# Nursing Sensitive Outcomes in Patients with Rheumatoid Arthritis: A Systematic Literature Review

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# Abstract

### *Background*

Although rheumatology nursing has been shown to be effective in managing patients with rheumatoid arthritis, patient outcomes sensitive to nursing interventions (nursing sensitive outcomes) have not been systematically studied.

### *Objectives*

The objective of this study was to identify and delineate relevant patient outcomes measured in studies that reported nursing interventions in patients with rheumatoid arthritis.

### *Design*

A systematic search was conducted from 1990-2016. Inclusion criteria were (i) patients with rheumatoid arthritis, (ii) adult population age ≥ 16 years, (iii) nurse as part of the care team or intervention delivery, (iv) primary research only, (v) English language, and (vi) quantitative studies with nursing sensitive outcomes.

### *Data sources*

Medline, CINAHL, Ovid nursing, Cochrane library and PsycINFO databases were searched for relevant studies.

### *Review methods*

Using the predetermined inclusion/exclusion criteria, nine reviewers working in pairs assessed the eligibility of the identified studies based on titles and abstracts. Papers meeting the inclusion criteria were retrieved and full texts were further assessed. Critical Appraisal Skills Programme tools were used to assess the quality of the included studies. Data on nursing sensitive outcomes were extracted independently by two reviewers. The Outcome Measures in Rheumatology comprehensive conceptual framework for health was used to contextualise and present findings.

### *Results*

Of the 820 articles retrieved, 7 randomised controlled trials and 3 observational studies met the inclusion criteria. Seventeen nursing sensitive outcomes were identified (disease activity, clinical effects, pain, early morning stiffness duration, fatigue, patient safety issues, function, knowledge, patient satisfaction, confidence in care received, mental health status, self-efficacy, patient attitude/perception of ability to control arthritis, quality of life, health utility, health care resources, death). These fitted into 10 health intervention domains in keeping with the pre-specified conceptual framework for health: disease status, effectiveness, safety, function, knowledge, satisfaction, psychological status, quality of life, cost, death. A total of 59 measurement instruments were identified comprising patient reported outcome measures (n=31), and biologic measures and reports (n= 28).

### *Conclusions*

This review is notable in that it is the first to have identified, and reported, a set of multidimensional outcome measures that are sensitive to nursing interventions in rheumatology specifically. Further research is required to determine a core set of outcomes to be used in all rheumatology nursing intervention studies.

# 1. Introduction

Rheumatoid arthritis is a chronic systemic inflammatory disease characterised by inflammation of multiple joints and may lead to severe disability and premature mortality (Gabriel and Michaud, 2009). Pharmacological management targets the immune system and requires vigilant monitoring by health-care professionals and patients. Non-pharmacological interventions, such as exercise, joint protection, foot care and patient-education, aim to help patients manage their disease, participate in social, leisure and work-related activities and thus optimise their health (National Collaborating Centre for Chronic Conditions, 2009, Zangi et al., 2015).

Rheumatology nursing is a practice specialty which contributes significantly to the management of patients with rheumatoid arthritis (American Nurses Association and Rheumatology Nurses Society, 2013, Carr A, 2001, van Eijk-Hustings et al., 2012). Rheumatology nurses have many roles within the context of the multidisciplinary team ranging from disease management to coordination of the overall care for people with rheumatoid arthritis (National Collaborating Centre for Chronic Conditions, 2009, van Eijk-Hustings et al., 2012). Within rheumatology services, nurse-led care continues to grow as a model of care delivery in the backdrop of the global shortage of rheumatologists, increased need for patient monitoring in the out-patient departments and the increasing standard of education and experience of rheumatology nurses (Garner et al., 2017, Ryan, 2017). Rheumatology nursing development follows a worldwide tendency among healthcare practitioners to provide a more proactive, evidence-based and patient-preference-based care (Laurant M et al., 2004, Loveman et al., 2003, Quill and Holloway, 2012). In 2012, a European League against Rheumatism (EULAR) task force developed evidence-based recommendations for the role of the nurse in the management of chronic inflammatory arthritis (van Eijk-Hustings et al., 2012). The recommendations were aimed to enhance standardisation and harmonisation of rheumatology nursing across countries.

While the evidence confirming that patient benefit from rheumatology nursing continues to grow, more high quality studies including international comparisons are required to further strengthen this evidence (van Eijk-Hustings et al., 2012). However, one of the critical challenges to evidence synthesis is lack of agreement on which outcome domains should be covered when evaluating rheumatology nursing care. Furthermore, methods to measure outcomes directly related to nursing interventions are limited (Begley et al., 2010, Gerrish, 2011). This hampers comparability of studies and pooling of outcomes in meta-analyses, and consequently limits clear and robust conclusions regarding nursing interventions (Craig et al., 2008, Ndosi et al., 2011).

In order to capture the valuable and unique contribution of nursing to health care, it is important to identify outcomes that are sensitive to nursing (International Council of Nurses, 2009). As a concept, a nursing sensitive outcome can be defined as an individual's, family or community state, behaviour or perception that is measured along a continuum in response to nursing intervention(s) (Moorhead et al., 2013). In the context of this study a nursing sensitive outcome was defined as an individual's area of health, behaviour or perception that responds to an intervention which includes nursing. Identifying patient outcomes in rheumatology that are sensitive to nursing interventions is a crucial first step in the development of a core outcome set for use in this context.

An international initiative to improve outcome measurement in Rheumatology (OMERACT) developed a conceptual framework for health, and delineated a process for developing core outcome sets, collectively termed OMERACT Filter 2.0 (Boers et al., 2014). This comprehensive OMERACT framework (Figure 1) is designed to lead to the development of an all-inclusive core set of outcome measures specific to the context for which this core set is intended. This framework comprises two overarching concepts (Impact of health Conditions and Pathophysiological Manifestations). Impact of health conditions encompass three aspects of health (core areas); (i) death, (ii) life impact, (iii) resource use/economic impact. Pathophysiological manifestations as a concept is not further subdivided into areas (Figure 1). Each core area is subdivided into 'domains', defined as a further specification of the aspect of health or health impact to be measured. In all studies, domains are intended to be disease and context specific. As a next step in the development of core outcome sets, OMERACT recommends the identification of at least one valid, reliable and responsive measurement instrument to measure each domain (Boers et al., 2014). This step usually requires a combination of literature review and a consensus process.

This OMERACT conceptual framework for health and delineated process for development of core set outcomes was chosen to underpin this study. With a long-term goal of developing a core outcome set in the context of rheumatology nursing, an international group of rheumatology nurses and patient research partners undertook a systematic review to delineate all outcomes used in nursing intervention studies. The aim of this systematic literature review therefore, was to identify nursing sensitive outcomes and measurement tools that have been used to date in studies of nursing interventions in patients with rheumatoid arthritis.

## 2. Methods

### *2.0. Design*

The review team comprised two patient research partners (from Ireland and the UK) and seven nurses and academics from Ireland, The Netherlands, the UK and the USA. Patient research partners are persons with a relevant disease who operate as active research team members on an equal basis with professional researchers, adding to the benefit of their experiential knowledge to a research project (de Wit et al., 2011). The patient research partners were all trained for and experienced in participating within all steps of the OMERACT research process, and were involved in the study from its inception. They participated as full researchers in the discussion about the necessity of this work; design of the review; study selection and in finalising the manuscript. A research librarian was consulted for advice on search terms at the beginning of the project although she was not part of the research team.

The systematic review was guided by the Cochrane Collaborative methodology (Higgins and Green, 2009). The review protocol detailing the research question, objectives and inclusion/exclusion criteria was developed and agreed upon by the review team in June 2014 although this was not registered or published.

### *2.1. Inclusion Criteria*

Inclusion criteria were (i) patients with rheumatoid arthritis, in accordance with American College of Rheumatology classification criteria for rheumatoid arthritis (Arnett et al., 1988) and the American College of Rheumatology/European League against Rheumatism (ACR/EULAR) rheumatoid arthritis classification criteria (Aletaha et al., 2010), (ii) adult population age ≥ 16 years (onset of arthritis prior to the age of 16 years is classified as juvenile idiopathic arthritis (JIA), as distinct from rheumatoid arthritis (Petty et al., 2004)), (iii) rheumatology nurse as part of the care team or intervention delivery, (iv) dated 1990 – 2016, (v) primary research only, (vi) English language, and (vii) quantitative studies with nursing sensitive outcomes.

### *2.2. Information Sources*

A systematic literature search was executed in Medline, CINAHL, Ovid Nursing, Cochrane library and PsycINFO in September 2014, and the search was updated in March 2016.

### *2.3. Search*

The search strategy was discussed at length and agreed by the review team. Several preliminary searches were conducted to identify terms to encompass interventions and outcomes specific to rheumatology nursing. However, a large variation between descriptions of interventions and outcomes was found. On account of this diverse terminology, to ensure capture of all pertinent papers, it was agreed to undertake broader search terms using nurse truncated (nurs*) only. The final search terms used in all databases were “rheumatoid arthritis” (in all fields) AND “nurs*” (in title or abstract).

### *2.4. Study selection*

The study selection process comprised 7 steps, which are summarised in Figure 2. Using EndNote® software results from all database searches were merged and duplicates were removed (steps 1 & 2). For step 3 the review team sub-divided into four working groups, minimum two reviewers per group. All abstracts and titles that resulted from the search were screened for eligibility using three of the above inclusion criteria (adults age >16 years at disease onset, nurse as part of care team or intervention delivery, primary research). Records were retained if they did not contain an abstract or if reviewers were unable to ascertain if the above inclusion criteria applied. For step 4 the partners were rotated between working groups to enhance the validity in re-screening titles and abstracts. Only studies meeting the following criteria were retained: (i) quantitative studies with nursing sensitive outcomes in the results and (ii) English language. In step 5, full texts were obtained. Papers were assessed to ensure that nursing was a part of the intervention and reported nursing sensitive outcomes. In step 6, studies with mixed diagnostic groups (i.e. rheumatoid arthritis and psoriatic arthritis) and interventions delivered by non-specialised rheumatology nurses (for example, generic smoking cessations programmes not delivered by a rheumatology nurse), were excluded. Step 7 was an update of the literature search.

### *2.5. Quality Assessment*

Critical Appraisal Skills Programme tools (Cohort Checklist and Randomised Controlled Trial Checklist) were used to assess the quality of the included studies (CASP, 2013). Questions 1-6 relate to the internal validity of the studies, 7-8 relate to validity of the results and questions 9-11 relate to relevance to practice (external validity) of the study. Quality assessment was conducted independently by each group. Disagreements were resolved by discussion either between the group partners or in consultation with the whole group.

### *2.6. Data extraction*

For this study, a data extraction tool was devised to guide the extraction of information from the records in line with the study aim. The data extracted included: author, title, origin, year, type of patients, age of patients, study design, language, if nursing was part of intervention, outcomes and instruments and covariates (the template of the data extraction tool can be found in the Supplementary material S1). Data were extracted by all researchers independently and then these were checked between pairs and later by all reviewers. Subsequently, the following data were also extracted: outline of intervention, methods of analysis, results related to effectiveness of the interventions.

### *2.7. Synthesis of results*

Data synthesis was carried out qualitatively by one reviewer and subjected to rigorous discussion, cross checking and consensus by the research team. All nursing sensitive outcomes that were reported in the studies were delineated. Using a content analysis approach, context specific domains for this study were identified and defined. The nursing sensitive outcomes were categorised into these domains and subsequently were mapped onto the OMERACT core areas and domains (Table 1).

## 3. Results

### *3.0. The search results*

Figure 2 presents the flow diagram of the systematic search. Of the 820 titles originally identified, 115 full texts were screened and eventually 11 papers reporting 10 studies (two papers (Hill et al., 1994 and Hill, 1997) reported results of one study) were included in this review.

### *3.1. Characteristics of the included studies*

An overview of the 10 studies summarising patient-related characteristics, the nursing sensitive outcomes, the associated measurement instruments and a summary of key results are presented in Table 2. The 10 included studies represented 7 RCTs (Dougados et al., 2015, Hill, 1997, Hill et al., 1994, Hill et al., 2003, Ndosi et al., 2014, Primdahl et al., 2014, Ryan et al., 2006, Tijhuis et al., 2003) and 3 observational studies comprised of 2 cohort studies (Maravic et al., 2000, Watts et al., 2015) and 1 cross-sectional study (Arthur and Clifford, 2004). The majority (n=6) of the studies were conducted in the UK (Arthur and Clifford, 2004, Hill et al., 1994 and Hill, 1997, Hill et al., 2003, Ndosi et al., 2014, Ryan et al., 2006, Watts et al., 2015), 2 in France (Dougados et al., 2015, Maravic et al., 2000), and one each in Denmark (Primdahl et al., 2014) and in The Netherlands (Tijhuis et al., 2003). The purpose of all studies was to evaluate patient outcome.

Seven of the prospective studies assessed the effects of nurse-led care by comparing patient outcomes following nurse-led care or usual (physician-led) care (Hill et al., 2003, Ndosi et al., 2014, Primdahl et al., 2014, Ryan et al., 2006, Watts et al., 2015) or team care (Tijhuis et al., 2003). The other two studies (Dougados et al., 2015, Maravic et al., 2000) were slightly different. Dougados et al (2015) used two active interventions to assess the efficacy of nurse-led care in managing co-morbidities and patients' self-assessment of rheumatoid arthritis disease activity. Maravic et al., (2000) was not a comparative study but the effects of the nursing care were assessed within the context of multidisciplinary care, with patient outcomes and costs followed prospectively for six months. The last study (Arthur and Clifford 2004) was a cross-sectional study demonstrating the association of patient satisfaction with care provided in secondary care (rather than primary care).

### *3.2. The quality assessment*

The results of the quality assessment of the included studies are presented in Table 3 (CASP, 2013). All randomised controlled trials and cohort studies were of a good quality, on the basis that they had a positive answer to at least 7 of the 11 main questions. Only 1 of the randomised controlled trials satisfied all 11 questions of the CASP appraisal tool (Primdahl et al., 2014), 3 satisfied 10 of the 11 questions (Dougados et al., 2015, Ndosi et al., 2011, Ryan et al., 2006), and the remaining two satisfied 9 and 7 of the 11 questions respectively (Hill et al., 1994 and Hill, 1997; Hill et al., 2003). For the 3 cohort studies only 1 study (Watts et al., 2015) satisfied all 11 appraisal questions, the other 2 each satisfied 9 of the 11 questions (Arthur and Clifford 2004, Maravic et al., 2000).

### *3.3. Key findings*

From the study summaries (Tables 1-2) the nursing sensitive outcomes and measurements instruments were identified and categorised into domains and mapped onto the OMERACT Filter 2.0 four core areas (Table 4) (Section 2.7). In total, 10 domains for health intervention were identified, these included: (i) disease status, (ii) effectiveness, (iii) safety, (iv) function, (v) knowledge, (vi) satisfaction, (vii) psychological status, (viii) quality of life, (ix) costs and (x) death. These domains were derived from the 17 nursing sensitive outcomes identified, including, (1) disease activity, (2) clinical effects, (3) pain, (4) early morning stiffness (EMS) duration, (5) fatigue, (6) patient safety issues, (7) function, (8) knowledge, (9) patient satisfaction, (10) confidence in care received, (11) mental health status, (12) self-efficacy, (13) patient attitude/perception of ability to control arthritis, (14) quality of life, (15) health utility, (16) health care resources, and (17) death. A total of 59 measurement instruments were identified. These comprised patient reported outcome measures (n= 31) and an amalgam of biologic measures and reports (n= 28) (Table 4). The OMERACT Filter 2.0 framework mapping is outlined below.

### *3.4. OMERACT Filter 2.0 core area 1: Pathophysiological manifestations*

Domains identified from this systematic review as pathophysiological in nature were disease status, effectiveness and safety (Table 3). These were further subcategorised into groups of nursing sensitive outcomes as considered appropriate, as explained below. The domain of disease status had only one nursing sensitive outcome, namely disease activity, which was assessed within 8 studies through a combination of patient reported outcome measures and biologic measures and reports. The patient reported outcome measures included joint assessment using the composite disease activity score (DAS), the Richie articular index (RAI), and the rheumatoid arthritis disease activity assessment (RADAI), global health score (GH) visual analogue scale (VAS), physician and patient global assessment-VAS, and patient reported disease activity. Biological measures and reports included c-reactive protein (CRP), erythrocyte sedimentation rate (ESR), plasma viscosity, and physical activity levels derived from walk time and grip strength assessments (Dougados et al., 2015, Hill et al., 1994, and Hill, 1997, Hill et al., 2003, Maravic et al., 2000, Ndosi et al., 2014, Primdahl et al., 2014, Ryan et al., 2006, Tijhuis et al., 2003).

In the effectiveness domain four nursing sensitive outcomes were identified in 7 studies, namely, clinical effects, pain, early morning stiffness (EMS) duration, and fatigue. Clinical effectiveness as a domain was also assessed through a combination of patient reported outcome measures and biological measures and reports. Patient reported outcome measures included Rheumatology Attitude Index (RAI) and DAS28. Biological measures included biochemical measures of CRP, ESR, plasma viscosity, and urinalysis; radiographic imaging of hands and feet; self-reported side effects. Pain and early morning stiffness (EMS) were assessed using patient reported outcome measures only, namely, a pain 5-point ordinal scale; pain-VAS; Arthritis Impact Measurement Scale (AIMS); Rheumatoid Arthritis Impact of Disease (RAID); EMS duration in minutes. Similarly, fatigue was assessed using a fatigue-VAS and the RAID fatigue scale (Dougados et al., 2015, Hill et al., 1994, Hill et al., 2003, Maravic et al., 2000, Primdahl et al., 2014, Ryan et al., 2006, Tijhuis et al., 2003).

The patient safety domain had only patient safety issue as a nursing sensitive outcome, identified in two studies. These were assessed by monitoring and documentation of adherence, out of range blood tests, missing relevant reaction on out of range tests, RADAI alerts, Health assessment Questionnaire-(HAQ)-alerts, side-effect alerts, total number of alerts, initiated biologic treatment, telephone consultation and health utility (Primdahl et al., 2014, Tijhuis et al., 2003).

### *3.5. OMERACT Filter 2.0 core area 2: Life Impact*

In this area five domains were identified; functional, patient knowledge, patient satisfaction, psychological status and quality of life (QoL).

The life impact domain related to function was identified as a nursing sensitive outcome measured through nine different tools across 10 studies (Dougados et al., 2015, Hill, 1997, Hill et al., 1994, Hill et al., 2003, Maravic et al., 2000, Ndosi et al., 2014, Primdahl et al., 2014, Ryan et al., 2006, Tijhuis et al., 2003, Watts et al., 2015). Patient reported outcome measures used to assess function included the AIMS; HAQ-Disability index (-DI); modified HAQ (mHAQ); Nottingham Health Profile (NHP); McMaster Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR); Short-form-12 (SF-12) physical health composite score (PSC) and RAID. Biological measures and reports used to assess function included grip strength and documented aids and adaptations.

The patient knowledge domain had one nursing sensitive outcome, knowledge, measured in 2 studies (Hill et al., 1994, Hill et al., 2003). This patient reported outcome was measured using the Patient Knowledge Questionnaire (PKQ). The patient satisfaction domain had two nursing sensitive outcomes, namely, satisfaction and confidence in care received, measured in 5 studies (Arthur and Clifford, 2004, Hill, 1997 and Hill et al., 1994, Hill et al., 2003, Ndosi et al., 2014, Primdahl et al., 2014).

Satisfaction was measured using patient reported outcome measures only, namely the Leeds Satisfaction Questionnaire (LSQ), a satisfaction –VAS, and confidence in care received –VAS.

The psychological status domain had three nursing sensitive outcomes, namely, mental health, self-efficacy and patient attitude/perception of ability to control arthritis, measured in 6 studies (Dougados et al., 2015, Hill, 1997 and Hill et al., 1994, Maravic et al., 2000, Ndosi et al., 2014, Primdahl et al., 2014, Ryan et al., 2006), using the following patient reported outcome measures : AIMS, NHP; SF-12 mental health composite score (MCS); arthritis self-efficacy scale Danish version (ASES-DK); rheumatoid arthritis self-efficacy scale (RASE); rheumatology attitude index (RAI); hospital anxiety and depression scale (HADS), and RAID.

Quality of life was the final domain in this area and the only nursing sensitive outcome measured in 5 studies (Dougados et al., 2015, Maravic et al., 2000, Ndosi et al., 2014, Primdahl et al., 2014, Tijhuis et al., 2003), all of which used patient reported outcomes to measure quality of life. These included the NHP; rheumatoid arthritis quality of life questionnaire (RAQoL); the RAND 36-item Health Survey (RAND-36); RAID, and SF-12.

### *3.6. OMERACT Filter 2.0 core area 3: Resource Use*

The domain identified under resource use was costs and had two nursing sensitive outcomes, namely, health utility and health care resource use, measured in 5 studies (Dougados et al., 2015, Ndosi et al., 2014, Ryan et al., 2006, Tijhuis et al., 2003, Watts et al., 2015). The patient reported outcome measure used was the EuroQoL (EQ5D) health economic questionnaire, while resource use was captured from records of health care data; number of hospitalisations; use of home help; drug use; consultation with other health professionals; changes in rheumatoid arthritis disease modifying anti-rheumatic drug (DMARD) therapy, and measures taken against co-morbidities.

### *3.7. OMERACT Filter 2.0 core area 4: Death*

Death had itself as a domain, and as a nursing sensitive outcomes was reported as a patient safety measure in 1 study (Primdahl et al., 2014)

### *3.8. Evidence of validation*

Out of the 59 nursing sensitive outcomes identified, 31 of these were assessed using patient reported outcome measures. Evidence of instrument applicability in the chosen scope is a requirement of the OMERACT Filter 2.0 in the process of core set development (Boers et al., 2014). By and large, the authors of the included studies cited validation papers of the patient reported outcome measures used within their studies, as evidence of the instruments' validity.

## 4. Discussion

While outcomes sensitive to the role of nurses in general have been studied before (Ingersoll et al., 2000, Lenz et al., 2004, Mundinger et al., 2000), our study is the first review to identify outcomes that are sensitive to nursing intervention in patients with rheumatoid arthritis. All outcomes identified were in keeping with the broad conceptual framework of OMERACT Filter 2.0 encompassing pathophysiological manifestation, life impact, resource use and economic impact, and death related to rheumatoid arthritis. Rheumatology nurses are an integral part of the multidisciplinary team contributing to the coordination and delivery of patient care. Assessing the value of nursing contribution has been a challenge over the years therefore identification and delineation of a set of nursing sensitive outcomes and appropriate measures for capturing these outcomes is a positive contribution to nursing and to patients with rheumatoid arthritis. Nursing sensitive outcomes may help patients to know what outcomes to expect from rheumatology nursing. For the profession, nursing sensitive outcomes will help demonstrate the evidence of rheumatology nursing effectiveness so that their contribution can be acknowledged and valued.

Our results contribute to advancement of nursing science in terms of outcome measurement in rheumatoid arthritis and may be extended to other inflammatory arthritides (ankylosing spondylitis and psoriatic arthritis). It is interesting to find that many core outcomes measured in routine clinical care are also sensitive to nursing interventions. The fact that nursing interventions reported in most included studies involved disease management as part of holistic care may account for this. Working in extended role capacity blurs the professional boundaries in order to meet patients' needs; therefore it is not surprising that most routine clinical outcomes (such as disease activity, pain, morning stiffness and fatigue) were also nursing sensitive outcomes. It is worth mentioning that nurses' roles differ across countries depending on legal frameworks, health policy and funding for health, and differences in educational systems. While extended roles are not practised everywhere and studies often lack an extensive description of nurses' roles and responsibilities, it is still important to delineate nursing sensitive outcomes as these may contribute towards the development of more detailed recommendations for the role of the nurse in the care of people with rheumatoid arthritis.

While routine clinical outcome measures were identified, the number of patient reported outcome measures was many and varied. Further research is warranted to test the properties of each patient reported outcome measure, within the context of nursing sensitive outcomes. Then, recommendations can be made as to which patient reported outcome measures should be used to best assess aspects of care when evaluating the impact of rheumatology nursing. Appropriate measures would include those focused on the ten nursing domains reported here i.e. (i) disease status, (ii) effectiveness, (iii) safety, (iv) function, (v) knowledge, (vi) satisfaction, (vii) psychological status (viii) quality of life, (ix) costs and (x) death. Although death was reported in one study (Primdahl et al., 2014), this was not presented as an outcome of the interventions. All clinical trials are required to report all serious events (including death) therefore making death an implicit outcome in all clinical studies. Our results provide a good foundation upon which to develop methodologically sound research designs to further examine the multidimensional, complex and complementary role that rheumatology nursing plays in the care of people with rheumatoid arthritis (Campbell et al., 2000, Craig et al., 2008).

The importance of outcome research and the challenges of identifying outcomes sensitive to advanced nursing practice have been discussed (Kleinpell and Gawlinski, 2005, Resnick, 2006). These reports reflect the evolution of rheumatology nursing practice into what can be described as multilevel nursing practice (Begley et al., 2010). With this evolution of nursing practice comes the seminal caveat which urges nurses to capture both the art and science of high level nursing care (Wiedenbach, 1963). The question as to the 'added value' the 'art of nursing' brings to bear on patient outcome remains a challenge which our research is only beginning to address with respect to patients with rheumatoid arthritis. This challenge of capturing both the easily identifiable quantitative outcomes and the unspecified, qualitative aspects of nursing care has been noted by Gerrish (2011). One proposed approach used to comprehensively evaluate the impact of advanced practice nursing is a model which encompasses (i) symptomatology, (ii) quality of life, (iii) social significance, and (iv) social validity (Begley et al., 2010, Gerrish, 2011, Schulz et al., 2002). Another approach is to use the 'complex interventions framework' to assess structure and process of care in addition to outcomes (Campbell et al., 2000, Campbell et al., 2007, Craig et al., 2008). This would require mixed methods research in order to capture the role of the rheumatology nurse in providing added value to the care of patients with the chronic, potentially debilitating rheumatic disease that is rheumatoid arthritis. Findings from this study provide a basis for such further research.

### 4.1. Strengths and limitation of the review

Strengths of this review include the use of the OMERACT Filter 2.0 as the overarching conceptual framework for health. This framework is respected across the rheumatology communities where it has been in use since 1992. It was the framework of choice for this review so as to maintain alignment with the wider rheumatology community. Both another strength and attraction is the involvement of multinational researchers and active involvement of patient partners in the OMERACT review process in keeping with what has become international best practice (de Wit et al., 2011, Kirwan et al., 2008, Speight and Barendse, 2010). The patient research partners participated as full researchers in the discussion about the necessity of this work; design of the review; study selection and in finalising the manuscript therefore their involvement ensured that the nursing sensitive outcomes identified were relevant to patients (de Wit et al., 2011). The main limitations of this review include its confinement to RCTs, cohort studies and one cross-sectional study in English language only. As the aim of the study was specifically to measure nursing sensitive outcomes and the tools used for their measurement qualitative studies were excluded. This exclusion of qualitative studies is likely to have missed an opportunity to determine aspects of nursing practice not ordinarily reported in RCTs, especially the 'structure' or 'processes' of care both of which contribute to patient outcomes (Campbell et al., 2000, Campbell et al., 2007, Craig et al., 2008). Not all studies gave enough detail about the role of the nurse in the development, delivery and testing of the varied interventions. Therefore, this review can only confirm that nurses had a role in the interventions. Furthermore, as this review did not intend to delineate the role of the members of the multidisciplinary team, we acknowledge that nursing sensitive outcomes are not exclusive to nursing, as the contribution of other healthcare professionals may also influence these outcomes.

## 5. Conclusions

This systematic literature review identified the extent and nature of recognised patient outcomes in rheumatoid arthritis that may be affected by rheumatology nursing interventions. Furthermore, the review provides robust evidence that the delineated validated instruments, used in RCTs and increasingly in routine clinical practice, are appropriate for use in all studies which aim to evaluate the impact of nursing interventions on patient outcome in rheumatoid arthritis. The alignment of these nursing sensitive outcomes to the OMERACT conceptual framework confirms how nursing impacts all domains of health in this potentially debilitating chronic disease.

Our study therefore is the foundation step in the development of an agreed upon core set of outcomes to be measured in all nursing intervention studies involving patients with rheumatoid arthritis. Further research is needed to strengthen our knowledge about the contributions of nursing sensitive outcomes to the OMERACT Filter 2.0. Moreover, further exploratory study is required to more comprehensively examine aspects of patient-centered care unique to rheumatology nursing in order to optimise the impact of nursing both in promoting health and caring for patients with rheumatoid arthritis and, by extension, all patients with chronic rheumatic diseases.

## Author contributions

PM, YvEH, VM, conceived the original idea, PM, GMcK, AK, MN, SC, VM, DOS, PR, YvEH, undertook the review, participated in drafting the manuscripts and approved the final version to be published. All authors have fulfilled the four ICMJE authorship criteria.

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## Conflict of interest

All authors have completed the Unified Competing Interests form at http://www.icmje.org/coi_disclosure.pdf (available from the corresponding author) and report a research grant from the Irish Rheumatology Nursing Forum and an educational grant from Roche Pharmaceuticals during the conduct of the study; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

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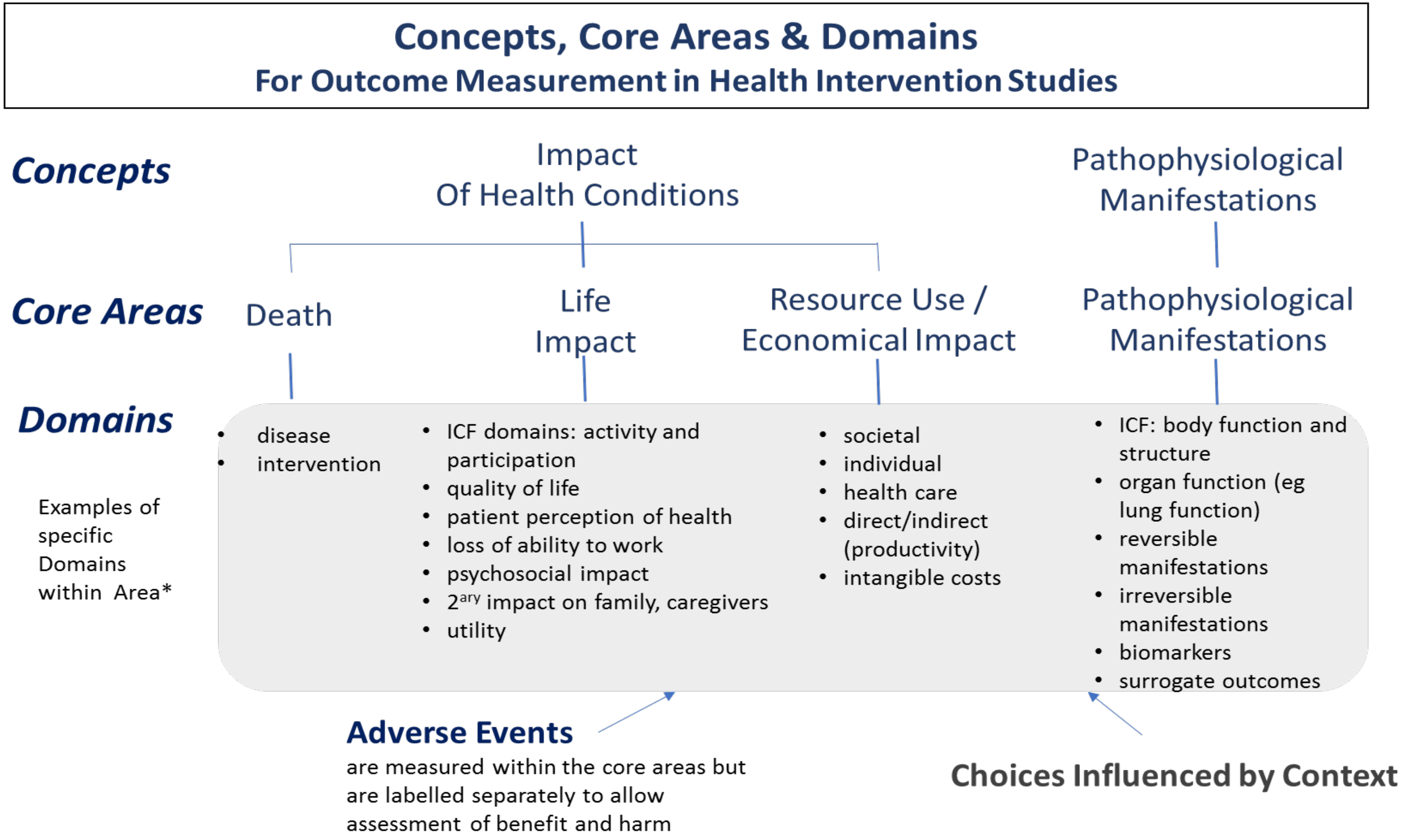
**Figure 1: Concepts, Core Areas, and Domains for outcome measurement in health intervention studies.**



**Adverse Events** are measured within the core areas but are labelled separately to allow assessment of benefit and harm

**Figure 2: Study flow diagram**

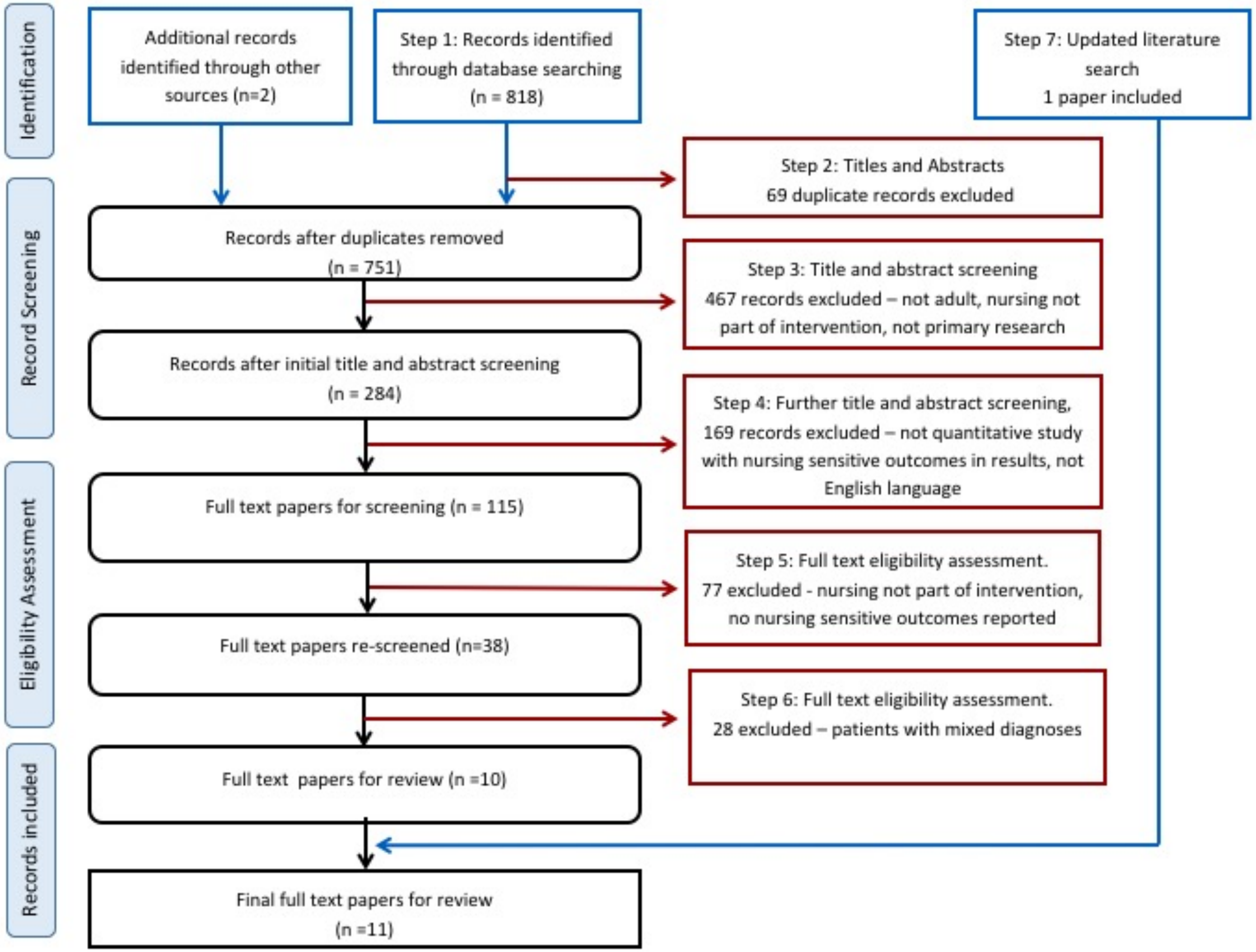


**Table 1: Identified and defined context specific nursing sensitive outcomes and domains mapped to OMERACT conceptual framework**

| Nursing sensitive outcomes | Domains identified in the context of rheumatoid arthritis | Definition of context specific domains | OMERACT Core Area | OMERACT domains and examples relevant for rheumatoid arthritis |
|---|---|---|---|---|
| Disease activity | Disease status | All direct measures to monitor disease and treatment such as swollen and tender joints, biomarkers such as ESR or CRP, patient and clinicians opinions about disease activity, but also indirect measures such as grip strength and ability to walk, as surrogate markers for disease activity. | **Pathophysiological manifestations** | Organ function: *joint inflammation*<br>Reversible manifestations: *out of range blood tests, medication related adverse events.*<br>Irreversible manifestations: *radiographic joint damage*.<br>Biomarkers and surrogate outcomes: *ESR, CRP, radiographic images of joints, urine analysis indicative of drug induced renal disease, grip strength and walk ability.* |
| Clinical effects<br>Pain<br>Stiffness<br>Fatigue | Effectiveness | Clinical effects on disease status but also on patients' symptoms such as pain, stiffness, fatigue. | | |
| Patient safety issues | Safety | Patient safety issues related to the disease, the treatment or the patient health condition in general. | | |
| Function (physical)<br>Patient knowledge | Functional | Effects on the patient's functional health status and mental health status, perceived health but also more indirect measures that can contribute to a better | **Life Impact** | Activity and participation<br>Quality of life |

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| Patient satisfaction<br>Psychological status<br>Quality of Life | | perception, such as knowledge. | | Patient perception of health<br>Psychosocial impact |
| Health utility<br>Healthcare resources | Costs | Direct and indirect healthcare costs and health utility for economic /cost-effectiveness evaluations. | **Resource Use** | Costs |
| Death* | Death | All reported causes of death: disease related; treatment related or other. | **Death** | Death |

*Reporting mortality is a regulatory requirement for all clinical studies.

**Table 2. Characteristics of included studies, nursing sensitive outcomes, measurement instruments and results**

| Publication<br>Country | Participants | Study Aim, Setting, Design, and Method | Nursing Sensitive Outcomes<br>(Measurement Instruments) | Results |
|---|---|---|---|---|
| Arthur and Clifford (2004)<br>UK | 80 patients, on disease-modifying antirheumatic drugs (DMARDS)<br>76% female | Cross sectional comparison of satisfaction with routine follow-up between two groups.<br>i) Rheumatology Nurse Specialist (RNS) in secondary care<br>ii) General practitioner in primary care<br>Patient questionnaire<br>Descriptive and bivariate statistics | • Patient satisfaction (Leeds Satisfaction Questionnaire)<br>• Knowledge of drug therapy (No instrument listed)<br>• Knowledge of monitoring requirements (No instrument listed)<br>• Knowledge of drug effects (No instrument listed) | **Significant improvements in the RNS secondary care group for:**<br>• satisfaction (overall, information, empathy, technical quality, attitude, access)<br>**No significant between group differences in:**<br>• knowledge of drug therapy, knowledge of monitoring requirements<br>**Significant improvements** (reported without statistics) **in the RNS secondary care group in:**<br>• knowledge of drug effects |

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| Dougados et al. (2015)<br>France | 970 patients<br>79% female | Randomised Controlled Trial (RCT), comparing patient outcome of two active intervention arms:<br>i) nurse led programme on comorbidity (NLC)<br>ii) patient self-assessment of disease activity (PSD)<br>Six months duration<br>Patient notes/booklet and questionnaires<br>Mixed logistical regression analysis | • Disease activity (DAS28)-ESR<br>• Functional status (MHAQ)<br>• Quality of life Rheumatoid Arthritis Impact of Disease (RAID)<br>• Number of measures taken against co-morbidities<br>• Number of medication changes for RA | **No-significant between group difference in:**<br>• DAS28-ESR<br>• MHAQ<br>• RAID<br>**Significant between group differences in favour of the**<br>**NLC group in:**<br>• number of measures taken against co-morbidities (cardiovascular disease, cancer, infections, osteoporosis)<br>**Significant between group differences in favour of the**<br>**PSD group in:**<br>• number of medication changes (increase in DMARD therapy changes) |

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| Hill et al. (1994), Hill (1997)<br>UK | 70 patients<br>74% female | RCT comparing the effectiveness, safety and acceptability of:<br>i) Rheumatology Nurse Practitioner (RNP)<br>ii) consultant rheumatologist care<br>Outpatient clinic for up to 48 weeks<br>Data from patients' notes and patient questionnaire<br>Bivariate analyses | • Arthritis Impact Measurement Scales (AIMS)<br>• Patient Knowledge Questionnaire (PKQ)<br>• Patient Satisfaction by Leeds Satisfaction Questionnaire (LSQ)<br>• Safety/effectiveness, Plasma Viscosity (PV), C-Reactive Protein (CRP), urinalysis<br>• Richie Articular Index (RAI)<br>• Early Morning Stiffness duration (EMS)<br>• Pain (5 point ordinal scale) | **Significant between group differences in favour of the**<br>**RNP group in:**<br>• PKQ<br>• Patient Satisfaction (overall, information, empathy, technical quality, attitude, access)<br>**No significant between group differences in:**<br>• PV, CRP, RAI, EMS, pain,<br>• AIMS (depression, anxiety) |
| Hill, (2003)<br>UK | 80 patients<br>79% female | RCT comparing outcomes of:<br>i) Rheumatology nurse practitioner RNP<br>ii) Junior hospital doctor (JHD)<br>Outpatient clinic for up to 48 | • Disease activity (DAS28)<br>• Fatigue (Duration in minutes),<br>• Morning stiffness (Duration in minutes)<br>• Pain (VAS), physical function, psychological status (AIMS)<br>• Knowledge (PKQ)<br>• Satisfaction (LSQ) | **Significant between group outcomes in favour of RNP group in:**<br>• Fatigue – improved (p = 0.038)<br>• Knowledge<br>• Pain-decreased (p = 0.044)<br>• Satisfaction (access and |

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| | | weeks.<br>Patient notes and patient questionnaires.<br>Bivariate analyses. | • Plasma viscosity,<br>• Articular index (28 swollen and tender joint count), | continuity)<br>**Significant between group outcomes in favour of the JHD in:**<br>• Physical function: Significant deterioration<br>**No significant between group differences or outcomes in:**<br>• Plasma viscosity<br>• Articular index<br>• Morning stiffness<br>• Psychological status<br>This RCT's findings indicate RNP care as compared to JHD care is effective and safe with increased patient satisfaction, better symptom control and self-care improvement |
| Maravic et al., (2000)<br>France | 20 patients<br>80% Female | Cohort study of medical outcomes and quality of life over 6 months<br>3 types of in-patient direct nurse | • Pain (VAS )<br>• Disease activity by patient (VAS)<br>• DAS28<br>• ESR, CRP<br>• Quality of life (NHP)<br>• Function (HAQ) | **Significant improvements in outcomes for:**<br>• Pain<br>• Disease activity by patient<br>• Disease activity (tender |

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| | | care were recorded:<br>i) basic care<br>ii) technical<br>iii) support/education<br>Patient notes and questionnaires<br>Bivariate analyses | • AIMS | and swollen joint count , ESR, CRP)<br>• NHP<br>• HAQ<br>AIMS (physical and symptoms only) |
| Ndosi, (2014)<br>UK | 181 patients<br>70% female | RCT comparing the effectiveness and cost-effectiveness of:<br>i) nurse-led care (NLC)<br>ii) rheumatologist-led care (RLC)<br>Outpatient follow up care to 52 weeks<br>Patient notes and questionnaire<br>Linear regression (controlling for | • Primary outcome: Improvement in disease activity (Change in DAS28)<br>• Secondary outcomes: Pain (VAS)<br>Fatigue (VAS)<br>Morning stiffness (duration in minutes)<br>Quality of life (RAQoL)<br>Function (HAQ-DI )<br>Anxiety and depression | **Non-inferiority of the NLC confirmed based on:**<br>• Average changes in DAS28 scores at 52 weeks (primary outcome)<br>• Pain<br>• Fatigue<br>• Stiffness<br>• Quality of life<br>• Function and<br>• Anxiety and |

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| | | age gender, centre, baseline, DAS28). | (HADS)<br>Arthritis self-efficacy (ASES)<br>Patient satisfaction (LSQ)<br>Cost<br>EQ5D)<br>Record of health care resource data. | depression<br>• Self- efficacy<br>**Significant between group differences in favour of the**<br>**NLC in satisfaction and costs at 52 weeks** |
| Primdahl (2014)<br>Denmark | 287 patients<br>70% female | RCT comparing patient outcomes of three groups:<br>i) planned rheumatologist consultation<br>ii) shared care without planned consultations<br>iii) planned nursing consultations<br>Follow up care for two years<br>Low disease activity patients | • Primary outcome :<br>Disease Activity Score with 28 joint measurement (DAS28-CRP, Visual Analog Scale (VAS) patient global score, joint examinations of ankles and feet)<br>• Secondary outcomes (SO):<br>Self-efficacy by the RA Self-Efficacy Questionnaire (RASEQ), Arthritis Self-Efficacy Scale-Danish version (ASES-DK) (pain, function)<br>Function by the Health Assessment Questionnaire (HAQ) | **Significant between groups differences in favour of nurse consultation group in:**<br>Primary outcomes:<br>• Lower disease activity (2 year), in favour of nursing consultations<br>Secondary outcomes:<br>Increased Self-efficacy |

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| | | Patient notes and questionnaires<br>Logistical regression controlling for interactions | Global Health from (VAS)<br>Pain by (VAS)<br>Fatigue by (VAS)<br>Quality of life (Short form 12 Physical Health Composite (PCS) & Mental Health Composite (MCS)<br>Satisfaction by (VAS)<br>Confidence in care received (VAS)<br>RA disease activity index (RADAI)<br>Self-reported side effects<br>Initiated biologic treatments<br>Death | (ASES-DK) (1 and 2 years)<br>Increased Confidence (2 year only),<br>• Increased Satisfaction (1 and 2years,<br>• All in favour of nursing consultations |
| Ryan, (2006)<br>UK | 71 patients<br>starting on DMARDS<br>56% female | RCT comparing the effect on wellbeing of:<br>i) nurse-led clinical nurse specialist (CNS) drug monitor clinic<br>ii) rheumatologist-led clinic for 52 weeks | • Health status (physical function, psychological distress, AIMS)<br>• Patients' perceptions of ability to control their arthritis (RAI)<br>• Disease activity (DAS)<br>• Consultation with other health care professionals (Self-developed non- | **No significant difference between groups at 52 weeks in:**<br>• AIMS<br>• RAI<br>• Number of consultations,<br>• NSAIDS, DMARDS, steroid usage |

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| | | Patient notes and questionnaire<br>Linear regression (controlling for demographics and baseline clinical values) | validated questionnaire (no statistics provided) | **Significant between group differences in favour of nurse group in:**<br>• Improved DAS at 52 weeks |
| Tijhuis, (2003)<br>The Netherlands | 210 patients<br>With increasing difficulty with Activities of Daily Living (ADL's) over last six weeks<br>79% female | RCT comparing the effectiveness of care across three groups:<br>i) clinical nurse specialist care (CNS) ii) in-patient team care (IPT)<br>iii) day-patient team care (DPT)<br>Two year follow up<br>Patient notes and questionnaires<br>Bivariate analyses (adjusted for age and differences at baseline) | • Functional status (HAQ, MacMaster Toronto Arthritis patient preference interview (MACTAR)<br>• Quality of life (RAND-36 (physical and mental))<br>• RA quality of life (RAQoL),<br>• Grip strength<br>• Walk test<br>• Disease activity(DAS)<br>• Health utility (Uptake of paramedic services: Physiotherapist, occupational therapist, social worker, CNS),<br>• home adaptations<br>• number of hospitalisations<br>• use of home help, drug use | **No significant between groups differences with improvement of outcomes in all groups over time in:**<br>• HAQ<br>• RAND 36 – Physical and Mental<br>• RAQoL<br>• Grip<br>• Walk<br>• DAS<br>**Significant between groups differences in favour of CNS group in:**<br>• MACTAR (yr1)<br>• Receiving home help (yr 2)<br>• Number of nurse visits (yrs 1 & 2)<br>**Significant between groups** |

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| | | | | **differences in favour of IPT group in:**<br>- Functional Status – yr 1 |

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| Watts et al. (2015)<br>UK | 349 patients<br>70% female | Cohort study of the cost-effectiveness and outcomes of:<br>i) community nurse-led care (NLC)<br>ii) rheumatologist led out-patient care (RLC) for rheumatoid arthritis, thereby reflecting real life<br>care<br>12 month duration<br>Questionnaires<br>Linear regression analyses. | • Functional status using Stanford health assessment questionnaire (HAQ)<br>• Economic evaluation (healthcare perspective) estimated cost relative to change in HAQ and quality-adjusted life years (QALY) derived from EuroQoL-5D (EQ-5D-3L). | **No significant between group differences in :**<br>• Functional status (HAQ, QALY)<br>NLC group: HAQ and QALY<br>• Cost: |

*Abbreviations in alphabetical order* : AIMS: Arthritis Impact Measurement Scale, ASES, Arthritis Self-Efficacy Scale, CNS: clinical nurse specialist CRP: C-reactive protein,DAS28: Disease Activity Score 28 joints, DMARDS: Disease Modifying Anti Rheumatic Drugs; EMS: early morning stiffness duration,, ESR: erythrocyte sedimentation rate, HADs: Hospital anxiety and depression scale, HAQ-DI: health assessment questionnaire disability index, LSQ, Leeds Satisfaction Questionnaire, MACTAR: McMaster Toronto Arthritis Patient Preference Disability Questionnaire, MCS: Mental health composite score, MHAQ Modified Health Assessment Questionnaire, NHP: Nottingham Health Profile, NSAIDS: Non-steroidal anti-inflammatory drugs, PKQ: Patient Knowledge Questionnaire, PCS: Physical health composite score, RADAI : rheumatoid arthritis disease activity index, RAI: Rheumatology Attitude Index, RAID Rheumatoid Arthritis Impact of Disease RAND: RAND 36-item Health Survey, RCT: randomised controlled trial; RAQoL: Rheumatoid Arthritis Quality of Life Scale, RASEQ: Rheumatoid arthritis self-efficacy questionnaire, TJC: Tender joint count, SJW: swollen joint count, RNS: rheumatology nurse specialist, RNP: rheumatology nurse practitioner, VAS: visual analogue scale.

Table 3 Critical appraisal skills programme (CASP) results of included studies

| **Appraisal questions** | **Trials** | Dougados et al., 2015 | Hill et al. 1994, Hill 1997 | Hill, 2003 | Ndosi, 2014 | Primdahl 2014 | Ryan, 2005 | Tijhuis, 2003 | **Appraisal questions** | **Cross Sectional* and Cohort and studies** | Arthur & Clifford* 2004 | Maravic et al., 2000 | Watts, 2015 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Did the trial address a clearly focused issue? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | Did the study / trial address a clearly focused issue? | 1 | 1 | 1 |
| 2 | Was the assignment of patients to treatment | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | Was the cohort recruited in an acceptable way? | 2 | 1 | 1 |

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| | randomised? | | | | | | | | | | | |
| 3 | Were all the patients who entered the trial accounted for in the conclusion? | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 3 | Was the exposure accurately measured to minimize bias? | 1 | NA | 1 |
| 4 | Were patients, health workers and study personnel blind to treatment | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 4 | Was the outcome accurately measured to minimize bias? | 1 | 1 | 1 |
| 5 | Were all the groups similar at the start of the | 2 | 3 | 1 | 2 | 1 | 1 | 1 | 5a | Have the authors identified all important | 3 | 3 | 1 |

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| | trial? | | | | | | | | | confounding factors? | | | |
| 6 | Aside from the experimental intervention were the groups treated equally? | 1 | 2 | 1 | 1 | 1 | 2 | 2 | 5b | Have they taken account of the confounding factors in the design and/or analysis? | 3 | 3 | 1 |
| 7 | How large was the treatment effect[#] | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 6a | Was the follow up of subjects complete enough? | 1 | 1 | 1 |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 8 | How precise was the estimate of the treatment effect?* | 1 | 3 | 3 | 1 | 1 | 1 | 1 | 6b | Was the follow up of subjects long enough? | NA | 1 | 1 |
| 9 | Can the results be applied in your context/ local population? | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 7 | What are the results of this study? | 1 | 1 | 1 |
| 10 | Were all the clinically important outcomes considered? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 | How precise are the results? | 2 | 2 | 1 |

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| 11 | Are the benefits worth the harms and costs? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | Do you believe the results? | 1 | 1 | 1 |
| | | | | | | | | | 10 | Can the results be applied to the local population? | 1 | 1 | 1 |
| | | | | | | | | | 11 | Do the results of this study fit with other available evidence? | 1 | 1 | 1 |
| | Total number of yes responses | 10 | 7 | 9 | 10 | 11 | 10 | 9 | | Total | 8 | 9 | 11 |

1 = Yes, 2 = Cant' tell, 3 = No, NA = not applicable; # 1= Clear result , 2 =Can't tell, 3= Unclear; * 1= Precise, 2 =Can't tell, 3= Imprecise

**Table 4 Identified nursing sensitive outcomes and measurement instruments categorised into domains and core areas according to the OMERACT Filter 2.0**

| OMERACT framework | Domains | Nursing sensitive outcomes | Measurement instruments (Reference papers) | |
|---|---|---|---|---|
| Core Areas n=4 | n=10 | n=17 | Patient reported outcomes measures (n=31) | Biologic measures and reports (n=28) |
| **Pathophysiological manifestations** | Disease status | Disease activity | DAS28* (Dougados et al., 2015, Hill et al., 1994, Hill et al., 2003, Ndosi et al., 2014, Primdahl et al., 2014, Ryan et al., 2006, Tijhuis et al., 2003). | CRP and ESR (Hill et al., 1994, Hill et al., 2003, Maravic et al., 2000). |
| | | | RAI* (Hill, 1997, Hill et al., 1994). | Plasma viscosity (Hill et al., 1994, Hill et al., 2003). |
| | | | RADAI* (Primdahl et al., 2014) | Walk-time (Maravic et al., 2000, Tijhuis et al., 2003). |
| | | | Global health score –VAS (Primdahl et al., 2014) | Grip strength ( Tijhuis et al., 2003) |
| | | | Disease activity evaluated by physician and patient (VAS 100-mm)(Maravic et al., 2000) | |

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|---|---|---|---|---|
| | Effectiveness | Clinical effects | Articular indices* (RAI and 28 TJC, SJC) (Hill et al., 2003, Maravic et al., 2000, Primdahl et al., 2014). | Plasma viscosity (Hill et al., 1994, Hill et al., 2003) |
| | | | DAS28* (Dougados et al., 2015, Hill et al., 2003, Ryan et al., 2006). | CRP and ESR (Hill et al., 1994, Hill et al., 2003, Maravic et al., 2000) |
| | | | | Urinalysis (Hill et al., 1994) |
| | | | | X-ray hands and feet (Primdahl et al., 2014, Tijhuis et al., 2003) |
| | | | | Self-reported side effects (Primdahl et al., 2014) |
| | | Pain | Pain 5 point ordinal scale (Hill, 1997, Hill et al., 1994). | |
| | | | Pain VAS (Hill et al., 2003, Maravic et al., 2000, Ndosi et al., 2014). | |
| | | | AIMS* (Hill et al., 1994, Hill et al., 2003, Maravic et al., 2000, Ryan et al., 2006). | |
| | | | RAID* (Dougados et al., 2015) | |

| | | | | |
|---|---|---|---|---|
| | | Stiffness | EMS duration in minutes (Hill et al., 1994, Hill et al., 2003, Ndosi et al., 2014) | |
| | | Fatigue | Fatigue VAS (Ndosi et al., 2014) | |
| | | | RAID* (Dougados et al., 2015) | |
| | Safety | Patient safety issues | | Adherence (Primdahl et al., 2014)<br>Out of range blood tests (Primdahl et al., 2014)<br>Missing relevant reaction on out of range tests (Primdahl et al., 2014)<br>RADAI alerts (Primdahl et al., 2014)<br>HAQ-alerts (Primdahl et al., 2014)<br>Side-effect alerts (Primdahl et al., 2014)<br>Total number of alerts (Primdahl et al., 2014),<br>Initiated biologic treatment (Primdahl et al., 2014), |

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|---|---|---|---|---|
| | | | | Telephone consult (Primdahl et al., 2014, Tijhuis et al., 2003)<br>Health utility (Tijhuis et al., 2003) |
| **Life Impact** | Functional | Function (physical) | AIMS* (Hill et al., 1994, Hill et al., 2003, Maravic et al., 2000, Ryan et al., 2006). | Grip strength (Tijhuis et al., 2003) |
| | | | HAQ-DI* (Maravic et al., 2000, Ndosi et al., 2014, Primdahl et al., 2014, Tijhuis et al., 2003, Watts et al., 2015). | Aids and adaptations (Tijhuis et al., 2003) |
| | | | mHAQ*(Primdahl et al., 2014) | |
| | | | NHP* (Maravic et al., 2000, Primdahl et al., 2014) | |
| | | | MACTAR* (Tijhuis et al., 2003) | |
| | | | SF-12 (PCS)* (Primdahl et al., 2014, Tijhuis et al., 2003) | |
| | | | RAID* (Dougados et al., 2015) | |
| | Patient knowledge | Knowledge | PKQ *(Hill et al., 1994, Hill et al., 2003) | |
| | Patient satisfaction | Satisfaction | LSQ* (Arthur and Clifford, 2004, Hill, 1997, Hill et al., 1994, Hill et al., 2003, Ndosi et al., 2014). | |
| | | | Satisfaction –VAS (Primdahl et al., 2014) | |
| | | Confidence in care received | Confidence in care received-VAS (Primdahl et al., 2014) | |

| | | | | |
|---|---|---|---|---|
| | Psychological status | Mental health status | AIMS* (Hill et al., 1994, Hill et al., 2003, Maravic et al., 2000, Ryan et al., 2006)<br>HADS*(Ndosi et al., 2014) | |
| | | Self-efficacy | NHP* (Maravic et al., 2000, Primdahl et al., 2014) | |
| | | Patient attitude/ perception of ability to control arthritis | SF-12* (MCS) (Primdahl et al., 2014)<br>ASES- DK* (Ndosi et al., 2014, Primdahl et al., 2014)<br>RASEQ* (Primdahl et al., 2014)<br>RAI* (Ryan et al., 2006) | |
| | | | RAID* (Dougados et al., 2015) | |
| | Quality of life | Quality of Life | NHP* (Maravic et al., 2000, Primdahl et al., 2014)<br>RAQoL* (Ndosi et al., 2014, Tijhuis et al., 2003)<br>RAND-36* (Tijhuis et al., 2003)<br>RAID* (Dougados et al., 2015)<br>SF-12* (Primdahl et al., 2014) | |
| **Resource Use/ Economic Impact** | Costs | Health utility | EQ5D* (Ndosi et al., 2014, Watts et al., 2015) | Record of health care resource data (Ndosi et al., 2014) |

| | | | | |
|---|---|---|---|---|
| | | Healthcare resources | Health Utility Rating Scale* (Ndosi et al., 2014) | Number of hospitalisations (Tijhuis et al., 2003)<br>Use of home help (Tijhuis et al., 2003)Drug use (Tijhuis et al., 2003)<br>Consultations with other health care professionals (Ryan et al., 2006, Tijhuis et al., 2003)<br>Changes in RA DMARD therapy (Dougados et al., 2015)<br>Measures taken against comorbidities (Dougados et al., 2015) |
| **Death** | Death | Death** | | Death (Primdahl et al., 2014) |

** Reporting mortality is a regulatory requirement for all clinical studies.

**Table 4 legend**

*Index paper reference provided by author

*Abbreviations in alphabetical order* : AIMS: Arthritis Impact Measurement Scale, ASES, Arthritis Self-Efficacy Scale, CNS: clinical nurse specialist CRP: C-reactive protein,DAS28: Disease Activity Score 28 joints, EMS: early morning stiffness duration, EQ5D: EuroQoL, ESR: erythrocyte sedimentation rate, HADs: Hospital anxiety and depression scale, HAQ-DI: health assessment questionnaire disability index, LSQ, Leeds Satisfaction Questionnaire, MACTAR: McMaster Toronto Arthritis Patient Preference Disability Questionnaire, MCS: Mental health composite score, MHAQ Modified Health Assessment Questionnaire, NHP: Nottingham Health Profile, PCS: Physical health composite score, PKQ: Patient Knowledge Questionnaire, RADAI :Rheumatoid arthritis disease activity index, RAI: Rheumatology Attitude Index, RAID Rheumatoid Arthritis Impact of Disease RAND: RAND 36-item Health Survey, RAQoL: Rheumatoid Arthritis Quality of Life Scale, RASEQ: Rheumatoid arthritis self-efficacy questionnaire, SF-12; short-form 12; SJW: swollen joint count, TJC: Tender joint count, VAS: visual analogue scale.