

# Essentials of Nursing Care in Randomized Controlled Trials of Nurse-Led Interventions in Somatic Care: A Systematic Review

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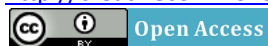
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## Abstract

**Background:** Nursing practice has to contribute to evidence pointing out why there is a need for more nurse-designed randomized control trials (RCTs) focusing on evidence-based practice (EBP). How far this EBP has progressed in different health aspects is usually established by systematic reviews of RCTs. Nurse-led RCTs exist but no study has addressed the essentials of nursing care. **Aim:** The aim was therefore to determine the essentials of nurses' interventions by means of nurse-led RCTs in somatic care focusing on the stated context, goals, content, strategies as well as the nurse's role related to effectiveness. **Methods:** A systematic review was realized according to Cochrane review assumptions to identify, appraise and synthesize all empirical evidence meeting pre-specified eligibility criteria. The PRISMA statement guided the data extraction process (n = 55) from PubMed and CINAHL. **Results:** Of the RCTs in somatic care, 71% showed a positive effectiveness of nurse-led interventions, of which the nurse had a significant role with regard to being the main responsible in 67% of the studies. Also, 47% of the RCTs presented a theoretical standpoint related to the nurse-led interventions and most prominent were international evidence-based guidelines. Goals were found to have either a patient-centered or a professional-centered ambition. Strategies were based on patient-directed initiatives, nurse-patient-directed initiatives or nurse-directed initiatives, while contents were built upon either a patient-nurse interaction or a nursing management plan. **Conclusions:** This review underlines the necessity of a holistic view of a person, as nurse-led RCTs comprising a patient-centered ambition, patient-directed initiative and patient-nurse interaction plan showed beneficial nursing care effectiveness, particularly if

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**theory-based. In a nurse-led RCT, a basic theoretical perspective is advantageous as well as to elucidate the role of the nurse in relation to the estimated effects.**

## Keywords

**Nurse-Led; Nursing Care; Randomized Controlled Trial; Somatic Care; Systematic Review**

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## 1. Introduction

Nursing practice has during the years often been based on experience, tradition and intuition rather than on scientific validation [1]. However, today's healthcare organizations as well as policy-making bodies are emphasizing the importance of evidence-based practice (EBP) [2]. Such EBP has become essential to answering a clinical question, by both awareness of the resources available to nurses and their skills in using them [3]. Still an obvious gap exists between the everyday clinical nursing practice and available empirical evidence about nursing care interventions [4]. Randomized controlled trials (RCTs) are recommended to document the effects of care and treatment [5][6], and in nursing research to evaluate the effectiveness of nursing care interventions [7]. To ascertain the validity and reliability of RCTs, there should be a careful control regarding possible problems, *i.e.* dropouts, random assignment, identifying and maintaining an adequate control condition, non-adherence to protocols and assessment of clinically meaningful change [8].

Several nursing studies exist aiming to spread knowledge of how to implement EBP, starting with a description of how to search for evidence through the PICOT (Population, Intervention, Comparator, Outcome, Time-frame) format [9], and to form a critical appraisal of the studies available [10]. What seems to be lacking in several RCTs of nursing care interventions is a careful specification how the nursing care has been performed [11]. Few Cochrane reviews exist concerning nurse-led RCTs which also is evident in the somatic care. In a Cochrane review of nursing care interventions such as patient education to improve the ability of self-management, the interventions were often not clearly specified resulting in a conclusion that the evidence did not show effectiveness for the nursing care [12]. In one review concerning RCTs of nursing care interventions for secondary prevention in patients with coronary artery disease, more than half of the trials (57%) showed positive effectiveness in at least one outcome. However, there were no consistent relationships observed between intervention characteristics and the effectiveness of interventions [13]. This lack of knowledge needs to be developed by establishing not only whether something works, but also why, for whom and in what circumstances [14]. These three aspects could be enlightened by specifying the essentials of nursing care interventions in terms of context, goal, strategy and content in general as well as the significance of the registered nurse's (RN's) role in designing nurse-led RCTs (initiating, organizing, implementing, documenting) in particular. Accordingly, nursing practice has to contribute to evidence and there is an obvious need for more nurse-designed RCTs with focus on EBP [1]. How far this EBP has progressed with reference to the level of evidence in different health aspects is usually established by systematic reviews of RCTs [10]. Results from nurse-led RCTs exist but no study has so far addressed the essentials of nursing care [15]. Consequently, the aim of this systematic review was to determine the essentials of nurses' interventions by means of nurse-led RCTs in somatic care focusing on the stated context, goals, strategies, content as well as the nurse's role related to effectiveness.

## 2. Methods

### 2.1. Eligibility Criteria

In accordance with our aim we included nurse-led RCTs that evaluated the effectiveness of nursing care interventions in the context of somatic care; defining nurse as a RN. To narrow our target area, studies in the field of women's (gynecology/obstetrics), children's (pediatrics) and mental (psychiatric) health were excluded. Participants of interest were patients; hence studies of *e.g.* relatives were excluded. Outcome measures of interest were patient-reported outcome measurements (PROM) thus excluding studies focusing on *e.g.* cost analyses and healthcare personnel.

## 2.2. Literature Search

A review team of 13 nursing researchers, experienced in somatic care performed a literature search in the databases PubMed and CINAHL, with the limits to publication the last five years 2006 to 2010, the English language as the most established international and scientific language, Randomized Control Trials and age group “Adult: 19+ years”. In the identification we used both controlled vocabulary (e.g. Medical Subject Headings [MeSH]) and free-text words. The MeSH-terms were “Nurse Clinicians” OR “Nurse Practitioners” and the free-text words were nurse specialist, nurse practitioner, nurse-led and nurse-managed. The literature search also excluded, with the Boolean operator NOT, the following free text words from the search: gynecology, pediatrics, pregnancy and psychiatric. In all; 244 references were found in PubMed and CINAHL and after extracting references already retrieved in PubMed, 207 were left for screening.

## 2.3. Study Selection and Data Abstraction

All retrieved titles and abstracts were screened to determine eligibility. Studies were excluded, if non-RCTs, only study protocols or only pilot studies. After getting full text copies publications were excluded, if non-nurse-led, team-led, non-somatic care, non-patient-directed, or non-PROM (Figure 1).

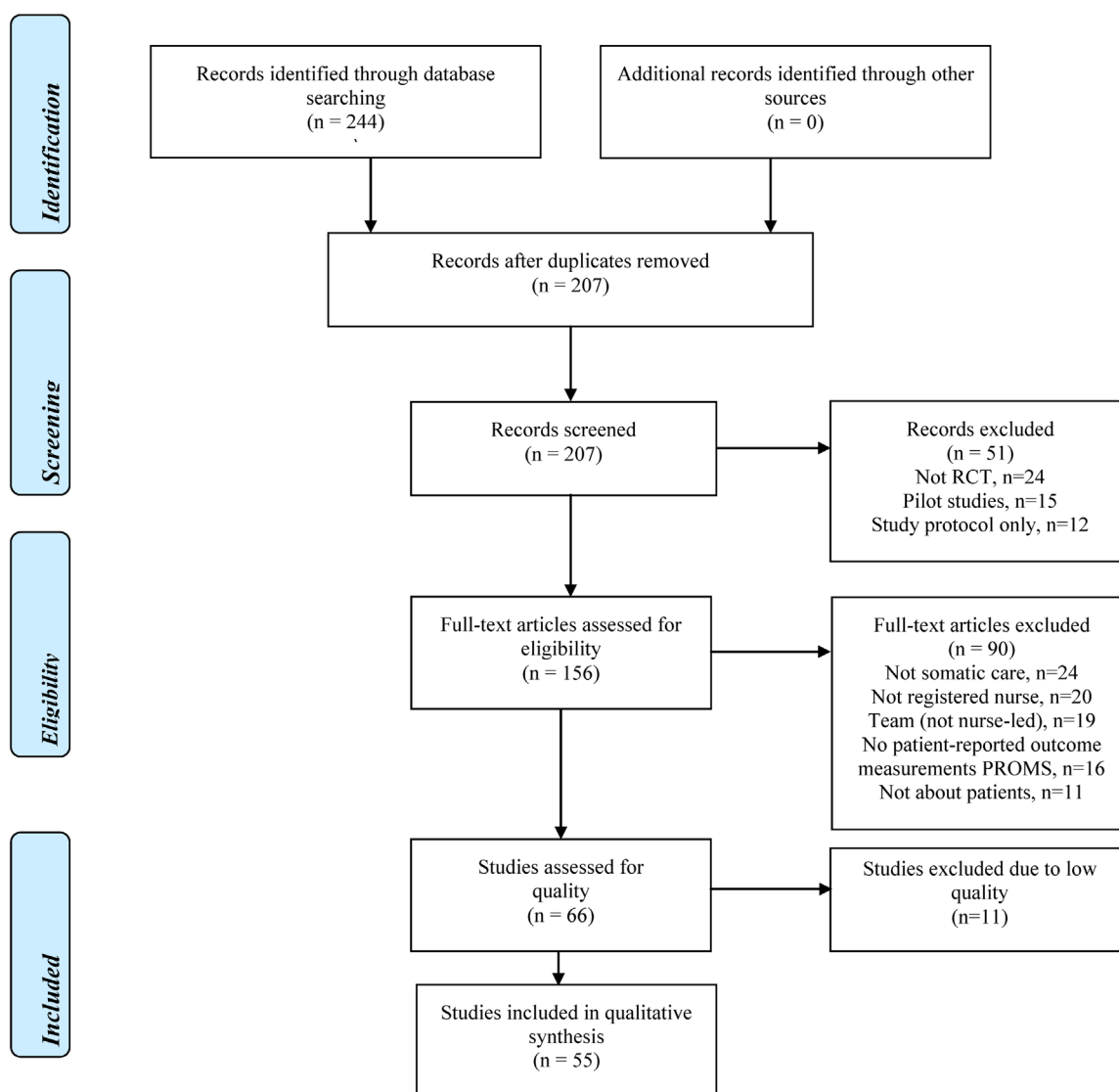


Figure 1. Flow diagram of the systematic review process.

## 2.4. Quality Assessment

The review team under the direction of first, second and last reviewers abstracted information about and reviewed the publications according to The Swedish Council on Health Technology Assessment's well-established audit template [16]. The following keywords in the audit template were considered: study population, selection criteria, sample size, power calculation, randomization strategy, comparability between groups, blinding, compliance/adherence, primary outcomes, description of intervention and control care and treatment, drop-outs, primary/secondary outcome measures, efficacy/effectiveness, side effects, results, precision, bonds and disqualification. Accordingly, the publications were graded for methodological quality from low through medium to high, the latter indicating a stronger likelihood of the RCT design to generate unbiased results.

## 2.5. Data Analysis

A study protocol inspired by the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement [17] was used to guide the review team through the data extraction process. The systematic review was then realized according to Cochrane review assumptions [18]; *i.e.* a transparent and replicable procedure attempting to identify, appraise and synthesize all empirical evidence meeting pre-specified eligibility criteria to answer a given research question. We extracted the following data: context of care, goal, strategy and content, as well as the RN's role based on at least two of four criteria (initiating, organizing, implementing, documenting). The effectiveness was based on the primary outcome stated in the studies. All reviewers scrutinized the extracted data independently followed by review team discussions concerning data quality until consensus was reached.

## 3. Results

### 3.1. Demographical and Contextual Data

As shown in **Table 1**, over 85% ( $n = 47$ ) of the 55 nurse-led RCTs in somatic care had their origin in Europe ( $n = 34$ ) and North America ( $n = 13$ ); more specific eight European countries were represented, whereas the Netherlands ( $n = 13$ ) and UK ( $n = 12$ ) had prominent positions. In all, four continents were represented; besides Europe and North America, also Asia ( $n = 6$ ) and Oceania ( $n = 2$ ). Eight care contexts in somatic care were identified among the 55 RCTs whereas cardiac care ( $n = 18$ ) and primary care ( $n = 10$ ) were the two most prominent ones (**Table 1**).

### 3.2. Goals, Strategies and Content

Forty-seven percent ( $n = 26$ ) of the RCTs in somatic care presented a theoretical standpoint related to the nurse-led intervention (**Table 2**) and most prominent were international evidence-based guidelines ( $n = 9$ ). As displayed in **Table 3**, goals were abstracted into two main categories; a patient-centered ambition and a professional-centered ambition, both comprising almost equal number of categories, *i.e.* goals. The most prominent goal with the patient-centered ambition was quality of life ( $n = 11$ ) while prevention was the most common goal as to the professional-centered ambition ( $n = 15$ ). Strategies were abstracted into three main categories; patient-directed initiatives, nurse-patient-directed initiatives and nurse-directed initiatives (**Table 3**). Nurse-patient-directed and nurse-directed initiatives comprehended nearly three times more categories, *i.e.* strategies than patient-directed initiatives. The most prominent strategy for patient-directed initiatives was video/telemonitoring ( $n = 4$ ) while the corresponding figures for nurse-patient-directed and nurse-directed initiatives were dialogue ( $n = 14$ ) and assessment ( $n = 17$ ), respectively. Contents were abstracted into two main categories (**Table 3**); a patient-nurse interaction and a nursing management plan, both comprising close equal numbers of categories, *i.e.* contents. The most prominent content for patient-nurse interaction plan was support and counselling (both,  $n = 7$ ) while follow-up/feedback ( $n = 10$ ) was the corresponding content for nursing management plan.

### 3.3. The Nurse's Role and Its Effectiveness

In all, 71% of the RCTs in somatic care ( $n = 39$ ) showed positive effectiveness of a nurse-led intervention, of which the nurse had had a significant role with regard to being the main responsible in 67% ( $n = 26$ ) of the studies. Furthermore the theory-based RCTs presented a higher figure (20 of 39; 51%) with regard to positive ef-

**Table 1.** Descriptive overview of the studies included (n = 55); context, interventions, effects and role of the nurse.

Title	Authors and country [ref]	Context of care (diagnose or target group)	Nurse-led intervention			Effect based on primary outcome	*Nurse Sign.
			Main Goal	Main Strategy	Main Content		
The impact of a nurse-led care programme on events and physical and psychosocial parameters in patients with heart failure with preserved ejection fraction: a RCT in primary care in Russia	Andryukhin <i>et al.</i> 2010, Russia [19]	Cardiac (chronic heart failure)	QoL	Practical training	Consultation	Yes, improved emotional and physical status, and QoL	No
A randomized community-based intervention trial comparing faith community nurse referrals to telephone-assisted physician appointments for health fair participants with elevated blood pressure	Baig <i>et al.</i> 2007, USA [20]	Cardiac (hypertension)	Prevention	Assessment	Screening	No, community nurse not as effective as physician (less reduction in SBP)	Yes
<sup>a</sup> A RCT to evaluate a nurse-led programme of support and lifestyle management for patients awaiting cardiac surgery "Fit for surgery: Fit for life" study	Goodman <i>et al.</i> 2008, UK [21]	Cardiac (awaiting cardiac surgery)	Self-care behaviour	Dialogue	Counseling	No effect on anxiety, LOS, BP, BMI or S-cholesterol	Yes
Improving outcomes after myocardial infarction: a randomized controlled trial evaluating effects of a telephone follow-up intervention	Hanssen <i>et al.</i> 2007, Norway [22]	Cardiac (AMI)	QoL	Dialogue	Follow-up	Yes, improved HRQoL (physical dimension)	Yes
Effect of moderate or intensive disease management program on outcome in patients with heart failure: Coordinating Study Evaluating Outcomes of Advising and Counseling in Heart Failure (COACH)	Jaarsma <i>et al.</i> 2008, The Netherlands [23]	Cardiac (heart failure)	Adherence	Self-efficacy	Support	No effect on time to death or hospitalization	Yes
<sup>a</sup> A nurse-led cardiac rehabilitation programme improves health behaviours and cardiac physiological risk parameters: evidence from Chengdu, China	Jiang <i>et al.</i> 2007, China [24]	Cardiac (coronary heart disease)	Self-care behavior	Adult learning	Support	Yes, improved health behavior and physiological risk parameters	Yes

## Continued

Surveillance and treatment of dyslipidemia in the post-infarct patient: can a nurse-led management approach make a difference?	Lapointe <i>et al.</i> 2006, Canada [25]	Cardiac (AMI)	Adherence	Assessment	Follow-up	No effect on lipid profile	Yes
<sup>a</sup> Effects of a self-care program on the health-related quality of life of pacemaker patients: a nursing intervention study	Malm <i>et al.</i> 2007, Sweden [26]	Cardiac (pace maker patients)	QoL	Dialogue	Education	No effect on HRQoL	Yes
<sup>a</sup> Outcomes of cardiac rehabilitation with versus without a follow-up intervention rendered by telephone (Luebeck follow-up trial): overall and gender-specific effects	Mittag <i>et al.</i> 2006, Germany [27]	Cardiac (post cardiac event)	Self-care behavior	Dialogue	Counseling	Yes, reduction of behavioral coronary risk factors	No
<sup>a</sup> A telephone-delivered empowerment intervention with patients diagnosed with heart failure	Shearer <i>et al.</i> 2007, USA [28]	Cardiac (heart failure)	Self-management	Dialogue	Empowerment	Yes, facilitated self-management	Yes
Using technology to create a medication safety net for cardiac surgery patients: a nurse-led RCT	Sherrard <i>et al.</i> 2009, Canada [29]	Cardiac (post-surgery)	Adherence	Tele-monitoring	Support	Yes, increased compliance (medication) and decreased adverse events	Yes
Effects of nurse management on the quality of heart failure care in minority communities: a randomized trial	Sisk <i>et al.</i> 2006, USA [30]	Cardiac (ethnically diverse patients with heart failure)	Prevention	Assessment	Advice	Yes, improved functioning and fewer hospitalizations	No
<sup>a</sup> Nurse-led self-management group programme for patients with congestive heart failure: RCT	Smeulders <i>et al.</i> 2010, The Netherlands [31]	Cardiac (congestive heart failure)	Self-management	Self-efficacy	Empowerment	No effect on psychosocial attributes, self-care behavior or QoL	Yes
<sup>a</sup> Effects of a post-discharge transitional care programme for patients with coronary heart disease in China: a RCT	Zhao and Wong 2009, China [32]	Cardiac (coronary heart disease)	Self-management	Self-efficacy	Empowerment	Yes, positive effect on diet, medication and health-related life-style	Yes
Nurse practitioners substituting for general practitioners: RCT	Dierick-van Daele <i>et al.</i> 2009, The Netherlands [33]	Primary (primary care patients)	Patient satisfaction	Assessment	Consultation	Yes, NP as effective as GP (patient satisfaction with care)	Yes
Larval therapy for leg ulcers (VenUS II): RCT	Dumville <i>et al.</i> 2009, UK [34]	Primary (leg ulcer)	EBC	Assessment	Wound care	No effect on rate of healing	Yes

## Continued

<sup>a</sup> Effectiveness of a falls-and-fracture nurse coordinator to reduce falls: a RCT of at-risk older adults	Elley <i>et al.</i> 2008, New Zealand [35]	Primary (elderly identified for falls)	Prevention	Assessment	Screening	No effect on proportion of falls	Yes
<sup>a</sup> Randomized clinical effectiveness trial of nurse-administered small-group cognitive behavior therapy for persistent insomnia in general practice	Espie <i>et al.</i> 2007, UK [36]	Primary (persistent insomnia)	EBC	CBT	Consultation	Yes, improved sleep	No
<sup>a</sup> Nurse clinic versus home delivery of evidence-based community leg ulcer care: a randomized health services trial	Harrison <i>et al.</i> 2008, Canada [37]	Primary (leg ulcer)	EBC	EBC algorithm	Wound care	Yes, clinic delivery of care as effective as home delivery (3 months healing rate)	Yes
<sup>a</sup> A minimal psychological intervention in chronically ill elderly patients with depression: a randomized trial	Lamers <i>et al.</i> 2010a, The Netherlands [38]	Primary (chronically ill elderly with depression)	Self-management	CBT	Counseling	Yes, reduced symptoms of depression	No
The Winchester falls project: a RCT of secondary prevention of falls in older people	Spice <i>et al.</i> 2009, UK [39]	Primary (elderly identified for falls)	Detection	Assessment	Screening	No effect on proportion of falls	Yes
<sup>a</sup> Preventing weight gain: one-year results of a randomized lifestyle intervention	ter Bogt <i>et al.</i> 2009, The Netherlands [40]	Primary (overweight or obesity)	Prevention	Dialogue	Counseling	Yes, reduced body weight	Yes
Effect of an intensive nurse-managed medical care programme on ambulatory blood pressure in hypertensive patients	Ulm <i>et al.</i> 2010, Germany [41]	Primary (hypertension)	Prevention	Self-monitoring	Advice	Yes, decline of systolic BP	No
Nurse led, home based self help treatment for patients in primary care with chronic fatigue syndrome: RCT	Wearden <i>et al.</i> 2010, UK [42]	Primary (chronic fatigue syndrome)	QoL	Listening therapy	Support	No effect on fatigue or physical functioning	Yes
<sup>a</sup> Managing uncertainty in diabetes: an intervention for older African American women	Amoako and Skelly 2007, USA [43]	Diabetes (Afro American women with diabetes)	Self-management	Dialogue	Counseling	Yes, reduction of diabetes-related uncertainty	Yes
<sup>a</sup> Improving glycemic control in older adults using a videophone motivational diabetes self-management intervention	Hawkins 2010, USA [44]	Diabetes (uncontrolled diabetic adults)	Self-management	Self-efficacy	Empowerment	Yes, decreased HBA1c	Yes
<sup>a</sup> Diabetes specialist nurse as main care provider for patients with type 2 diabetes	Houweling <i>et al.</i> 2009, The Netherlands [45]	Diabetes (type 2 diabetes)	EBC	EBC algorithm	Consultation	Yes, CNS as effective as internist (HBA1c decrease)	Yes

## Continued

Preventing glycaemic relapse in recently controlled type 2 diabetes patients: a RCT	Huizinga <i>et al.</i> 2010, USA [46]	Diabetes (type 2 diabetes)	Prevention	Dialogue	Support	No effect on HBA1c	Yes
A nurse short message service by cellular phone in type-2 diabetic patients for six months	Kim and Jeong 2007, South Korea [47]	Diabetes (type 2 diabetes)	EBC	Self-monitoring	Advice	Yes, improved HBA1c	Yes
An intensive nurse-led, multi-interventional clinic is more successful in achieving vascular risk reduction targets than standard diabetes care	MacMahonTone <i>et al.</i> 2009, Ireland [48]	Diabetes (type 2 diabetes)	Prevention	Assessment	Support	Yes, reduction in vascular risk	No
Effect of telephone follow-up on adherence to a diabetes therapeutic regimen	Nesari <i>et al.</i> 2010, Iran [49]	Diabetes (type 2 diabetes)	Adherence	Dialogue	Follow-up	Yes, decreased HBA1c	Yes
Active care management supported by home telemonitoring in veterans with type 2 diabetes: the DiaTel RCT	Stone <i>et al.</i> 2010, USA [50]	Diabetes (veterans with type 2 diabetes)	Adherence	Tele-monitoring	Follow-up	Yes, decreased HBA1c	Yes
A RCT of nurse-led care for symptomatic moderate-severe obstructive sleep apnea	Antic <i>et al.</i> 2009, Australia [51]	Respiratory (obstructive sleep apnea)	QoL	Assessment	Consultation	Yes, care model as effective as physician directed care (daytime sleepiness)	Yes
<sup>a</sup> Improving quality of life in depressed COPD patients: effectiveness of a minimal psychological intervention	Lamers <i>et al.</i> 2010b, The Netherlands [52]	Respiratory (COPD and depressive symptoms)	Self-management	CBT	Counseling	Yes, reduced symptoms of anxiety and depression, improved QoL	No
A RCT of follow-up of patients discharged from the hospital following acute asthma: best performed by specialist nurse or doctor?	Nathan <i>et al.</i> 2006, UK [53]	Respiratory (post-acute asthma)	Prevention	Assessment	Follow-up	Yes, CNS as effective as respiratory doctor (number of exacerbations)	Yes
A nurse led intermediate care package in patients who have been hospitalised with an acute exacerbation of chronic obstructive pulmonary disease	Sridhar <i>et al.</i> 2008, UK [54]	Respiratory (post-acute exacerbation of COPD)	Prevention	Care plan	Education	No effect on hospital admission rate	Yes
Weekly self-monitoring and treatment adjustment benefit patients with partly controlled and uncontrolled asthma: an analysis of the SMASHING study	van der Meer <i>et al.</i> 2010, The Netherlands [55]	Respiratory (asthma)	Self-management	Self-monitoring	Advice	Yes, improved asthma control	Yes



## Continued

Tele-assistance in chronic respiratory failure patients: a RCT	Vitacca <i>et al.</i> 2009, Italy [56]	Respiratory (COPD)	Prevention	Assessment	Consultation	Yes, fewer hospitalizations	No
<sup>a</sup> The effectiveness of nurse-led telemonitoring of asthma: results of a RCT	Willems <i>et al.</i> 2008, The Netherlands [57]	Respiratory (asthma)	QoL	Tele-monitoring	Symptom management	No effect on asthma-specific QoL	Yes
The PRaCTICaL study of nurse led, intensive care follow-up programmes for improving long term outcomes from critical illness: a pragmatic RCT	Cuthbertson <i>et al.</i> 2009, UK [58]	Acute (intensive care patients)	QoL	Dialogue	Follow-up	No effect on HRQoL	Yes
Injured road users' health-related quality of life after telephone intervention: a RCT	Franzén <i>et al.</i> 2009, Sweden [59]	Acute (injured road users)	QoL	Dialogue	Advice	Yes, increased HRQoL	Yes
Infection, rejection, and hospitalizations in transplant recipients using telehealth	Leimig <i>et al.</i> 2008, USA [60]	Acute (transplant recipients)	Detection	Dialogue	Symptom management	Yes, as effective as standard care (infection, rejection and hospitalization)	Yes
Randomized trial of a delirium abatement program for postacute skilled nursing facilities	Marcantonio <i>et al.</i> 2010, USA [61]	Acute (elderly with acute illness)	Prevention	Assessment	Symptom management	No effect on persistence of delirium	Yes
<sup>a</sup> Effects of nurse-managed telemonitoring on blood pressure at 12-month follow-up among urban African Americans	Artinian <i>et al.</i> 2007, USA [62]	Cardiovascular (Afro Americans with hypertension)	Prevention	Tele-monitoring	Feedback	Yes, improved BP control (reduction in SBP)	Yes
<sup>a</sup> A randomized, controlled trial for risk factor reduction in patients with symptomatic vascular disease: the multidisciplinary Vascular Prevention by Nurses Study (VENUS)	Goessens <i>et al.</i> 2006, The Netherlands [63]	Cardiovascular (symptomatic vascular disease)	Prevention	Care plan	Support	Yes, improved cardiovascular risk profile	Yes
<sup>a</sup> The role of self-efficacy in vascular risk factor management: a randomized controlled trial	Sol <i>et al.</i> 2007, The Netherlands [64]	Cardiovascular (symptomatic vascular disease)	Self-care behavior	Self-efficacy	Empowerment	No effect on self-efficacy	Yes
<sup>a</sup> Effect of nurse counselling on metabolic risk factors in patients with mild hypertension: a randomised controlled trial	Tonstad <i>et al.</i> 2007, Norway [65]	Cardiovascular (hypertension)	Self-care behavior	Dialogue	Counseling	Yes, improved weight control and lower triglycerides	No

## Continued

A RCT of structured nurse-led outpatient clinic follow-up for dyspeptic patients after direct access gastroscopy	Chan <i>et al.</i> 2009, UK [66]	Medical (dyspepsia after gastroscopy)	Prevention	Assessment	Follow-up	Yes, NP as effective as GP (dyspepsia severity, HRQoL, drug use and cost)	No
<sup>a</sup> Health-related quality of life in patients undergoing peritoneal dialysis: effects of a nurse-led case management programme	Chow & Wong 2010, Hong Kong [67]	Medical (peritoneal or hemo-dialysis)	QoL	Care plan	Motivation	Yes, improved QoL (within group differences over time)	Yes
Telephonic management of rectal bleeding in young adults: a prospective RCT	Raje <i>et al.</i> 2007, UK [68]	Medical (rectal bleeding)	Prevention	Assessment	Advice	Yes, symptomatic improvement (resolution of rectal bleedings)	No
<sup>a</sup> Evaluation of a nurse-led disease management programme for chronic kidney disease: a RCT	Wong <i>et al.</i> 2010, Hong Kong [69]	Medical (chronic kidney disease)	Self-management	Self-efficacy	Empowerment	Yes, improvement in diet, dialysis, quality of life and satisfaction with care	Yes
Patient satisfaction with nurse-led telephone follow-up after curative treatment for breast cancer	Kimman <i>et al.</i> 2010, The Netherlands [70]	Oncological (breast cancer)	Patient satisfaction	Dialogue	Follow-up	Yes, same level of patient satisfaction (compared to hospital follow-up)	No
Nurse-led follow-up of patients after oesophageal or gastric cardia cancer surgery: a randomised trial	Verschuur <i>et al.</i> 2009, The Netherlands [71]	Oncological (esophageal or gastric cancer)	QoL	Assessment	Follow-up	Yes, CNS home visits as effective as follow-up by clinicians (HRQoL)	Yes
Do OA patients gain additional benefit from care from a clinical nurse specialist? A RCT	Hill <i>et al.</i> 2009, UK [72]	Rheumatology (osteoarthritis)	Patient satisfaction	Assessment	Consultation	Yes, CNS clinic as effective as JHD clinic (health status and self-efficacy)	Yes
<sup>a</sup> Impact of a rheumatology expert nurse on the wellbeing of patients attending a drug monitoring clinic	Ryan <i>et al.</i> 2006, UK [73]	Rheumatology (osteoarthritis)	QoL	Assessment	Consultation	Yes, improved wellbeing (health status and arthritis control)	Yes

AMI = Acute Myocardial Infarction, BMI = Body Mass Index, BP = Blood Pressure, CBT = Cognitive Behavioral Therapy, CNS = Clinical Nurse Specialist, COPD = Chronic Obstructive Pulmonary Disease, EBC = Evidence-Based Care, GP = General Practitioner, HRQoL = Health-Related Quality of Life, JHD = Junior Hospital Doctor, LOS = Length of hospital Stay, NP = Nurse Practitioner, QoL = Quality of Life, RCT = Randomized Controlled Trial, SBP = Systolic Blood Pressure, \* = Significant role of the nurse, <sup>a</sup> = Theory-based intervention.

fectiveness compared to the non-theory-based RCTs (6 of 16; 38%). The RCTs with positive effectiveness showed prominent figures as to patient-centered ambition with regard to goal, nurse-directed and nurse-patient-directed initiatives with regard to strategy, and patient-nurse interaction with regard to content (Table 4). These figures should be compared to RCTs without effectiveness showing more prominent figures at professional-centered ambition (goal), at nurse-directed initiatives (strategy) and both at patient-nurse interaction and nursing management plans (content).

**Table 2.** Theoretical standpoints used in the theory-based studies (n = 26).

[24] Jiang et al. 2007, [30] Sisk et al. 2006, [37] Harrison et al. 2008, [40] ter Bogt et al. 2009, [45] Houweling et al. 2009, [57] Willems et al. 2008, [62] Artinian et al. 2007, [63] Goessens et al. 2006, [77] Elley et al. 2008	International evidence-based guidelines	9
[31] Smeulders et al. 2010, [44] Hawkins 2010, [64] Sol et al. 2007	Bandura's self-efficacy theory	3
[21] Goodman et al. 2008, [44] Hawkins 2010, [65] Tonstad et al. 2007	The trans-theoretical model of health behavior change	3
[38] Lamers et al. 2010a, [52] Lamers et al. 2010b	Minimal psychological intervention	2
[32] Zhao and Wong 2009, [69] Wong et al. 2010	The four Cs model: comprehensiveness, collaboration, coordination, continuity	2
[27] Mittag et al. 2006, [36] Espie et al. 2007	Cognitive-behavioral and health psychology /Cognitive behavioral therapy	2
[43] Amoako & Skelly 2007	Mishel's uncertainty-in-illness theory	1
[22] Hanssen et al. 2007	Lazarus and Folkman's theory on stress, appraisal, and coping	1
[26] Malm et al. 2007	Orem's self-care theory	1
[73] Ryan et al. 2006	Pendelton's framework	1
[67] Chow & Wong 2010	Evidence-based care and motivational interviewing	1
[28] Shearer et al. 2007	Empowerment using Roger's science of unitary human being person-environment process	1

**Table 3.** Categorization matrix the interventional goal, strategy and content in the studies analysed (n = 55).

Goal		Strategy		Content	
Category	Main category	Category	Main category	Category	Main category
Quality of life (11) Self-management (9) Self-care behaviour (5) Patient satisfaction (3)	<i>Patient-centered ambition</i> (28)	Video/telemonitoring (4) Self-monitoring (3) Practical training (1)  Dialogue (14) Self-efficacy (6) CBT (3) Listening therapy (1) Adult learning (1)	<i>Patient-directed initiatives</i> (8)    <i>Nurse-patient-directed initiatives</i> (25)	Counselling (7) Support (7) Empowerment (6) Advice (6) Education (2) Motivation (1)	<i>Patient-nurse interaction plan</i> (29)
Prevention (15) Adherence (5) EBC (5) Detection (2)	<i>Professional-centered ambition</i> (27)	Assessment (17) Care plans (3) EVB algorithm (2)	<i>Nurse-directed initiatives</i> (22)	Follow-up/feedback (10) Consultation (8) Screening (3) Symptom management (3) Wound care (2)	<i>Nursing management plan</i> (26)

**Table 4.** Studies with effect (n = 39) and without effect (n = 16) in relation to interventional goal, strategy and content.

Intervention	Studies with effect, n (%)	Studies without effect, n (%)
Intervention goal		
Patient-centered ambition	21 (54)	7 (44)
Professional-centered ambition	18 (46)	9 (56)
Intervention strategy		
Patient-directed initiatives	10 (26)	4 (25)
Nurse-patient directed initiatives	14 (36)	5 (31)
Nurse-directed initiatives	15 (38)	7 (44)
Intervention content		
Patient-nurse interaction plan	21 (54)	8 (50)
Nursing management plan	18 (46)	8 (50)

## 4. Discussion

### 4.1. Methodological Issues

It is interesting and remarkable that less than one-third of the RCTs identified reached the final review process indicating the importance of setting up inclusion and exclusion criteria as well as quality assessment, even in “the RCT world”. At the same time it is of importance to remember that also qualitative designs are essential in nursing to identify patients’ needs and desiderata in order to develop the most appropriate and effective PROM interventions [74]. A possible limitation was that only two data bases were screened with regard to nurse-led RCTs; but it is important to stress that these data bases were the most relevant ones—CINAHL and PubMed for the purpose of nurse-led interventions in somatic care. Another possible limitation was to study the phenomenon in just one context; the somatic one. From a methodological standpoint it is essential to handle data in a proper way with a sufficient review competence; in this case it was likely so, as all reviewers were researchers familiar within the somatic care context. Of course it would be of value to compare if, and in what way nurse-led RCTs in somatic care differ from the context of women’s, children’s and mental health. Another limitation is the extensive review team with a risk of bias in the extraction and interpretation processes; but at the same time the review process was guided by an established study protocol [16] as well as the Cochrane review assumptions [18] implying that every single review was scrutinized by the review team until negotiating consensus was reached. It is also a risk to make a fair and proper decision concerning effectiveness or not, due to the studies’ choice of primary outcome and the magnitude of clinical relevance and utility from a nursing perspective. Also to determine the nurse’s role was sometimes limited due to scanty descriptions of the nurse-led interventions especially with regard to nurses’ functions both in a partial and a holistic perspective.

### 4.2. Nursing Care Intervention Issues

Considering the fact that most of the nurse-led intervention studies have been carried out in Europe and North America, it is questionable how well the results are generalizable outside these areas. On the other hand the need for more nurse-led interventions has been emphasized [7], and this seems particularly true for all countries. It is also striking that two care contexts in somatic care stand out; cardiac care and primary care. Both are typical fields engaging both clinical and academic nurses, and the range of lethal diseases like coronary artery disease is extensively engaging both professional interests and socioeconomic resources [13] while the primary care has an increased responsibility for the public health including the whole flora of symptoms, conditions and diagnoses of acute as well as chronic characters [6]. It is satisfactory that as much as 71% of the nurse-led RCTs ended up with a beneficial nursing care [13], indicating what already has been pointed out [75]. A good reason why nurse-led interventions are successful is obviously the holistic view of the person, e.g. a person-centered care covering all aspects of the person [76] [77]. RCTs with a person-centered care are showing promising figures [5] [78]. Our review underlines this holistic view of a person as RCTs comprising a patient-centered ambition, patient-directed initiative and patient-nurse interaction plan were more prevalent in the nurse-led RCTs with beneficial nursing care effectiveness compared to those without effectiveness. Also that the nurse’s role was of significance in two-thirds of these nurse-led RCTs substantiating that the holistic view, *i.e.* a person-centered care is of importance and a necessity in order to counsel, support, and follow-up the patient in maintaining health or preventing or recovering from disease [79] [80]. Besides the holistic perspective involving a participating patient in his/her total care situation, the person-centered care also advocates the need for and use of EBP [77]. Accordingly, such reasoning highlights the necessity of using theoretical standpoints when operationalizing the study design by using appropriate measurements in order to establish both relevant and effective outcomes. As our study indicates, the theory-based studies (51%) brought more effectiveness than the non-theory-based ones (38%), but the use of theory-based strategies is still premature [77]. A theory-based nurse-led RCT intervention points out the grounds in planning and developing the context, goals, strategies, content as well as the nurse’s role related to estimated effectiveness.

## 5. Conclusions and Implications

Nurse-led RCTs with a distinct and clear patient-centered ambition, patient-directed initiative and patient-nurse interaction plan seem to promote beneficial nursing care effectiveness. Also a sound theoretical frame was seen to be of importance when designing a nurse-led RCT. Accordingly, more nursing care interventions in nurse-led

RCTs are needed and can advantageously and theoretically be based on for example a person-centered care. Basic theoretical perspectives are essential when planning and developing evidence-based practice as well as elucidating the role of the nurse in relation to the estimated effects. Concerning effectiveness of nursing care interventions, more reviews are needed in order to compare nurse-led RCTs in somatic care with mental health as well as women's and children's health.

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