Proposition de projet "bonnes pratiques cliniques" sur les lombalgies (2020).

AXXON, Kinésithérapie en Belgique asbl, octobre 2020

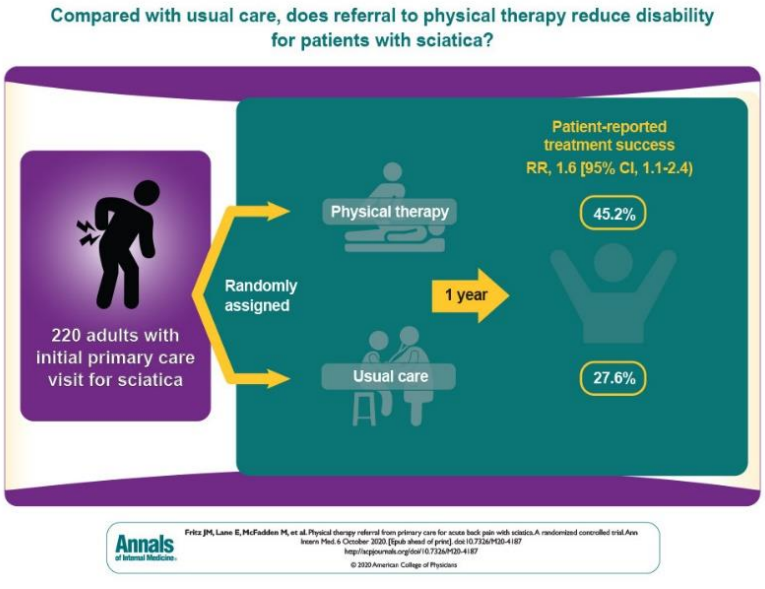
1. TITLE

Direct access to **Physio**therapy for acute low back pain: a pragmatic pilot trial (the Direct-Physio trial)

2. BACKGROUND AND RATIONALE

Low back pain (LBP) is the number-one cause of disability worldwide, affecting an estimated 672 million people at any one time. Disease burden due to LBP has increased by 54% since 1990, threatening the sustainability of healthcare and social systems (Disease GDB, 2017; Hartvigsen et al. 2018). Moreover, the estimated yearly total cost for LBP is 1-25 billion dollars in industrial countries (Dagenais et al. 2008). Belgium has even worse or more concerning figures for LBP compared to the global average in terms of cost (1.2 billion euros), disability-adjusted life years (1923 years per 100.000 persons), point prevalence (18.23%, 2 million Belgians) and incidence rate (6715 new cases per 100.000/year) (Disease GDB, 2017). The increase of disease burden and the high health-related costs beg for an optimization of care pathways that may lead to better and faster treatment effects for LBP.

Several studies have evaluated alternate clinical pathways for LBP and other musculoskeletal complaints such as **physiotherapist (PT)-led direct referrals** or screening and management of patients on orthopaedic waiting lists. The results have been favourable with respect to reduced waiting times and patient and referrer satisfaction with the care provided, and show no adverse effects (Oakley C et al. 2015). Moreover, when referral for PT is warranted for patients with acute LBP (with sciatica), immediate referral and initiation (within 3 days) may lead to lower health care utilization and LBP-related costs (Foster & Reddington, 2020; Liu et al. 2018). It has already been shown that early PT resulted in statistically significant improvement in disability in (sub)acute LBP (**See infographic**), however this improvement did not achieve the minimum clinically important difference compared with usual care, nor differences were found in terms of healthcare use and sick leave days (Fritz et al. 2020). There is until now still insufficient evidence from high quality studies that early PT is cost-effective compared with usual care (Babatunde et al. 2020; Buchbinder R et al. 2020; Desmeules et al. 2012). Moreover, direct PT access has not been evaluated in Belgium yet.



When investigating early PT referral, it is important to consider **health care practitioners' (HCP) knowledge, attitudes and beliefs** as it relates to guideline-adherence in the management of LBP. Indeed, the attitudes and beliefs of HCPs (general practitioners, physiotherapists, rheumatologists) are related to the work and activity recommendations given to the patients (Bishop et al. 2008). Previous studies have shown that especially HCPs with a biomedical/biomechanical treatment orientation (Houben et al. 2005b), biomedical training courses (Ostelo et al. 2003), higher fear avoidance beliefs (Linton et al. 2002; Coudeyre et al. 2006; Poiraudeau et al. 2006) and a strong belief that the relationship between pain and function partially explains the variation in disability in patients with low back pain (LBP) (Rainville et al. 2000; Houben et al. 2005b), do not adhere to clinical guidelines, and advice their patients to restrict work or activities (Bishop et al. 2008).

Taken together, the rationale and relevance of direct access for PT is well established but not implemented or tested in Belgium. The Federal Council of PT has submitted a request to Maggie Deblock about direct access in 2015 (See Adviestekst DTV). Moreover, also in the Netherlands (Scheele et al. 2014) as well as in the United Kingdom (Bishop et al. 2015) direct access for PT is well-established in private PT practices. However, it remains unknown what the added value of direct access for PT in Belgium is, and more specifically in case of acute LBP. This despite the fact that the level of the physiotherapy education in Belgium is one of the highest worldwide (master program).

3. RESEARCH QUESTIONS & OBJECTIVES

- **Research question: What is the added value (in terms of pain, disability and cost-effectiveness) of direct access for PT compared to usual care for patients with acute LBP lasting >24 hours and <6 weeks?**
- **Project objective: To compare the (cost-)effectiveness of direct access for PT compared to usual care for patients with LBP, lasting >24 hours and <6 weeks, on pain, disability.**

4. METHODOLOGY

Ethical approval of the protocol will be requested at the Medical Ethical Committees of the involved universities. When approved, the protocol will be registered in an international public study registration domain (www.clinicaltrials.gov). The study will be in accordance to the Good Clinical Practice guidelines.

4.1. Study Design

The study involves a two-arm single-blinded randomized controlled clinical trial.

Outcomes will be assessed by means of an app (e.g. Mobile Health Unit) at the following time points:

- At baseline (inclusion)
- at the end of intervention
- at 3 months following enrolment
- at 1 year following enrolment
- at 2 years following enrolment

The flowchart of the study can be found in **Appendix 1**. To avoid drop-out, regular reminders will be sent.

4.2. Participants

In total, 600 individuals with LBP lasting > 24 hours and < 6 weeks will be recruited (n= 300 in Wallonia and n= 300 in Flanders)

Inclusion criteria:

- Patients with non-specific acute LBP defined as (based on Nicol et al. 2020):
    - pain between the 12th rib and buttocks
    - associated or not with non-dominant leg pain
    - looking for LBP care for the first time in case of first episode, OR for the first time for the current episode in case of recurrent or persistent LBP
    - lasting > 24 hours and < 6 weeks
    - with an average pain intensity during the past 24 hours of ≥ 3 on an 11-point Numerical Pain Rating Scale
    - with an Oswestry Disability Index score (version 2.1a) of at least 20% (Denteneer et al. 2018).
- Patients aged between 18 and 65 years
- Patients accepting to install an app on their smartphone

Exclusion criteria:

- Recent lumbar surgery (< 1 year)
- Pregnancy
- History of (any) treatment for the current pain episode
- Red flags suggesting specific LBP (e.g. resulting from infection or neoplasm, cauda equina), based on the Belgian Health Care Knowledge Center (KCE, BEL) who published evidence-based guidelines to manage LBP and radicular pain (Van Wambeke et al. 2017) **(See Appendix 2)**
- Generalized musculoskeletal pain (based on fibromyalgia criteria) (Galvez-Sánchez CM et al. 2020).

4.3. Recruitment of patients

The general population will be informed regarding this trial through:

- Local newspaper advertisements
- E-mail lists (e.g. panel of Limburg) and social media
- A website (similar to the one developed in the “claudicare” project) so that patients are informed about the PTs taking part in the study
- Staff members of Belgian universities and hospitals
- Members of relevant associations such as the Belgian Back Society, Axxon, Mathera, WVVK, etc.
- Alumni and clinical internship partners of the Belgian universities
- GPs and PTs who will inform potential participants about the study (when patients taking contact for an appointment)

The general population will be informed that individuals with LBP, lasting at least 24 hours and not longer than 6 weeks, planning to visit consult are invited to participate in this trial. They will be invited to consult a website to check where the clinicians involved in this trial are located (so that they do not have to drive too far from their home). If they are interested in the study they will be invited to contact

a specific phone number (central point of contact = 2 research assistants (FR & NL)) to get additional information regarding the study and provide email (or postal address) to receive the informed consent to be signed and the app so that they can fill in the battery of questionnaires at the first consultation (baseline outcomes). This study visit can be organized by video conference.

4.4. Outcomes

The assessments will be conducted by means of an app (developed by Mobile Health Unit) that will be specifically developed for the present study. This app will allow to use "reminders" so that participants fill in weekly a questionnaire regarding their use of healthcare and fill in the battery of questionnaires at the requested time points. All assessments include all primary and secondary outcomes; the baseline also includes questions about demographic information + the Start Back Screening Tool.

Demographic information (baseline)

- Age, weight, height, BMI, gender, level of education, work status

Start Back Screening Tool (baseline)

Primary outcomes

1. Pain

- *Pain intensity* 'at this moment' and 'during the past week', both for back pain and leg pain will be assessed with a 11-point Numerical Rating Scale (NRS, 0-10), with 0 = "no pain" and 10 = "the worst pain imaginable" (Jensen MP et al. 1986). The NRS is the preferred pain rating scale due to its excellent reliability and validity (Breivik EK et al. 2007).
- *Pain Location & extent* will be assessed by a Pain Drawing (PD). Two paper body charts with a full body (frontal and dorsal view) will be completed. The body charts include anatomical details such as skin folds and bone protuberances in order to facilitate the pain location identification for the patients. The assessment of pain location and extent will be performed with a custom developed software. Pain extent is defined as the number of coloured pixels inside the body chart perimeter. In the case that patients draw outside the body chart perimeter, the pixels outside the body area are removed automatically. To describe the pain location, the full body chars is analysed according to a rating system (i.e. a grid with 45 anatomical regions) proposed by Margolis et al. A binary value (1= painful; 0 = not painful) is assigned to each of the areas in the following way: if the area has at least 10% of pixels coloured in, the region was considered "painful". If an area has no pixels or less than 10% of its area coloured in, it is considered "not painful". In this way, pain location for each body chart is described as an array of binary values. For descriptive purposes, pain frequency maps and pain location histograms are computed to illustrate the most common painful areas across the cohort. Procedure: The PD is presented to the volunteers as a clinical tool to describe precisely where they feel their pain. The investigator highlights the importance of fully illustrating all pain sites. Some technical notes on how to use the pen are also included in the verbal explanation. After a demonstration and brief training to familiarize the patients with the PD, they were asked to complete their two PD (full body front and back). Patients are instructed to 'Please draw where you felt your usual pain during the last seven days on this body chart and try to be as precise as possible' and are instructed to colour every part of the body where they perceived pain, independently from the type and the severity of pain.

2. Disability due to LBP will be assessed with the validated Dutch version of the Modified Low Back Pain Disability Questionnaire (ODI). The ODI is a 10-item self-report questionnaire that quantifies the extent of functional limitation in daily life due to LBP. Each item should be given a score between 0 and 5. The total score is multiplied by 2 to obtain a percentage score, with higher scores corresponding to more severe disability (In Dutch: Denteneer L, et al. 2018; van Hoof et al. 2015; in French: Volger et al. 2008)

Secondary outcomes

1. A cost-effectiveness analysis (CEA) from individual and societal perspective is a powerful tool to assess whether the direct access is worthwhile implementing from a health-economic point of view. The CEA will compare direct access (PT) to usual care (GP) based on (1) the incremental health improvement and (2) the incremental costs. The result of the CEA will be expressed as an Incremental Cost-Effectiveness Ratio (ICER) in €/QALY gained. As recommended by the Belgian Healthcare Knowledge Centre (KCE), the base-case analysis will be performed from a societal perspective, incorporating all relevant costs for the health care system irrespective of the payer. Additionally, results will also be reported separately from the patient's perspective.
    - (1) Health effects: Quality-Adjusted Life Years (QALYs), a composite measure of length of life and quality of life (QoL), will be determined for each participant in the intervention (PT) and control group (GP). QoL will be measured using the 5-dimensional EuroQol (EQ-5D) tool (see secondary outcome 5) and converted to health utilities for the required analyses.
    - (2) Costs: The costs will be obtained from patient-reported healthcare use, which patients are asked to register at fixed time intervals in the mobile app specifically designed for this study. This method is frequently used in health economic research, especially when health care is not limited to the hospital setting (Bishop et al. 2017, Goossens et al. 2000). In accordance to KCE guidelines, the base-case analysis will only take into account direct health care costs (e.g. number of PT sessions, imaging, labs, medication, surgery, number of MD visits, etc.). Health care resource use (services and medication) will be valued using the official unit prices of the Belgian reimbursement scheme (Nomenclatuur and RIZIV/INAMI data). In a second, separate analysis all costs will be taken into account, including absenteeism, presenteeism and productivity loss related to unpaid work (Bishop et al. 2017). The iMTA Productivity Cost Questionnaire (iPCQ), which will be incorporated in the mobile application, will deliver the necessary input to calculate the costs associated to productivity loss using the Human Capital Approach (HCA) for short-term absence and the Friction Cost Method (FCM) for long-term absence (Bouwmans et al. 2015, Cleemput et al. 2012).
2. The Fear-Avoidance Beliefs Questionnaire (FABQ) to assess the patient's *fear avoidance beliefs.* This questionnaire consists of 16 statements for which the participant rates her agreement with the statement on a scale from 0 (completely disagree) to 6 (completely agree). Higher scores on the FABQ indicate more strongly held fear avoidance beliefs. The FABQ shows good test-retest reliability in patients with low back pain (*Waddell G et al. 1993, In Dutch: Ventrig A et al. 1998; In French: Chaory et al. 2004)*
3. The Back Beliefs Questionnaire (BBQ) (Short version) will be assessed both in the patients as well as in the participating PTs and GPs. The BBQ is designed to explore beliefs and thoughts

related to LBP. Unlike the Fear Avoidance Beliefs Questionnaire (FABQ) score, which explores beliefs related to consequences of LBP on physical and work activities avoidance, the objective of the BBQ is to determine the presence of various inevitable consequences of LBP in patient's future among 14 determinants (In Dutch:; In French: Dupeyron A et al. 2017)

4. a 7-point global perceived effect of change dichotomized to define patient-reported success as occurring when 1 of the top 2 ratings were selected ("full recovery" or "much better") (Kamper et al. 2010).
5. The 5-Dimensional EuroQol (EQ-5D) (REF) tool assessed quality of life based on 5 domains (mobility, self-care, usual activities, pain/ discomfort, and anxiety/depression) (Herdman et al. 2011). Patients self-rated their overall health using the EQ-5D visual analogue scale ranging from 0 (worst) to 100 (best imaginable) health.
6. Duration/length of work disability (days). Time to successful return-to-work (days till successful return-to-work counted from start from intervention) according to widely accepted Steenstra et al. criteria (Steenstra IA et al. 2012)
7. Amount of flare ups. A flare-up is defined according to Costa N. et al. (2019) as "a worsening of the condition that lasts from hours to weeks that is difficult to tolerate and generally impacts usual activities and/or emotions"
8. Patients satisfaction will be evaluated based on the global rating of perceived change (1 item (Kamper et al. 2010)) and the Flemish Patient Satisfaction Questionnaire (29 items (Sermeus et al. 2015)).

This trial involves two arms: (1) direct access to PT (n= 300), and (2) usual care (n= 300). Participating PTs and GPs are not specifically trained. However, PTs will be included based on an a priori test; GPs will also complete this test to have background information on the knowledge, skills and attitudes of HCP (for GPs not as a criterium to select).

4.4.1. Direct access to PT group (experimental group)

- *Inclusion criteria for treating PTs.*

  An e-course (educational material) and subsequent pass-fail test will be organised to include the PTs, based on

  (1) the PTs' competence (according to the guidelines) of:

    - ruling out red flags as well as specific-LBP in accordance with direct access in The Netherlands ('pluis', 'niet pluis')
    - identification and management of the risk factors of chronicity
    - LBP patients' misbeliefs and the way to manage them
    - education related to pain neurophysiology
    - communication strategies for reassure, inform patients with LBP
    - self-management strategies for patients
    - exercises tailored to the patient' needs (appropriate consideration of treatment timing, dosage parameters and progression of interventions)
    - spinal mobilisation techniques (techniques, indications, contra-indications, risks,..)

(2) the PTs' cognitions and beliefs. We will use the following validated questionnaires: The Pain Attitudes and Beliefs Scale for Physiotherapists (PABS-PT), the Health Care Providers' Pain and Impairment Relationship Scale (HC-PAIRS*),* and the Back Pain Attitudes Questionnaire (BACK PAQ). Validated cut-off scores will be used as criterium.

- *Therapy content:* In addition to an extensive evaluation of the patient (during the first session), the treatment will be based on national (e.g. KCE) and international guidelines (e.g. NICE) on LBP therapy; i.e., providing information/education to reassure the patient and favour the patient's self-management and empowerment as well as exercises. Passives techniques (soft-tissue techniques, mobilisations and manipulations) will not be used systematically and will always be used in combination with the previous techniques. Valued care will be used (no overdoing). In case a sick-leave certificate is requested by the patient, the PTs are encouraged/trained to discuss this with the GP to provide this when necessary, as they will practise multidisciplinary care to the maximal extent. The GP of the patient will be formally informed when the patient is included in the study.

We will include about 30 PTs, both n Flanders and in Wallonia (that would result in about 10 potential patients of the project for each PT).

4.4.2. Usual care group (control group)

- *Inclusion criteria for treating GPs:*
    - Using the networks of the Faculties of Medicine of the Belgian Universities
    - In Flanders through Domus Medica in Flanders (scientific contact person)
    - In Wallonia through "Be Hive" http://www.be-hive.be.
- *Therapy content:*
    - First point of contact is GP
    - Whether or not with referral to PT
    - No specific guidelines on how to manage patient

5. REQUESTED BUDGET

Category	Annual cost (€)			Project cost (€)
	Year 1 (start April 1)	Year 2	Year 3	
STAFF				
Project coordinator (postdoctoral level) - 0.5VTE	30,000	50,000	40,000	120,000
Research assistant FR (master level) - 0.4VTE	15,000	25,000	20,000	60,000
Research assistant NL (master level) - 0.4VTE	15,000	25,000	20,000	60,000
WORKING COSTS				
App development	15,000	0	0	15,000
Educational material for PT training	5,000	0	0	5,000
Statistical analysis	2,500	2,500	2,500	7,500
Health-economical analysis	5,500	4,500	20,000	30,000
Organisational committee (meetings)	2,000	6,000	7,000	15,000
Physiotherapeutic consults of exp group (300 patients x 9 sessions x 30 euro)	10,000	34,000	37,000	81,000
TOTAL	100,000	147,000	146,500	393,500

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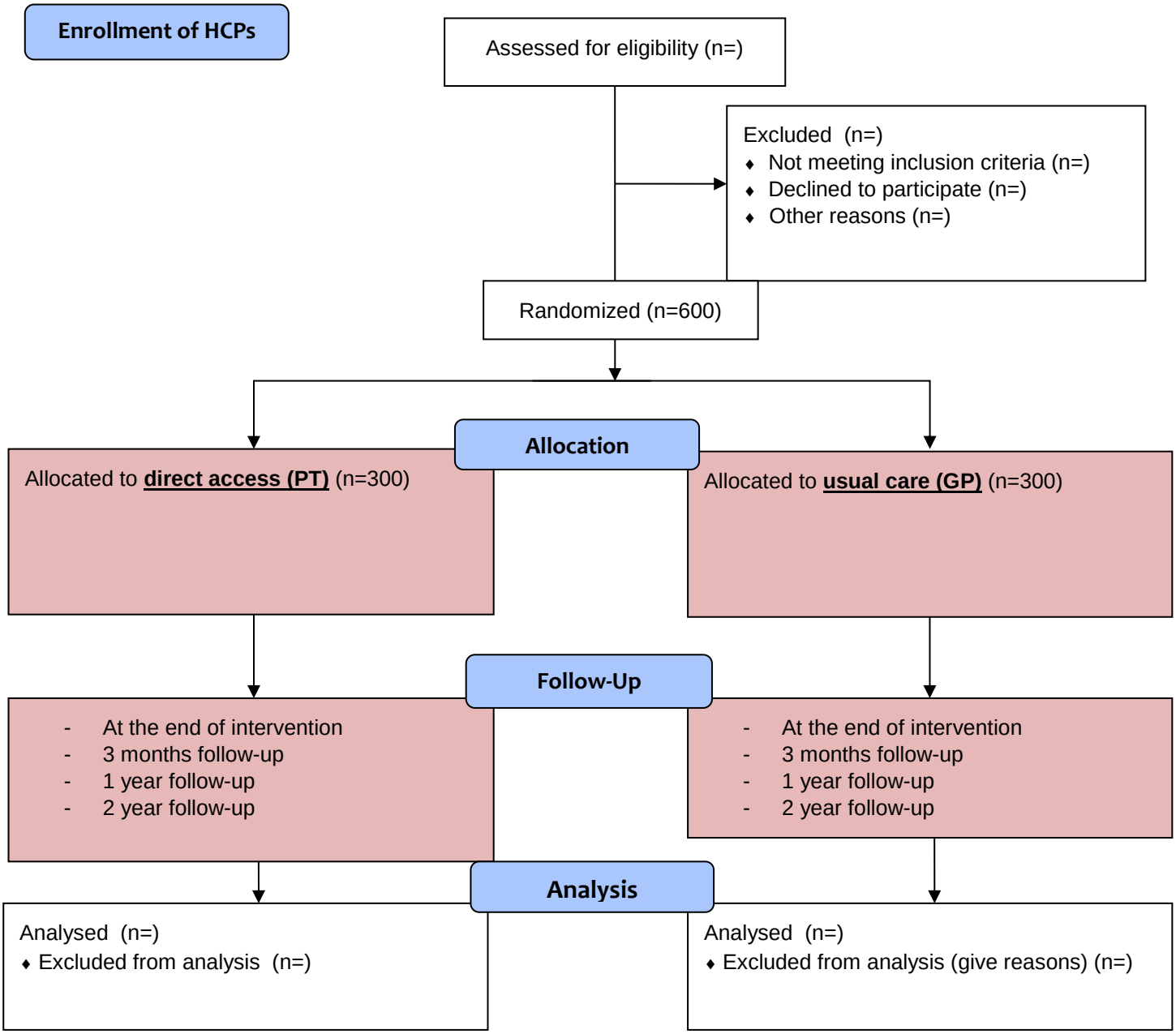
Appendix 2: Flowchart of the study

FIGURE 1. Flow Diagram of the study, based on the CONSORT statements



Appendix 2: Red flags for low back and radicular pain based on KCE Report

Tekstkader 1 – Lijst van rode vlaggen, gegroepeerd per cluster (expertopinie)

Dringend (onmiddellijk)	
Rode vlag	**Actie**
Neurologische noodgevallen • Wijdverspreide (bv. aan de armen, hersenzenuwen of bilateraal) neurologische symptomen (piramidale tekenen, coördinatieproblemen, motorische of gevoelsstoornissen …) • Progressieve neurologische symptomen • Zadelanesthesie/hypo-esthesie, urineretentie, fecale of urinaire incontinentie, geïsoleerde seksuele stoornissen (cauda equina syndroom) • Ernstig motorisch deficit (Medical Research Council score ≤3/5) opgetreden sinds minder dan 48 u	Stuur de patiënt naar de **spoeddienst**
Traumatische fractuur • Ernstige lage rugpijn na significant/hoge energie trauma • Rugpijn na trauma met spondylitis ankylosans	Stuur de patiënt naar de **spoeddienst**
Vasculaire problemen • Vasculaire tekenen (koude voet, verminderde perifere arteriële pulsatie) die kunnen wijzen op een gescheurd aneurysma van de aorta als ze gepaard gaan met lage rugpijn of zelfs met shock.	**Echografie** & consultatie **vaatchirurgie**

Semi-dringend (binnen de 48u)	
Rode vlag	**Actie**
Pathologische fractuur Lage rugpijn na mineur trauma of zelfs zonder notie van trauma met: • Voorgeschiedenis/risico van osteoporose • Chronisch corticoïdengebruik • Pijn in de borstkas • Hogere leeftijd • Onverklaard gewichtsverlies, vermoeidheid • Voorgeschiedenis van kanker	**1/ Röntgen** (of CT) **2/** Consultatie **rugchirurgie**
Infectie • Objectieve tekenen (bv. nachtzweten, koorts, rillingen) • Intraveneus druggebruik • Immunodeficiënte patiënt • Onverklaard gewichtsverlies • Gekende voorgaande of samengaande systemische infectie of risico op infectie • Recente chirurgische ingreep • Urinaire of huidinfectie	**1/ MRI** & **Bloedanalyse** (bv. leucocyten telling, CRP, sedimentatie) **2/** Consultatie **rugchirurgie** en/of Consultatie **internist/infectiespecialist**

Minder dringend	
Rode vlag	**Actie**
Tumor • Recente klachten van rugpijn bij leeftijd <18 of >55 • Voorgeschiedenis van kanker • Onverklaard gewichtsverlies, vermoeidheid • Ernstige nachtelijke pijn	**1/ MRI** **2/** Consultatie **oncologie** & consultatie **rugchirurgie**
Inflammatoire aandoening • Constante progressieve niet-mechanische pijn • Rugpijn verbetert bij lichaamsbeweging, maar niet in rust • Ernstige nachtelijke pijn • Ochtendstijfheid > 30 min of nachtelijk ontwaken bij jongere patiënten	Consultatie **reumatologie**
Varia • Toenemende postoperatieve pijn • Onhoudbare en therapieresistente lage rugpijn (> 6 weken) • Unilaterale piramidale tekenen	**1/ MRI** **2/** Consultatie **rugspecialist**, dwz een specialist in fysische geneeskunde en revalidatie, een orthopedisch chirurg of neurochirurg of een **anesthesist-algoloog**

De sensitiviteit en specificiteit van de rode vlaggen zijn beperkt, vooral bij afzonderlijke toepassing; clinici moeten zich focussen op clusters van rode vlaggen die wijzen op een specifieke ernstige pathologie.