

## Original article

# Integrative medicine for back and neck pain: Exploring cost-effectiveness alongside a randomized clinical pilot trial

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## Abstract

**Introduction:** Integrative medicine (IM), the integration of complementary therapies (CTs) and conventional care, is common despite a scarce evidence base of cost-effectiveness. This study explored the cost-effectiveness of IM from a healthcare perspective comparing conventional primary care to a comprehensive IM model in the management of patients with chronic non-specific back/neck pain.

**Methods:** Data on clinical management (planning and delivering IM), resource use (conventional care, CTs, prescription and non-prescription analgesics) and outcome effectiveness (SF-6D) were derived alongside a pragmatic randomized clinical pilot trial ( $n=80$ ) with 16 weeks follow-up. Costs and effects, i.e. quality-adjusted life years (QALYs), were estimated over different time periods and willingness-to-pay thresholds. Net monetary benefit and bootstrapping methods were used to address uncertainty in the cost-effectiveness analyses.

**Results:** The IM model, on average integrating 7 CT sessions with conventional primary care over 10 weeks, resulted in increased QALYs, somewhat higher cost of health care provision but a reduced cost of using health care resources, including less use of analgesics compared to conventional primary care. The costs/QALY ranged between €24,000 and 41,000.

**Conclusion:** Given the threshold value of €50,000 per QALY gained, and a remaining effect of one year, it is indicated that IM might be cost-effective compared with conventional primary care. Future cost-effectiveness studies of IM should be carried out from a societal perspective and should be based on large scale pragmatic randomized clinical trials.

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**Keywords:** Integrative medicine; Cost-effectiveness; Back pain; Neck pain; Primary care

## Introduction

Back and neck pain may impose high costs, disability and decreased quality of life for individuals, placing an economic burden on Swedish society [1–3]. In Sweden, conventional management of back and neck pain is typically organized within the primary care system, where common strategies include advice and prescription of analgesics, which may be complemented by short term sick-leave or physiotherapy [4,5]. Despite such strategies, however, studies have shown back and neck pain to be two of the main reasons for patients to seek help outside of conventional care, i.e. to use complementary therapies (CTs) [6–8]. Provision of CTs in Swedish conventional care

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settings is also common [8,9]. Previous health economic investigations comparing conventional care and CTs have commonly focused on different CTs in isolation. A recent review reported that 90% of economic evaluations in the fields of CT and integrative medicine (IM) between 2001 and 2010 targeted single CT interventions and that there was only one evaluation, a retrospective audit of patients with chronic health problems, that involved access to multiple CTs [10,11]. Thus research targeting comprehensive IM services in conventional care settings, and testing them against conventional usual care models, is indeed scarce, especially when it comes to prospective randomized clinical trials of managing chronic conditions. This implies that decision-makers currently have to rely on a generally scant and contested evidence base of cost-effectiveness for comprehensive IM models of care [10,12–14].

We previously developed a comprehensive model for IM where CTs with an emerging evidence base were integrated with conventional primary care management of patients with non-specific back/neck pain [15]. The IM model was implemented and tested versus conventional primary care management in a pragmatic randomized clinical pilot trial [5]. The results showed that the IM model was feasible to implement and emerging trends in clinical data indicated that integrative care contributed to less use of healthcare resources, including prescription and non-prescription analgesics [5]. The general aim of this study was to use a healthcare perspective in exploring the cost-effectiveness of an IM model compared with conventional primary care in the management of patients with chronic non-specific back/neck pain. Specific objectives included estimating the cost of providing integrative care and assessing the cost-effectiveness of the IM model over a range of time periods and thresholds of willingness-to-pay for an additional quality-adjusted life year (QALY).

## Methods

### *Design and setting*

The economic evaluation was conducted as a cost-utility analysis alongside a pragmatic randomized clinical pilot trial with 16 weeks follow-up in Swedish primary care [5,15]. The investigation followed the intention-to-treat strategy with all patients kept in their assigned groups.

### *Participants*

In the trial, 80 patients, 18–65 years old, diagnosed with non-specific back/neck pain of mostly chronic duration (>3 months), were prescribed conventional care treatment plans by their general practitioners before being randomized (by an assistant not involved in patient care), to receive either continued conventional primary care ( $n = 36$ ) or the IM model of care ( $n = 44$ ) [5]. A computer generated procedure was used to randomize participants, without stratification or blocking, giving each patient the same chance of being allocated to either the IM group or the usual care group [5]. Extensive details about the randomized clinical trial including a CONSORT flow-chart has been published

elsewhere [5]. Eighty-two percent (36/44) of the integrative and 75% (27/36) of the conventional care group completed follow-up after 16 weeks in the clinical trial [5]. No variable had more than 7% (3/44) and 3% (1/36) of missing data at baseline, in the IM and the conventional primary care groups respectively.

### *Interventions in the clinical trial*

The conventional primary care treatment plans largely followed established county council guidelines [4], which meant the general practitioners mainly gave advice (85%), prescribed analgesics (50%) and sometimes offered limited sick leave (33%) or a referral for physiotherapy (25%) [5]. The study was designed to pragmatically reflect usual primary care practice. Hence, the conventional care provided, directed by the participating general practitioners, had no explicit study constraints [5]. The integrative management involved an IM team consensus-based integration of selected CTs into the conventional primary care treatment plan, as determined by IM case conferences [5,15]. The multidisciplinary IM team consisted of eight senior licensed/certified CT providers, representing Swedish massage therapy, manipulative therapy/naropathy, shiatsu, acupuncture and qigong, and was directed by a general practitioner with clinical CT experience [5]. Patients typically received seven CT treatment sessions of two different types of CTs over a period of ten weeks [5]. The integration of CTs and conventional care was tailored to meet each individual patient's needs. Detailed information about the IM model, the case conferences, the CT treatments and the randomized clinical pilot trial has been reported elsewhere [5,15].

### *Costs*

The cost estimates were derived from the clinical pilot trial and included the cost of integrative care provision, i.e. the planning and delivery of CTs in the Swedish primary care setting, and the cost of using selected health care resources, i.e. conventional care, CTs (outside of the IM model), prescription and non-prescription analgesics. All patients in both groups had a general practitioner consultation and received a conventional treatment plan before enrolment and randomisation in the clinical pilot trial. Only the costs that were expected to differ between the two treatment groups were included. Consequently, the additional cost of integrative care provision in combination with the subsequent cost difference of using selected health care resources was considered relevant in the economic analysis.

Costs were considered from a healthcare perspective. Data on indirect costs, relating to for example lost workdays, travelling expenses or the need for extra help by relatives were not available in the clinical trial. All cost estimates included overhead costs for county council administration, office space, rent, insurance, supplies and general payroll tax where applicable but did not include value added tax (VAT), normally exempted in Swedish health care. All costs were expressed in euro (EUR) in 2012 year's prices using the Swedish consumer price index [16] for recalculations if relevant. Costs were converted from Swedish kronor (SEK) to EUR using the average exchange rate during 2011 of 1 EUR = 9 SEK.

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