**Projekt protokol**

# The effectiveness of a stratified care model for non-specific low back pain in Danish primary care: a randomised controlled trial.

## Background

Low back pain (LBP) is a major global challenge and the leading cause of years lived with disability[1]. LBP accounts for an annual Danish societal cost of 16.8 billion DKK of which sickness and health related benefits make up the largest part[2]. Despite extensive research and focus on prevention the burden of LBP seems to continue to increase[3].

Emerging evidence indicates that stratified care of low back pain results in better clinical outcomes and reduced healthcare costs, compared to usual care [4]. Stratified care is a way of reducing the complexity of LBP[5]. It involves using a simple 9-item screening questionnaire, the STarT Back Tool (SBT) to allocate patient with non-red flag low back pain to one of three subgroups, based on prognostic indicators of disabling low back pain, and then managing them according to matched treatment pathway[6].

Patients are classified into low risk, medium risk and high risk subgroups based on the SBT score. Low risk patients are likely to have a good outcome with a one off good quality consultation consisting of reassurance; analgesia and high quality health information about good self-management, patients at medium risk receive evidence based physiotherapy treatment focusing on reducing pain & disability and enabling patients to manage ongoing and/or future episodes of LBP, whilst high risk patients receive a more comprehensive combined physical and psychosocial intervention[6], termed Psychologically Informed Physiotherapy (PIP).

The SBT has recently been translated and cross-culturally validated in a Danish speaking population[7;8]. Studies from the UK have shown stratified care to be superior to usual care in primary care LBP patients [4;9]. Furthermore the stratified care model resulted in 50% reduction in LBP related sickness absence and lower health care costs compared to current best practice[9]. Thus, stratified care may be associated with clinical benefits for LBP patients in primary health care at lower costs. However, health care and social systems may vary between countries and replication of these UK findings is warranted before implementation in Danish health care settings can be recommended. The current study will investigate whether the stratified care model of the SBT, applied within the Danish Regional disease management programs is more effective than current best practice care.

## Objective

The aim of this study is to evaluate the clinical and cost-effectiveness of a stratified care model in patients with NSLBP compared to current practice in a Danish primary health care settings.

## Methods, Design and Setting

The study will be performed as a two-armed randomized controlled trial in a Danish primary health care settings. Patients will be recruited by General Practitioners (GP), at the initial or second consultation (see flowchart 1). The GP will assesss, triage and refer patients according to their

normal practice specified in the recommendations of the Danish Society of General Practice[10]. Patients who decline referrel will be registered and asked to complete a short questionnaire.

**Inclusion and Exclusion criteria**

Inclusion criteria: None red flag low back pain patients with or without leg pain can be included in the study. Included patients must be 18 years and above, and understand Danish language.

Exclusion criteria: Serious pathology(malignancy, inflammatory arthritis, ect.), serious nerve root compression (cauda equina, paresis <3), influential comorbidity, psychiatric illness, personality disorder, spinal surgery during the last 6 months, pregnancy, or already receiving physiotherapy treatment.

**Randomization**

Patients will be referred by their GP to physiotherapy using the automated RefHost system. A research secretary will continiously review new referrels and contact patients by phone. If a patient agrees to participate and is eligible for the study a pre-consent is given over the phone and further information about the study is sent to the patient along with a consent form for them to signe and return. The research secretary computer-randomizes the patient into one of two interventions; (stratified care) or control treatment (current practice). Both interventions will be carried out by physiotherapists in clinical physiotherapy settings (See flow chart 1). The secretary supplies the patients with the contact details of the allocated clinic and informs the clinic of the referral of the patient.

**Procedure and interventions**

All collection of data will be administrated by an existing online datacollection (https://trialpartner.dk). In both study arms a link to a web based questionnaire including the SBT will be send to be completed by the patients prior to the first consultation. At 3 and 12 months follow up web-based questionnaires will be sent.

**Stratified care group**

A structured standardised physical examination will be performed. The results of the clinical examination, the questionnaires and the SBT in combination are used as clinical guidance. Patients are stratified according to the SBT subgroups (low, medium and high risk) and the appropriate matched treatment will be delivered accordingly. The treatment is delivered by physiotherapists who have received adequate training to deliver the matched treatments.

All patients will receive information aimed at reassuring them about the nature of low back pain. The topics of reassurance are guided by the SBT score and the result of the clinical examination. Patients will be encouraged to maintain or return to normal activity as soon as possible incl. work (if possible), and they will be given information about activities at local exercise venues. An educational video and informative back book are also provided to supplement the messages provided in the

consultation. Advice and information about medication, further investigations, work, prognosis, future episodes, and pain coping strategies will be provided and individuals patients concerns addressed. The model for the study interventions will be provided from the STarT Back Trial in the UK[4]. The main components of the subgroup interventions are provided below:

- **Low risk intervention:** Patients in the low-risk group will receive a good quality, evidence based consultation. Onwards referral, investigation or further treatment is not recommended unless the physiotherapist finds it highly relevant.
- **Medium risk intervention:** In addition to the above, patients will receive an evidence based standardised package of individualised treatment focusing on restoring function (targeting back pain, leg pain, co-morbid pain and disability)
- **High risk intervention:** In addition to above, , these patients will receive individualised psychologically informed physiotherapy aiming to reduce pain and disability, improve psychological functioning (where possible) and enable patients to manage ongoing and/or future episodes of LBP.

**Current practice**

In contrast to the intervention group the decision about whether patients in the control arm (current best practice) receive further physiotherapy treatment will be based on clinical judgement, clinical need and patient preferences. The physiotherapist has no access to scores of the questionnaire or guidance tools. Current best practice will be delivered by qualified physiotherapists. A standardised physical examination will be performed. The main treatment modalities to be used should broadly reflect current practice (e.g. Manual Therapy (Maitland), MDT, exercise, acupuncture, advice, reassurance, education). The model for current practice interventions will be provided from the STarT Back Trial I the UK[4]

**Recruitment of clinicians.**

The recruitment of GP practices and physiotherapy clinics will be conducted in different geographical parts of the Regions of Southern and Central Denmark. To avoid bias due to differences in rural/urban setting two major cities and four smaller cites will be chosen as inclusion areas for the study. Local information meetings will be held for GP practices. GP practices who decide to participate and are found eligible according to inclusion criteria will receive information regarding the study procedures. The physiotherapy services used in the study will be interested physiotherapy practices associated with the GP practices and within the same geographical areas. The physiotherapists will be trained/instructed to deliver either stratified care (intervention) or current practice (control). Regular contact between the research team and the clinics will secure that clinics who perform stratified care and clinics who perform current practice meet the study inclusion criteria and are fully informed of the procedures of the study.

**Outcome measures**

A core set of standardised and internationally recommended outcome measures will be applied in the trial[11]. The primary outcomes in the trial will be group differences in time off work, improvement in LBP disability measured by the Roland Morris Disability Questionnaire (RMDQ) patient reported global change. Time off work is considered a complicated measure[5], but standardized patient reported data from the FysDB database allows us to monitor short term sick leave, and information from the Danish National Register on Public Transfer Payments (DREAM) makes it possible to monitor long term sick leave and other health related benefits[12]. Secondary outcomes will be cost-effectiveness, pain intensity, patient satisfaction, and overall quality of life.

In collaboration with secondary care (the Spine Centre of Southern Denmark and the Regional Spine Centre, Silkeborg) it is furthermore planned to monitor the effectiveness of the stratified model at the time of referral to secondary care. The outcome measures here will be reductions of referrals to secondary care using the stratified model compared to current practice, increased detail and usefulness of referrals sent to secondary care and reduction in numbers of consultations in secondary care in patients using stratified care compared to usual referred patients. A detailed protocol has been developed for these measurements.

**Sample size**

In ealier studies[4;13] reduction of sick leave has shown to be about 50% and change scores on the RMDQ about 4.5 points. In this study we want to show a conservative reduction of 30% in sick leave at 3 months with a power of 80% and signifincance level at 5%. A sample size calculation was performed by using the 'days off work' numbers from the high quality STarT Back Trial[4]. The sample size was calculated using STATA 13 and showed that 350 patients are needed in each treatment arm. With an expected 15% drop out rate a total of 700 patients will be included in the study.

**Analyses**

Scores of primary and secondary continuous outcomes are compared between groups using mixed multi level models and Generalized Estimating Equations models for categorical outcomes at 3 and 12 months taking into account cluster effects of treating physiotherapist[14]. Missing data and loss to follow up will be handled by multiple imputation[15;16]. The health economic analysis will use a descion analytic framwork (E.g. Markov-model or/and Decision Tree analysis) to test the cost-effectiveness/cost-utility of SBT against current practice. Relevant sensitivity analyses will be performed to adress the robutsness of the results. A Budget Impact analysis will be made to describe the budget cost or potiential budget savings for the different health care payers of a fully implemented SBT in the Region of Southern Denmark compared to current practice.

**Ethics**

Participantion is based on informed consent. All patients in the study will recive verbal and written information regarding the study. The study will be notified to Scientific Ethics Committee of Southern Denmark and the Danish Data Protection Agency. The study is registred in Clinical trial registry https://clinicaltrials.gov/ct2/show/NCT02612467

**Research plan**

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| May 2015 – oct. 2015 | Contact to GPs and Physiotherapists and Education of Physiotherapists |
| Nov 2015. – dec. 2015 | Pilot study testing the flowchart |
| dec. 2015 – July. 2017 | Inclusion of patients in primary care |
| July. 2017 – July. 2018 | Follow up primary care and Datacollection in secondary care |
| July 2018 – End 2018 | Analyses, publication, presentation |

**Funding**

The study will primarily be based on external funding.

**Perspectives**

LBP constitutes a global health problem and stratified care that effectively targets treatment to relevant groups of patients has the potential to have great impact on the treatment pathways of LBP. If effective stratified care models may serve as a part of the national Danish implementation strategy for evidence-based LBP care in the primary health care. Potentially, this could significantly reduce the costs and at the same time result in better patient outcomes and less disability.

**Study organisation and mangement**

The study has the advantages of being conducted in an already existing frame work and data will be collected in already existing databases, which have been tested and found eligible.

Researchers from the Centre for Quality in the Regions of Southern and Central Denmark, the Research Units of General Practice, Odense and Aarhus and the Spine Centres of the two Regions will collaborate closely with Consultants from Danish primary care, the UK STarT Back team at Keele University and from other departments at SDU.

Management

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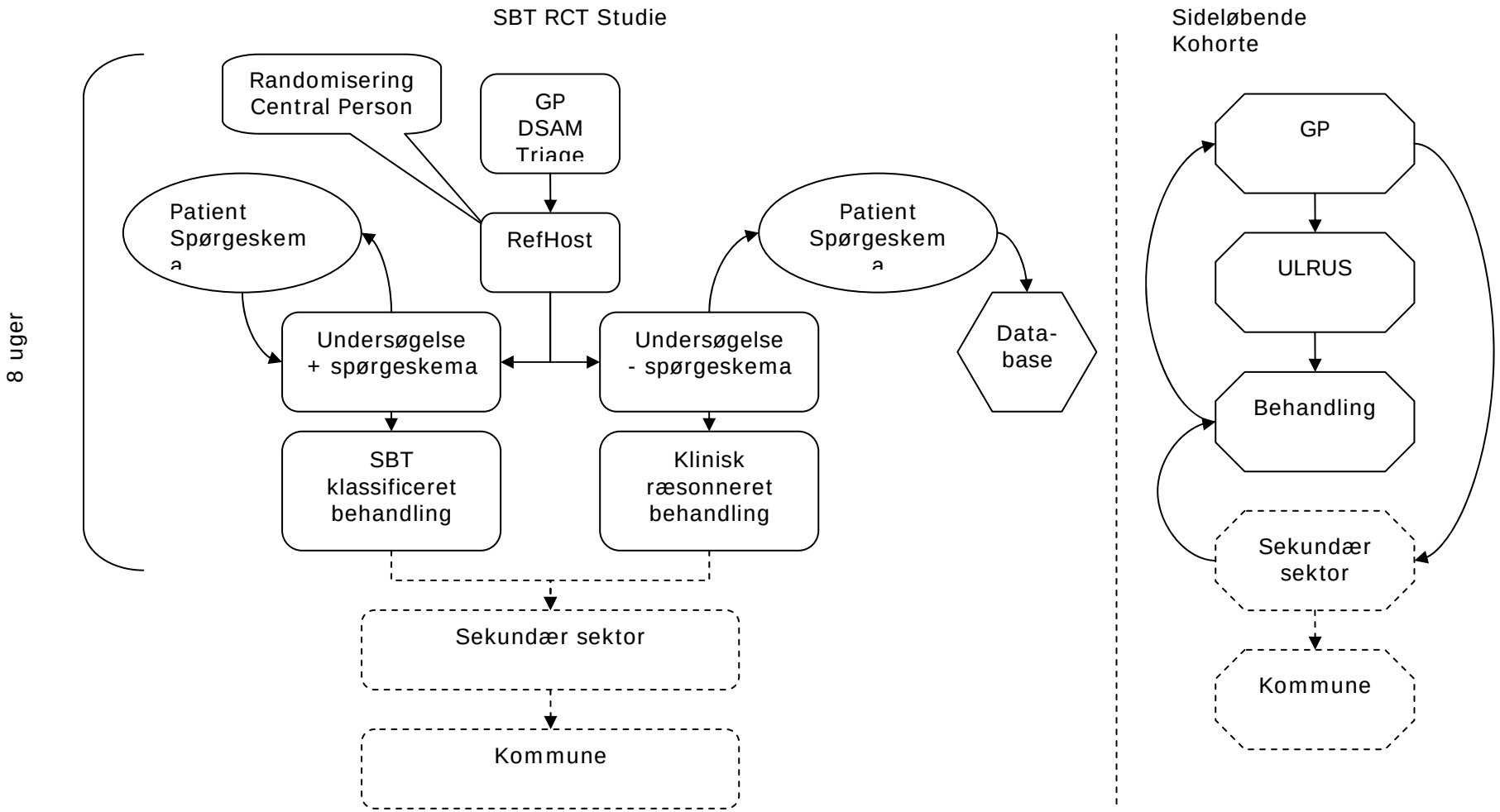
SBT RCT Studie
Sideløbende Kohorte
8 uger
Randomisering Central Person
GP DSAM Triage
RefHost
Patient Spørgeskema
Undersøgelse + spørgeskema
Undersøgelse - spørgeskema
Patient Spørgeskema
Data-base
SBT klassificeret behandling
Klinisk ræsonneret behandling
Sekundær sektor
Kommune
GP
ULRUS
Behandling
Sekundær sektor
Kommune