



# Manual Therapy by General Medical Practitioners for Nonspecific Low Back Pain in Primary Care: The ManRück Study Protocol of a Clinical Trial

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## Abstract

**Background:** Nonspecific low back pain (LBP) is a common reason for accessing primary care. Manual therapy (MT) may be an effective treatment, but data from clinical studies including relevant subgroups and clinical settings are sparse. The objective of this article is to describe the protocol of a study that will measure whether an MT protocol provided by general medical practitioners will lead to a faster pain reduction in patients with nonspecific LBP than does standard medical care.

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**Methods/Design:** The study is an experimental pre-/postintervention design. The intervention consists of add-on MT treatment by general medical practitioners who have received MT training but are otherwise inexperienced in mobilization techniques. Participating general medical practitioners (n = 10) will consecutively recruit and treat patients before and after their training, serving as their own internal controls. The primary end point is a combined outcome assessing change in pain score over days 0 to 3 and time until pain is reduced by 2 points on an 11-point numeric pain scale and painkiller use is stopped. Secondary outcomes are patients' functional capacities assessed using a questionnaire, amount of sick leave taken, patient satisfaction, and referrals for further treatment.

**Trial registration:** German clinical trials register: DRKS-ID DRKS00003240.

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## Introduction

Acute low back pain (LBP) is a major health problem accounting for frequent general medical practitioner (GP) consultations. Although spontaneous healing is the norm for nonspecific LBP,<sup>1</sup> the disease is costly because of the high number of visits to GPs and specialists and the sick leave incurred. Quality of life during the painful episode is poor, and there is a high risk that a chronic illness will develop.<sup>2,3</sup>

The National Treatment Guidelines recommend maintaining physical activity and taking painkillers (ie, nonsteroidal antiinflammatories as evidence-based therapeutic options).<sup>4</sup> Manual therapy (MT) is another therapeutic option, although its effectiveness for acute LBP remains controversial. Although a systematic review from 2012 concluded that the addition of MT offers no benefit,<sup>5</sup> more recent randomized controlled trials (RCTs) demonstrated positive effects of MT on pain and physical function.<sup>6,7</sup> International guidelines differ in their recommendations regarding MT; whereas some are in favor, others strongly advise against its use.<sup>8</sup>

In Germany, MT is taught using several different approaches and techniques and is considered to be highly beneficial by more than 80% of GPs.<sup>9</sup> More than 20 000 medical physicians, many of whom are GPs, have received training in MT from 1 of the 5 different schools.<sup>10</sup> In Germany, MT is frequently administered in the general practice setting, an approach that has also proven feasible in other countries.<sup>11,12</sup> In contrast to studies on MT where the treatment is mainly performed by chiropractors, manual therapists, and osteopaths,<sup>5</sup> the ManRück study (Manuelle Therapie bei unspezifischen akuten Rückenschmerzen) addresses the effects of MT provided by medical GPs. Studies focusing on provision of MT by a GP during a clinical appointment are scarce. In addition, the number of GPs already certified to

administer MT is very low compared to the prevalence of LBP. As a positive effect of MT on acute LBP seems likely, we set out to determine whether training in MT for acute LBP can improve outcomes in primary care patients treated by GPs who are otherwise inexperienced in MT. Therefore, the objective of this article is to describe the protocol of a study that will measure whether MT provided by general practitioners leads to a faster pain reduction in patients with nonspecific LBP than does standard care.

## Methods

### Study Overview

The study is designed as a prospective, multicenter, pre-/postintervention study to evaluate the benefits of GPs' training in MT for patients with acute LBP. Participating GPs who are not trained in MT will consecutively recruit all patients with LBP who fulfill the inclusion criteria. In the preintervention (control) section of the study, the GPs will provide standard treatment for their patients according to the national guidelines. After receiving an expert-approved training in MT for acute LBP, these GPs will continue the consecutive recruitment of eligible patients. In this second postintervention section, all patients will receive MT in addition to the standard treatment. We assume that the use of MT will lead to a more rapid reduction in pain intensity as measured using a numeric pain scale.

An overview of the study design is shown in Fig 1.

As only low-force techniques will be used, the risk of harm for participating patients is considered negligible. Ethics approval has been granted by the Hannover medical school Ethics Committee (no. 6006).

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