presented in Table 2. Despite the broad range of measures used to indicate the patients' state of health, the groups differed only in their recorded diagnosis for hypertension, which was most common in the non-user group.

Table 2. Differences in patient characteristics between user groups.

Characteristics	Non-users	Viewers	Interactive Users
Comorbidity	Most likely to have a hypertension diagnosis		
Monitoring	Most likely to have had their HbA1c measured and recorded		
	More likely than viewers to have had their BMI and BP measured and recorded	Less likely than non-users to have had their BMI and BP measured and recorded	
Service contacts	Most nurse visits		
	Least referrals to specialized care		
		Fewer nurse calls than interactive users	More nurse calls than viewers

Most differences were detected in the amount of care received during the year before access to the portal. The non-user group had more nurse visits and more measurements of relevant physiological outcomes than viewers and interactive users. They also had fewer referrals to specialized care during the year before access to the portal than the two other groups. The viewers and the interactive users differed from each other significantly in the number of nurse calls received, the interactive users having more calls than the viewers. No significant differences in age, gender, or patient activation were detected between the groups.

8 DISCUSSION

8.1 CONTRIBUTIONS

8.1.1 Cost-effectiveness evaluation of chronic care self-management interventions

The findings show that realist evaluation approach can complement the classical trials on outcomes in both natural and experimental study designs. Acknowledging how an intervention is proposed to generate the suggested final health outcomes and effects on costs aids in identifying outcome measures that operationalize the mechanisms of the intervention, and accumulates knowledge on the intervention benefits. Further, attention paid to the characteristics of the users and circumstances of the study aids in pointing out relevant contextual factors that should be controlled for or considered in further research.

In the non-experimental CCM study, the CMO-configuration was applied to identify the short-term outcomes relevant to the mechanisms of the CCM. This analysis showed the deficiencies of the data and indicated threats to the validity potentially present in the non-experimental evaluations using routinely collected administrative and clinical data. Further, the attention to contextual factors exposed patient and care provider characteristics that may compromise the validity of the study and should therefore be controlled for. In the experimental setting, an intermediary outcome for self-management interventions, namely patient activation, was used as the primary outcome to operationalize the potential effect mechanism of an electronic patient portal. To evaluate the cost-effectiveness of the portal, an analysis combining the intermediary health outcomes and economic outcomes was performed. Additional observational analyses on the contextual factors accumulated knowledge on for whom and in what circumstances an electronic patient portal may be cost-effective.

Use of EHR data has the potential to accelerate the accumulation of knowledge in health care intervention evaluation (Calonge, 2012; Peltola et al., 2011). The usability of routine data should, however, be assessed in terms of whether it can adequately operationalize the mechanisms that the intervention is expected to generate. Since the outcomes for self-management support are distinct from the medical excellence of care, self-management component should be identified and evaluated separately from the "medical effects". In the case organization, relevant outcomes for medical care and service use were detectable, whereas the short-term outcomes for the self-management component of the intervention, such as behavioral and psychological measures, were not collected on a regular basis. The present EHR data does not provide information on how well the care provider has succeeded in supporting patients' active participation in the man-

agement of their own health. Recently, Glasgow and colleagues (2012) have suggested adding patient-reported measures of psychosocial issues and health behavior to the electronic health records.

8.1.2 Cost-effectiveness of an electronic patient portal

Previous studies on electronic patient portals have predominantly assessed either their effect on the use of other health services (Palen et al., 2012; Zhou et al., 2007) or their impact on care outcomes (Grant et al., 2008; Solomon et al., 2012; Tenforde et al., 2012; P. J. Wagner et al., 2012). Few studies have assessed the effects both on care outcomes and on service use (Nagykaldi et al., 2012). In this study, the effects of an electronic patient portal on both components of cost-effectiveness, that is 1) on the effectiveness in terms of patient activation, and 2) on the cost of care, were investigated. Further, to the author's knowledge, this is the first study to assess these components simultaneously in a cost-effectiveness analysis.

No statistically significant positive effect of the patient portal was detected on patient activation. This result runs somewhat counter to previous research on electronic patient portals (Nagykaldi et al., 2012; Solomon et al., 2012). A focus on the intervention mechanism shows that the heterogeneous results may be because of the different sets of functionalities provided through the portals studied. In studies where significant positive effects on patient activation have been found, the interventions included features for patient-produced information of their health management (Nagykaldi et al., 2012) and interactive condition-specific health education (Solomon et al., 2012). The patient portal in the present study was relatively simple, so the addition of a greater number of activating functionalities might fortify its effect (Cotter et al., 2014).

Despite previous studies showing decreases in face-to-face visits due to patient portal use (Nagykaldi et al., 2012; Zhou et al., 2007, Chen et al., 2009), a recent literature review on electronic patient portals (Otte-Trojel et al., 2014) did not find compelling evidence of patient portals' cost-efficiency. The authors suggest that portals may have become complements to rather than substitutes for existing health services (Otte-Trojel et al., 2014). In this study, the effect of the portal access on cost of care was ambiguous, changing from more to less costly depending on the model used. To better understand the effects of electronic patient portals on cost of care, more research is needed on how electronic patient portals are implemented and integrated in the existing service offering and service operations.

Although no significant effects on patient activation or cost of care were found, the results of the cost-effectiveness analysis, in which both effects on patient activation and cost of care were assessed simultaneously, showed some support for the cost-effectiveness of the portal. Although no statistically significant improvement (> 90% probability) in cost-effectiveness was detected in the sample adjusted for plausible attrition bias, the results indicated over 50% probability

for cost-effectiveness of the intervention at willingness to pay 18 euros per one point increase in the patient activation score. For a clinically significant improvement in patient activation, that is over 5 points increase in patient activation score, the probability exceeded 50% probability at 700 euros per clinically significant change. To assess whether these investments in patient activation are acceptable from the service provider's perspective, consequences of the improvements in patient activation need to be considered.

In previous research, an increase in patient activation score has been shown to result in improved self-management behavior (Hibbard et al., 2007) and better health outcomes (Hibbard & Greene, 2013). Further, an association between low patient activation and high costs of care (Hibbard, Greene, & Overton, 2013), as well as between high patient activation and low costs of care after 2 years of activation assessment (Greene et al., 2015), have been found. Although the causal relationship between patient activation change and the change in cost of care remains to be empirically shown (Greene et al., 2015), increased patient activation may, indeed, decrease the cost of care in the long term. Previous findings, therefore, suggest that monetary investments in activating patients may well be acceptable to achieve cost-effectiveness of chronic care in the long-term.

Two contextual factors were found to have an effect independent of the intervention on patient activation. First, in line with a previous study by Solomon and colleagues (2012), change in patient activation was greater among patients starting at a lower level of activation. Second, a greater positive change in patient activation was identified among patients diagnosed with a severe condition during the intervention than among patients whose last severe diagnosis was made more than 2 years before. Previous research has found connections between time since diagnosis and disease control among diabetic patients (Karter et al., 2001; Blaum et al., 1997). Van den Arend and colleagues (2000) compared four different primary care programs for structured care of diabetes, and found that, the longer the time since patients had the diagnosis, the less their disease knowledge increased as a result of the programs. To the author's knowledge, this is the first study to examine the effect of time since diagnosis on patient activation. Understanding the effect of temporal proximity of a diagnosis may aid in identifying the sensitive periods in chronic care when "an exposure [to a specific chronic care intervention] has a stronger effect on development and hence disease risk than it would at other times" (Ben-Shlomo & Kuh, 2002).

In this study, the intervention effect itself did not differ significantly among patients starting from different levels of patient activation or with different proximity of a diagnosis. The regression toward the highest patient activation score detected in the entire sample may be attributable to the additional intervention delivered to both the intervention and control groups, namely the drafting of the care plan. Another explanation could be the patient activation survey itself, in that it might encourage patients to rethink their role in the management of their condition. Assuming the latter, future research should include control groups to distinguish between the survey instrument effect and the actual intervention effect on changes in patient activation scores.

Previous studies have found heterogeneous results on the association of previous service use, state of health (Earnest et al., 2004; Tenforde et al., 2012; Weingart et al., 2006), age (Ancker et al., 2011; Tenforde et al., 2012; Weingart et al., 2006), gender (Roblin et al., 2009; Weppner et al., 2010), and patient activation (Hibbard & Greene, 2011; Roblin et al., 2009) with electronic patient portal use. In this study, which was conducted among patients of a single primary care provider, where the access was explicitly offered to each potential participant, and where access to the internet or the novelty of running errands online were unlikely impediments to use, these factors had no significant association with patient portal use. Instead, the differences between the non-users, users, and interactive users of the portal differed by their previous service use. In broader settings and samples with greater ethnic, social, and demographic variation, sociodemographic differences may, however affect equal distribution of patient portal benefits (Otte-Trojel et al., 2014). Further, the patient portal in this study was relatively simple and easy to use. Benefits of more complicated functionalities of a patient portal may distribute unequally owing to differences in patients' health literacy.

Non-users, users, and interactive users of the patient portal differed mainly in their demand for different services and tendency to use different service channels. Whereas the non-user group had visited a nurse most often, they had fewer referrals to specialized care than the two groups that had logged in to the portal. Among the patients who had logged in, the interactive users differed from the viewers in having received more nurse calls during the year before access. Plausible explanations for these observations may be found by considering the patient needs that an electronic patient portal potentially meets. In Finland, routine monitoring of the chronically ill is mostly performed by nurses. A lack of referrals to specialized care, combined with a higher number of nurse visits, may indicate a stable medical condition where patient needs are met and new channels for medical services are not needed. The association between higher numbers of nurse calls and interactive use of a patient portal may be explained by the nature of the interaction performed through these service channels. Compared to face-to-face visits with a health care provider, service encounters conducted by phone may lend themselves better to substitution by online interaction. Whereas these possible explanations are just some of many alternatives, the findings of this study do encourage, in line with Varsi and colleagues (2013), a more fine-grained distinction between different types of health service encounters and respective patient–provider communication channels.

8.2 Practical implications

The practical implications of this dissertation are related to the use of EHR data and the patient activation measure in the performance management of chronic care, and to the cost-effective adoption and implementation of the electronic patient portals in chronic care. While the present EHR data contains information on the clinical outcomes of care and resource use, it does not reflect the outcomes

for self-management support of the patients. To evaluate the success in supporting patients' active self-management of health, health care managers need information on the changes in patients' health behavior and in their psychosocial predilections for self-management of health. PAM is a scientifically validated instrument for measuring patients' knowledge, skills and abilities in managing their health. Improvements in patient activation are associated with improved cost-effectiveness. When used for managerial purposes, it should be acknowledged that using the instrument itself might improve patient activation and aid the care professionals in meeting the patients' needs (Hibbard et al. 2009). Further, recently diagnosed patients may show greater improvements in patient activation than patients diagnosed with chronic conditions several years ago and perhaps expectedly, least activated patients hold the greatest potential for improvement in activation. In case intermediary outcomes of self-management support cannot be observed or collected, other practices for encouraging self-management support, such as training of the personnel, should be considered.

Electronic patient portals may improve cost-effectiveness of chronic care by activating patients in the management of their own health and by decreasing the demand and need for services provided through other, more traditional service channels. However, the potential benefits of the portals are highly dependent on the contextual factors related to the patients and health care professionals using the portals and to the health care service system as a whole. When adopting electronic patient portals, specific attention should be paid to the functionalities offered in the portal, their value perceived by the users, and to the integration of the portal to the existing service offering and processes. Also the patients' abilities and motivation to use the provided functionalities should be considered. In Finland, among the chronically ill customers of public primary care, the use of the studied relatively simple patient portal was not dependent on patients' age, gender, disease burden, or baseline patient activation but rather on the previous care received by the patient. Patients whose care was continuous were less likely to use the portal than patients who had received less monitoring and had been referred more often to the specialized care

8.3 METHODOLOGICAL STRENGTHS AND LIMITATIONS

The case study results are generalizable to a typical evaluation setting encountered by primary care managers: one in which the intervention is complex, the primary data source is routinely collected clinical and administrative data, and randomization of patients into two research arms is too resource-consuming to arrange. Further, the findings concerning the poor feasibility of the routine data in the described setting are only generalizable to other contexts where similar data on care outcomes, consisting mainly of physiological measures, is routinely gathered.

The main strengths of the patient portal study are the experimental setting with longitudinal design, the use of a scientifically validated, short-term outcome

measure for self-management interventions (Hibbard & Greene, 2013), the patient activation measure, and the simultaneous assessment of cost and effectiveness of the intervention. Following the realist evaluation approach, the secondary use of the collected data suggested plausible contextual factors that may affect the benefits of the portal. However, like any research, this study has several limitations. As the service was to be offered in a timely manner to all the customers of the target study organization, time periods for the recruitment and follow-up were limited. Sample size remained modest, and this likely reduced the statistical significance of the effects. Further, the 6-month follow-up period may have been too short to capture the full benefits of the portal. According to the professionals working in the study organization, both professionals and patients spent part of the intervention time learning how to use the portal effectively, despite the fact that a small-scale pilot study with a restricted group of patients had been organized to test the portal before this investigation began. However, a longer intervention period would have been difficult to justify in a publicly funded health care organization, the central duty of which is to provide equal services to all its patients.

Another limitation in the study setting concerns the allocation of the patients to the intervention and the control groups. Although birth date itself is not expected to affect the outcomes of the intervention, the allocation method is deterministic in the sense that the assigned intervention could be predicted before the allocation ("CONSORT Statement," 2010). This may have influenced the recruitment of the patients and may have contributed to the attrition imbalance between the intervention and control groups. Another likely reason for the attrition imbalance that could not have been avoided by randomization was the inability to blind the patients and the study recruiters (nurses and physicians) from the allocation of the participants to the intervention and control groups. Whereas blinding the patients from receiving the intervention would solve the attrition bias problem, it may be challenging to execute in a self-management intervention study, where patients are active participants in the intervention and when informed consent from the patient is required for ethical approval. In web-based intervention studies, Samoocha and colleagues (2010) suggest the use of "sham" websites to blind participants to not receiving the actual intervention. In this study, a sham portal could not be offered for practical reasons. To control for the plausible attrition bias, propensity score matching, a widely used statistical method for reducing the effects of confounding in observational studies (Austin, 2011), was applied.

Finally, when assessing cost of care, only the costs for the health care provider could be assessed in this study. Access to an electronic patient portal may also have a comparative advantage in terms of opportunity cost to the patients' time.

With observational analyses on the whole participant group, relevant contextual factors that may impact the effect of a patient portal could be identified. The limitations common in observational studies apply to these analyses. Without a controlled setting, the results are restricted to the patients who responded to the study request and who may fundamentally differ from those who decided not to

participate. These results are therefore not conclusive. CCI, used in defining time since severe diagnosis, is restricted to a set of typical severe diagnoses; thus, some relevant diagnoses that might affect change in patient activation may possibly have been omitted. Broadening the set of diagnoses may further specify the relationship between time since diagnosis and patient activation.

The study also has limitations regarding the coverage of the suggested generative mechanisms of electronic patient portals. In addition to the effects on patient activation and health care resource use studied in this dissertation, the effect of the portal on patient–provider communication and patient satisfaction are considered important potential mechanisms through which the benefits of a patient portal may be realized (Otte-Trojel et al., 2014). Sufficient patient satisfaction with the portal and its functionalities is necessary for the portal use in the first place. Further, in their recent literature review on the mechanisms of electronic patient portals, Otte-Trojel and colleagues (2014) find that communication between the professional and the patient facilitated by the patient portal may establish social connections between the two parties and provide rich information in the form of the accumulated messages. In order to increase the impact of health technology, researchers have suggested involving the end-users, the patients and the professionals, in the development and evaluation of the technologies (Bélanger et al., 2012; McGregor and Brophy, 2005).

8.4 Future research

The suggestions for future research concern the methodology of cost-effectiveness evaluation of self-management interventions in chronic care, the further validation of the PAM instrument, and the evaluation of electronic patient portals.

In terms of the methodology, more research is needed to understand the long-term effects of improvements in patient activation and other potential intermediary health outcomes on final health outcomes and on cost of chronic care. Rigorous evidence on these effects would point out acceptability thresholds for willingness to pay for improvements in the intermediary outcomes, and would therefore allow more precise short-term estimation of self-management interventions' cost-effectiveness. In the evaluation of costs, specific attention should be paid to the costs accrued to all parties of the health service system, most notably to the patient.

Future research should further investigate intermediary measures for assessing the health outcomes of the chronic care self-management interventions. The technological development generates new possibilities for data collection and will likely enable accurate measurements of intermediary outcomes of self-management interventions, such as health behavior, that are, at present, considered challenging to observe. In addition, further research on the potential "sensitivity periods" during which patients can benefit the most from specific chronic care

self-management interventions would aid in determining the contextual factors that may promote or dilute the effects of the self-management interventions.

In the patient portal study, the patient activation improved in both intervention and control groups. This may be due to the independent effect of the patient activation survey. To further validate the PAM as a practical assessment tool, more research is needed on its independent impact on the patients, and on the health care organization using it.

In terms of understanding how for whom and under what circumstances an electronic patient portal may be cost-effective, more research is needed on the types of health services encounters that can be provided through portals. As new features of the portals emerge, research is needed to assess their benefits for different patient groups and in different environments.

9 CONCLUSIONS

This dissertation contributes to the literature on evaluation of public health interventions by increasing understanding of how the cost-effectiveness of chronic care self-management interventions can be evaluated, and by providing empirical evidence of the cost-effectiveness of a specific self-management intervention, namely an electronic patient portal.

Realist evaluation can complement the classical outcome trials in the pursuit of accumulating knowledge on cost-effectiveness of complex health care interventions, such as self-management interventions. Health intervention researchers are encouraged to consider the contextual factors that may promote or dilute the cost-effectiveness of the interventions, and the mechanisms that are proposed to generate the economic and health outcomes of the evaluated intervention.

The present administrative and clinical data collected routinely in the Finnish primary care, serves poorly the cost-effectiveness evaluation of self-management interventions. The underlying mechanism of the self-management interventions, that is the improvement in patients' ability to manage their condition, cannot be observed in the present routine data. A Finnish translation of PAM, a viable instrument for assessing the effects of self-management interventions, was validated in this study. PAM assesses patient activation, that is, patient's knowledge, skills and self-confidence in the management of their condition. As the improvements in patient activation are associated with improved health outcomes and reductions in health service use, patient activation may serve as an intermediary outcome measure for cost-effectiveness of self-management interventions.

Researchers and practitioners using PAM should consider that collecting the PAM survey may have an independent effect on patient activation, and on the care practices in the health care organization. Further, a patient's activation is likely to increase when they are diagnosed with a new chronic disease.

A relatively simple electronic patient portal that provides the patient with access to their own health records and secured messaging with the care provider, may be a cost-effective tool for self-management among the chronically ill. The benefits of an electronic patient portal are dependent on the mechanisms that its functionalities generate, and on the contextual factors such as the characteristics of the patients and the health care professionals using it, the health care system that it is adopted in, and its implementation in the organization.

Among the chronically ill, patients' present access to health services may predict the use of an electronic patient portal rather than age, gender, disease burden or patient activation. Patients with discontinuous care may benefit from this alternative channel to services.

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