Implementering af rygretningslinjer i almen praksis

Riis, Allan

DOI (link to publication from Publisher):
10.5278/VBN.PHD.MED.00062

Publication date:
2016

Document Version
Publisher's PDF, also known as Version of record

IMPLEMENTATION OF LOW BACK PAIN GUIDELINES IN GENERAL PRACTICE

BY
ALLAN RIIS

DISSERTATION SUBMITTED 2016

AALBORG UNIVERSITY
DENMARK

Implementation of low back pain guidelines in general practice

Allan Riis

AALBORG UNIVERSITY
DENMARK

May 18, 2016

Thesis submitted: May 18, 2016

PhD supervisor: Prof. Martin B. Jensen
Department of Clinical Medicine
Aalborg University, Denmark

Assistant PhD supervisors: Prof. Flemming Bro
Research Unit for General Practice
Aarhus University, Denmark

Associate Prof. Helle T. Maindal
Department of Public Health
Aarhus University, Denmark

PhD committee: Clinical Professor Niels Bentzen (chairman)
Aalborg University, Denmark

Professor Berit Schiøttz-Christensen
Rygcenter Danmark, Denmark

Professor Maurits van Tulder
VU University Amsterdam, The Netherlands

PhD Series: Faculty of Medicine, Aalborg University

ISSN (online): 2246-1302
ISBN (online): 978-87-7112-429-3

Published by:
Aalborg University Press
Skjernvej 4A, 2nd floor
DK – 9220 Aalborg Ø
Phone: +45 99407140
aauf@forlag.aau.dk
forlag.aau.dk

Printed in Denmark by Rosendahls, 2016

PREFACE

This project was conducted between September 2011 and November 2015 as part of my full-time employment by the Research Unit for General Practice in Aalborg. I was enrolled as a PhD student in the Department of Public Health at Aarhus University in August 2012 and in January 2014 I was transferred to the Department of Clinical Medicine at Aalborg University.

The project took place in the North Denmark Region and I would like to thank the many patients who took part in the study, the general practitioners and personnel in the clinics who took the time to participate, and the North Denmark Region administration for supporting the project. I would also like to thank Jørgen Peter Ærthøj, Leo Thomsen, Tina Molbo, and the rest of the group at the Quality Unit for General Practice in the North Denmark Region for their participation in this project.

My profound thanks go to my main supervisor Martin Bach Jensen for opening the door for me and introducing me to the importance of studying guideline implementation. Your devotion has been important for conducting this large trial and your commitment in supervising has been greater than I could have possibly expected. I also wish to extend my appreciation to my assistant supervisors: Flemming Bro for advocating the importance of taking the general practices' point of view when designing interventions and for introducing me to important field of implementation science, and Helle Terkildsen Maindal for our theoretical discussions and for always advocating a strong methodological approach.

I would like to thank physiotherapists Anne Marie Pedersen Kjær, Jens Erik Jørgensen, Karen Thorsager, Laila Linneberg, and Marit Larsen for their courage and willingness to take on a new role as consultants in general practice. You took an active part in discussions on how to deliver the outreach visits and you are the main reason why all 28 practices allocated to receive outreach visits, actually were visited by one of you — that is quite an achievement. Thanks to Anders Benjamin Brask from the North Denmark Region Department of Information Technology for help in designing the on-line questionnaire platform and for data managing this project. Many thanks to Cathrine Elgaard Jensen, my fellow PhD student, with whom I shared responsibility for data collection to our parallel PhDs. We also co-authored each other's papers and I think we succeeded in integrating the clinical and the health-economic parts of this project.

I would also like to thank my colleagues Mia and Camilla, with whom I share an office at the Research Unit for General Practice in Aalborg. You contribute to an inspiring environment with good discussions as well as fun and laughter. My deepest thanks and love go to Dorthe, my spouse, for her great support.

This project was funded by TrygFonden, the Danish Rheumatism Association, Danish Research Foundation for General Practice, the Obel Family Foundation, the Spar Nord Foundation, and Medical Specialist Heinrich Kopps Grant.

Aalborg, May 18, 2016

Allan Riis

This thesis is based on the following papers:

1) Riis A, Jensen CE, Bro F, Maindal HT, Petersen KD, Jensen MB. Enhanced implementation of low back pain guidelines in general practice: study protocol of a cluster randomised controlled trial. Implement Sci 2013 Oct 20;8:124-5908-8-124.

2) Riis A, Jensen CE, Maindal HT, Bro F, Maindal HT, Jensen MB. Recruitment of General Practices: Is a Standardized Approach Helpful in the Involvement of Healthcare Professionals in Research? Submitted for publication.

3) Riis A, Jensen CE, Bro F, Maindal HT, Petersen KD, Bendtsen MD, Jensen MB. Implementation of low back pain guidelines in general practice by a multifaceted strategy: a cluster randomised controlled trial. Submitted for publication.

ABBREVIATIONS

AOR:	Adjusted Odds Ratio
CI:	Confidence Interval
CRCT:	Cluster Randomised Controlled Trial
DAMD:	Danish General Practice Database (Dansk AlmenMedicinsk Database)
EQ VAS:	EuroQol Visual Analogue Scale
GEE:	Generalised Estimating Equation
GP:	General Practitioner
ICD:	International Classification of Diseases
ICPC:	International Classification for Primary Care
IQR:	InterQuartile Range
LBP:	Low Back Pain
MuIS:	Multifaceted Implementation Strategy
NPR:	Numerical Pain Rating
NRS:	Numerical Rating Scale
OR:	Odds Ratio
PaIS:	Passive Implementation Strategy
RMDQ:	Roland Morris Disability Questionnaire
RR:	Risk Ratio
SD:	Standard Deviation
STarT:	Subgrouping for Targeted Treatment
VAS:	Visual Analogue Scale

TABLE OF CONTENTS

FIGURES & TABLES

ENGLISH SUMMARY

Low back pain (LBP) is a highly prevalent condition. The aetiology underlying most episodes is unknown, but may involve biological, psychological, and social factors. Even though most episodes of LBP are of short duration, it is a major cause of disability and a burden for many patients, the healthcare system, and society. Every Danish citizen is registered with a general practitioner (GP), who acts as a gatekeeper to the secondary healthcare system and decides if referral to secondary care is needed. However, most episodes of LBP are expected to be sufficiently treated in primary care. Therefore, addressing GPs' care of LBP in Denmark is seen as the optimal solution for improving LBP treatment.

Improving LBP treatment can be done by supporting the implementation of LBP guidelines which represent best available treatment guidance. Guidelines are, however, often slowly implemented into clinical practice, leaving a knowledge gab and thereby a potential for improving treatment. Passive diffusion of guidelines, such as making them available on the Internet, or the use of another single initiative to reach uptake of guideline concordant treatment, have been found ineffective. However, a wide range of interventions exists including educational outreach visits, feedback on performance, and computerised decision support. If used appropriately and in the right combination it can lead to better implementation of guidelines and thereby improve the care of patients. According to Danish guidelines care of most patients should take place in primary care and the referral of patients to the more

expensive secondary healthcare system should be kept at a minimum.

Interventions aimed at the primary care GPs are recommended to address three key conditions: capabilities, opportunities, and motivation. The interaction between these conditions can emerge chance in GPs choice of treatment and referral behaviour.

Regardless of how potentially effective an intervention is, it needs to be accepted and applied by GPs to help patients. Since GP participation in quality development and research often demands an investment of time and other resources, it can be a challenge to recruit a sufficient number of participants. Being aware of important factors that influence the decision to participate in a project such as relationship, reputation, requirements, rewards, reciprocity, resolution, and respect is important for achieving a high participation rate.

The aims of this thesis were to (I) describe the development of two intervention strategies, (II) evaluate the recruitment process of general practices to the project, and (III) report on findings from the cluster randomised controlled trial, which compared a multifaceted implementation strategy (MuIS) with a more passive implementation strategy (PaIS).

Two guideline implementation strategies were developed. Both involved the usual implementation activities and some project-related passive activities, which included a new referral opportunity for patients with extensive psycho-social problems, guideline-concordant structured computerised medical record pop-ups, financial incentives to participate, and reminders about project activities. In addition, the

MuIS practices had outreach visits (before including patients) by physiotherapists who were specially trained to convey the content of the LBP guidelines to GPs. During the study, the MuIS practices were offered follow-up contacts with the outreach visitor. The MuIS practices were also offered quality reports regarding the clinics' own treatment of LBP and stratification tools integrated into the electronic medical record system (STarT Back Tool and screening questions regarding psycho-social problems). Solbergs' checklist of the seven important factors for reaching a successful recruitment guided the recruitment of general practices in this project.

Between January 2013 and July 2014, 60 general practices were recruited to the project. We intended to include 100. Several of the practices that refused to participate expressed concerns about pop-ups and restructuring of their electronic medical record systems. Other reasons for refusal or deferring the decision to participate were related to the high workload in general practice. Practices often wanted to wait until they had more time for research participation.

Fifty-four practices (28 MuIS, 26 PaIS) included 1,101 patients (539 MuIS, 562 PaIS). Compared with patients receiving the PaIS, the MuIS reduced the 12-week referral to secondary healthcare from 10.5% to 5.0% with an adjusted odds ratio (AOR) of 0.52 [95% CI 0.30-0.90; p=0.020]. The MuIS had a tendency towards better functional levels and less sick leave among MuIS patients, but none of these secondary outcomes were statistical significant. Conversely, patients' satisfaction with received treatment and treatment outcomes were significantly lower for patients in the MuIS group. This project supported the application of a multifaceted implementation strategy

instead of a more passive implementation strategy when introducing guidelines for LBP in general practice.

DANSK RESUME

Lændesmerter er en hyppig forekommende tilstand. Årsagen til lændesmerter kan stamme fra biologiske, psykologiske eller sociale faktorer, men i de fleste tilfælde er den underliggende ætiologi ukendt. Selvom de fleste tilfælde af lændesmerter er kortvarige, så kan lændesmerter være en stor belastning for de mange patienter, for sundhedsvæsenet og for samfundsøkonomien. Alle danske statsborgere er tilknyttet en almen praktiserende læge og almen praksis er adgangen til de mere specialiserede behandlingstilbud i sekundærsektoren. De fleste tilfælde af lændesmerter forventes at kunne blive tilfredsstillende behandlet i primærsektoren. Derfor anses lægens behandling af rygsmerter, som det optimale fokuspunkt for at forbedre behandlingen af rygsmerter i Danmark.

Lægernes behandling kan forbedres ved bedre implementering af rygretningslinjer, som repræsenterer, de mest opdaterede anbefalinger for behandling og henvisning. Retningslinjer er dog ofte langsomt implementeret til klinisk praksis. Der findes derfor et vidensgab, som potentielt kan forbedre rygbehandlingen. Passiv udbredelse af retningslinjer, som for eksempel udelukkende at gøre retningslinjer tilgængelige på internettet eller anvendelse af andre simple udbredelsesstrategier er fundet uegnede til at ændre klinisk praksis. Der findes dog en bred vifte af implementeringstiltag, som eksempelvis besøgskonsulenter, kvalitetsrapporter og elektronisk indbyggede beslutningsstøtte-værktøjer. Hvis disse anvendes i en passende kombination, kan de føre til bedre implementering af retningslinjer og herved bedre behandling af lændesmerter. Et

specifikt fokuspunkt i danske retningslinjer og forløbsprogrammer, er at begrænse antallet af henvisninger til den dyrere sekundærsektor.

Ved design af en intervention for at ændre adfærd anbefales det at adressere både lægernes kompetencer, muligheder og motivation. Disse tre fokuspunkter betragtes som nøglepunkter for at ændre behandlingsvalg og henvisningsmønstre.

Uanset potentialet af en interventionsstrategi, så er den afhængig af lægernes accept og anvendelse hvis strategien skal medføre positiv effekt for patienterne. Lægers deltagelse i kvalitetsarbejde og forskning kræver oftest en investering af tid og andre ressourcer, det kan derfor være en udfordring at rekruttere et tilstrækkeligt antal læger, som deltagere i et projekt. For at forskere skal opnå høj deltagelsesprocent, er det vigtigt at være opmærksom på afgørende faktorer, som spiller ind i beslutningen om deltagelse, som for eksempel: kollegialt samarbejde, godt omdømme hos forskergruppen, begrænset ressourceforbrug hos deltagere, belønning/anerkendelse, klar kontrakt om hvad der kræves som deltager og hvordan forskergruppen vil hjælpe, udholdende rekrutteringspersonale og en respektfuld tilgang med forståelse for potentielle deltageres arbejdsforhold.

Formålene med denne afhandling var (I) at beskrive udviklingen af to implementeringsstrategier, (II) evaluere rekrutteringsprocessen af praktiserende læger og (III) afrapportere resultaterne fra det klyngerandomiserede kontrollerede forsøg, som sammenlignede en multistrenget implementeringsstrategi (MuIS) med en mere passiv implementeringsstrategi (PaIS)

Der blev udviklet to strategier til udrulning af forløbsprogrammet for lænderygsmerter. Begge strategier indeholdt de sædvanlige tiltag og nogle ekstra aktiviteter i forbindelse med at gennemføre projektet. Dette var en ny henvisningsmulighed til Socialmedicinsk Afdeling i Aalborg af patienter med store psyko-sociale problemer, beslutningsstøtte integreret i journalsystemet, aflønning for projektdeltagelse og påmindelser om patientinklusion. I tillæg fik klinikkerne i MuIS gruppen tilbudt konsulentbesøg (før påbegyndt inklusion af patienter), af fysioterapeuter som havde modtaget træning i at overlevere budskaberne i forløbsprogrammet. Under studiet fik MuIS klinikkerne tilbudt opfølgende kontakter med konsulenterne. MuIS klinikker fik også tilbudt behandlings feedback via adgang til kvalitetsrapporter omhandlende behandlingen af patienter med rygsmerter, og dertil fik MuIS klinikkerne indbygget subgrupperingsværktøjer sammen med den øvrige beslutningsstøtte i journalsystemerne. De to subgrupperingsværktøjer var STarT Back Tool og et socialmedicinsk screeningsværktøj, med spørgsmål om psykosociale problemstillinger. En checkliste udviklet af Solberg, over syv faktorer med væsentlig betydning for succesfuld rekruttering, guidede rekrutteringen af lægeklinikker til projektet.

I perioden fra januar 2013 til juli 2014 blev der rekrutteret tres lægeklinikker. Vi havde planlagt at rekruttere et hundrede. Flere klinikker, som afviste deltagelse, udtrykte bekymringer ved at skulle anvende pop-upper og omstrukturering af deres journalsystem. Andre årsager til at afstå fra deltagelse, var relateret til den høje arbejdsbyrde i almen praksis. Flere klinikker ønskede at vente til en periode med lavere arbejdsbyrde før de ville være klar til nye projekter.

Fireoghalvtreds lægeklinikker (28 MuIS og 26 PaIS) inkluderede 1.101 patienter (539 MuIS og 562 PaIS). Sammenlignet med patienter i PaIS gruppen, reducerede MuIS signifikant henvisningerne til sekundærsektoren efter 12 uger fra 10,5% til 5,0% med en odds ratio på 0.52 [95% konfidensinterval 0.30-0.90, p=0.020]. I MuIS gruppen var der en tendens til bedring i funktion og mindre sygefravær, ingen af disse resultater var dog statistisk signifikante. Patienter i MuIS gruppen var signifikant mindre tilfredse med resultaterne af deres behandling. Dette projekt understøttede anvendelsen af en multistrenget strategi ved introduktion af retningslinjer for rygsmerter i almen praksis.

CHAPTER 1. BACKGROUND

The global burden of low back pain (LBP) has been estimated to a point prevalence of 11.9%.[1] In the North Denmark Region and in other industrialised countries, the prevalence is even higher.[2-3] In the United Kingdom, LBP and neck pain are the leading causes of disability-adjusted life years.[4] As life expectancy increases, the number of seniors living with LBP rises, further increasing healthcare service demands everywhere.[5-7] In Denmark, LBP is the most common reason for sick leave and with more than 3.5 million annual consultations, LBP is the most frequent reason for patients seeking care in general practice.[3]

The duration of most episodes of LBP lasts only a few days, but many patients with LBP experience recurrent symptoms and some have persistent pain.[8-9] A sedentary lifestyle is not a risk factor for LBP.[10] However, among patients with LBP, healthy lifestyle behaviours, including leisure time physical activity, influence the prognosis for better outcomes for women.[11] On the other hand, LBP is more prevalent among women.[1,7] The precise aetiology underlying most cases of LBP is unknown, but biological, psychological, and social factors may all be important.[12-14] Therefore, care of patients is complex and treatment is varied and often not in line with guidelines.[15-16] Current evidence for LBP treatment has been synthesised in guidelines to assist general practitioners (GPs) and other healthcare professionals in treating LBP and guiding them when referrals are recommended. The translation of guidelines into practice is often slow, passive strategies are not recommended, and using a single implementation element, which can

result in the uptake of guidelines is generally found unsuccessful.[17-18] But adding several components and thereby using a multifaceted implementation strategy is not always in favour of single component interventions for generating change in clinical behaviour.[19-20] A synthesis of systematic reviews on guideline implementation strategies has highlighted the importance of actively engaging clinicians throughout the process and using multifaceted strategies.[21]

Slow translation of research evidence into clinical practice can be caused by factors related to healthcare professionals or patients.[22] Patients need to agree with treatment advice given by healthcare professionals and adhere to it. Healthcare professionals need to have adequate capabilities, opportunities, and motivation to change their clinical behaviour and researchers need to target the behaviours by considering a full range of possible interventions and policies to identify which techniques will most likely bring about change.[23]

Recruiting GPs for a project can be considered the first step in changing behaviour. However, recruitment of general practices for research can be a challenging task and typically lasts longer than anticipated.[24] Studies on recruitment have underlined the importance of targeting leaders of practices as contacts, followed by on-site meetings and placing emphasis on the importance of resolution in recruitment.[25-27] Recruitment consists of many activities and having more than one recruiter can be important in keeping a record of appointments, names and other information from potential participants.[28] Moreover, other recruiters have pointed to the importance of building personal contacts, offering incentives, and

choosing flexible recruitment strategies.[29] Friendship networks have also been reported as powerful tools in recruiting groups of healthcare professionals.[30] Conversely, previous participation in irrelevant studies and the lack of rewards and recognition might be barriers to participate in future studies.[31] In an attempt to summarise the field, four important characteristics for successful recruitment have been extracted: direct recruitment of clinicians by clinicians, co-operation with local medical organisations, on-going personal contact with practices, and recognition of the GP's time.[32] However, the most comprehensive attempt to describe how to recruit healthcare professionals has been carried out by Solberg.[33] Based on the recruitment literature and experience in the field, he has described a framework to guide the recruitment of medical groups for research, arguing for the awareness of seven factors: relationship, reputation, requirements, rewards, reciprocity, resolution, and respect — all influencing the decision to participate in research.[33] The involvement of GPs in guideline implementation interventions can be further supported by the use of systematic implementation approaches, whereby evaluations and adjustments to the implementation strategy and the intervention components, e.g. how to perform an outreach visit, can be performed at different stages of the implementation strategy.[34] This method is similar to the procedures used for testing a new drug. Using the ChiPP (change in professional performance) model, we planned a multifaceted intervention strategy (MuIS) to support the uptake of LBP guidelines in the North Denmark Region.[35-37]

1.1. Aims of the thesis

This thesis sought to:

I. Describe the development of a MuIS to change behaviour in general practice;

II. Evaluate the process of recruiting general practices to this project;

III. Report on the findings from the project, with the primary aim of reducing the referral of patients from general practice to secondary care within 12 weeks.

CHAPTER 2. METHODS

This project was established in cooperation with the regional bodies involved in planning and implementing the new LBP guidelines, the Quality Unit for General Practice in the North Denmark Region, and the regional research unit for general practice. With offices in the same building, this provided a good opportunity for discussing project activities between the stakeholders. One of the researchers worked part time as a GP in a practice located in the same building; this practice was used for testing the interventions in this project. GPs working for the Quality Unit for General Practice and experienced in visiting and advising other GPs, helped prepare physiotherapists for their new role as outreach visitors to general practices.

2.1. Cluster randomised controlled trial

In a two-armed cluster randomised controlled trial (CRCT), general practices were randomised 1:1, stratified by practice size, to an intervention group (MuIS) or a control group (PaIS). Clusters consisted of patients with LBP from the same practice. All outcomes pertained to the patient level and analysis followed the intention-to-treat principle. An economic evaluation of this project and methods used in this analysis will follow in another PhD thesis by Cathrine Elgaard Jensen.

2.2. Inclusion and exclusion criteria for general practices

General practices in the North Denmark Region were eligible for inclusion. Practices without the electronic data capture programme Sentinel, which linked the electronic medical record system to the Danish General Practice Database (DAMD), hosted by the Danish Quality Unit for General Practice, were excluded.[38] Prior to recruitment, a planned strategy was drawn up after brainstorming sessions with three GPs and use of Solberg's checklist for recruitment. During recruitment, feedback on barriers to and enablers of participation were collected from possible GP participants. Feedback was collected through personal phone contacts, mail correspondence, or letters to the recruitment group. Barriers to and enablers of recruitment were discussed at weekly meetings in the recruitment group and adjustments to the recruitment strategy were made.

2.3. Inclusion and exclusion criteria for patients

Patients aged 18 to 65 years presenting with LBP, with and without leg pain, based on ICPC-2 diagnosis coding L02, L03, L84, or L86 were included.[39] Patients with red flags (signs of serious pathology), pregnant women, and patients with insufficient Danish language skills, who were therefore not able to complete the questionnaires, were excluded.

2.4. Intervention

The intervention strategies were designed to support the implementation of the regional guideline for LBP without signs of serious underlying pathology (key-points in Table 1).

Table 1: Guideline recommendations

Make an initial assessment – triage. Classify patients as having nonspecific low back pain, nerve root pain, or red flags
Consider further subgrouping, e.g. by STarT Back Tool
Provide patients with advice and information to promote self-management of low back pain
Advice to stay physically active and continue with normal activities as much as possible
Make new appointments after 2, 4, and 8 weeks if the condition has not improved
Consider use of analgesics, referral to supplementary primary care treatment (physiotherapy or chiropractic)
Consider referral to secondary care if the condition has not improved within 8 weeks

Note: Key-points from the regional low back pain clinical guideline.

All participating practices received the usual implementation strategy, which involved guideline availability on the Internet, invitation to participate in information meetings together with GPs and other

clinicians in the North Denmark Region. All practices were also offered passive supportive activities, which included the opportunity to refer patients to an evaluation at the Department of Social Medicine, restructuring of the electronic medical record systems, and activities aimed at inclusion of patients. In addition, practices in the MuIS group were offered a combination of proactive activities, including outreach visits, patient stratification tools, and quality reports. We set out to develop a multifaceted strategy including several activities, with the purpose of actively supporting GPs in delivering guideline-concordant treatment. The specific activities in the multifaceted strategy were chosen in a pragmatic manner on the basis of discussions with GPs with experience in quality work in the North Denmark Region and on the basis of evidence.[40-41]

Five experienced physiotherapists with special interest in LBP were outreach visitors and received one full day and two half days of training. The last half-day session took place after the outreach visitors had their first practice visit. The training involved LBP guideline repetition, information about the LBP project, training in the neurological examination, and training for their new role as an outreach visitor. Training entailed a combination of instruction, demonstrations, discussions, and role plays. At the outreach visits, sub-grouping of patients was discussed and the STarT Back Tool and a screening tool with additional questions regarding psycho-social risk factors was demonstrated.[36,42] The additional questions regarding psycho-social risk factors in our setting inquired if LBP caused other problems than those addressed by the STarT Back Tool; these could be concerns related to work ability, related to financial claims, or other psychological or social barriers to recovery.[36] The tools can be

viewed in the context of the theory of the coloured flags.[13] The STarT Back Tool and the questions regarding psycho-social risk factors incorporate biological, psychological, and social aspects. Patients with red flags (serious pathology) were excluded from our project. Yellow flags (beliefs, emotional responses, and pain behaviour) were addressed by the STarT Back Tool. Blue flags (perceptions about the relationship between work and health), black flags (system or contextual obstacles such as legislation and injury claim conflicts), and orange flags (psychiatric factors) were encompassed by the additional questions regarding psycho-social problems. The tools were integrated into the electronic medical record systems. They automatically appeared at the second consultation, but the GP could choose to use them at the patient's first consultation.

GPs in the intervention practices could access quality reports and get feedback on their LBP patients during the project. This allowed them to reflect on consultation frequency, diagnosis coding, and referral of patients to supplement treatment in comparison with other practices in the MuIS group. Feedback was delivered in a familiar format similar to GPs' feedback on diabetes treatment.

2.5. Outcome measures

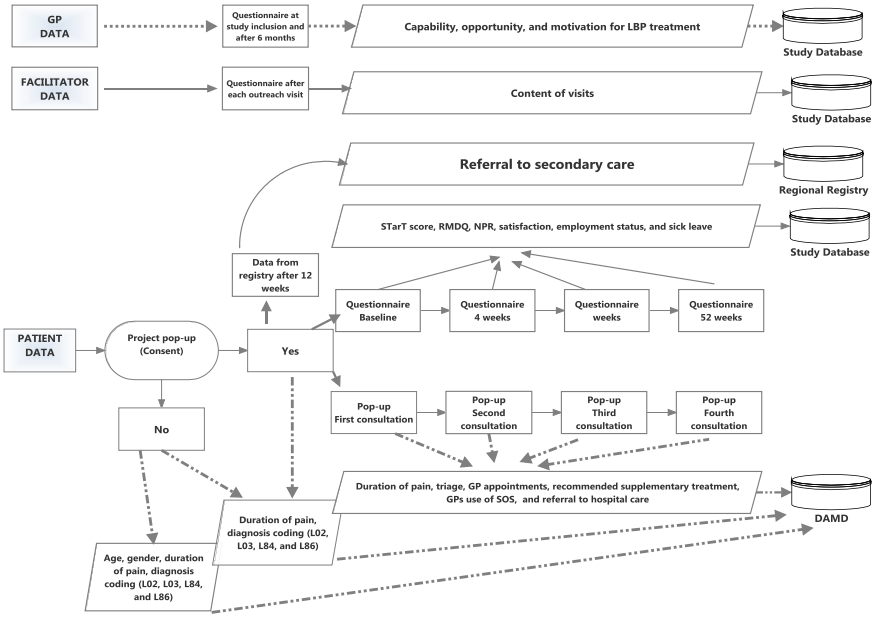
The primary outcome was referral of patients to secondary care within 12 weeks with an LBP code (ICD10 codes DM 40-43, DM 45-49, DM 51, DM 53-54, DM 95-96, and DM 99). The secondary outcomes were patients´ functional level measured by the Roland Morris Disability (RMDQ) score (0–23 points),[43] numerical pain rating (0–

10),[44] EuroQol visual analogue scale (EQ VAS),[45] employment status (y/n), sick leave (y/n), satisfaction with treatment received (0–5 or 6–10), and satisfaction with treatment outcome (0–5 or 6–10). Tertiary outcomes were the STarT Back Tool's ability to identify three groups with different outcomes after 52 weeks and to describe whether the three STarT groups had a different prognosis for functional disability (difference in RMDQ score from baseline to follow-up after 52 weeks).

2.6. Data collection

The North Denmark Regions administration provided data for the primary outcome, which included referrals to Danish hospitals for LBP. The secondary outcomes were self-reported and collected via questionnaires at baseline and after 4, 8, and 52 weeks. Patients could either reply on the Internet or choose to answer paper questionnaires. Data from outreach visits were entered into the database by the outreach visitor. Data from GP questionnaires were also electronically entered on the database. Data collection is depicted in Figure 1. The data were kept and merged by an external data manager at the North Denmark Region Department of Information Technology. Data on patients were merged using the Danish personal identification number.[46]

Figure 1. Flow of data



Note: Data were collected on patients, GPs, and facilitators. Dotted lines indicate reduced data collection.

2.7. Statistics

Descriptive statistics included number (%) for categorical variables, and mean (SD) or median (IQRs) for continuous variables depending on the distribution of the data. Differences in baseline characteristics between the two study groups were analysed using Fisher's Exact Test for categorical variables, and the two-sample t-test, or the Mann–Whitney U-test for continuous variables.

For the primary outcome (referral to secondary healthcare) and the secondary binary outcomes (employment status, sick leave,

satisfaction with received treatment, and satisfaction with treatment outcome), odds ratios (OR) between the two groups were estimated with a generalised estimating equation (GEE) model with logit link and interchangeable correlation to model the within-practice correlation.[47] The continuous outcomes (RDMQ, back pain intensity, and EuroQol VAS) were analysed with linear mixed-effects models with group and weeks from baseline as fixed effects and patients within practices as nested random effects. The fixed effects were modelled as an interaction term between group and weeks from baseline. The method described by Wu et al. was used to estimate the within-cluster correlation in this population using an intra-class correlation coefficient,[48] and a corresponding approximate confidence interval (CI) was calculated by bootstrapping. Results were presented as both unadjusted and adjusted for the patient's age (restricted cubic splines), patient's sex (binary), and practice size (restricted cubic splines).[49] Throughout the analyses, 95% CI were reported and a P value of < 0.05 was considered statistically significant. The power calculation was performed to detect a between-group difference of 5% in referrals to secondary healthcare: 13% in the MuIS group and 18% in the PaIS group. We expected to recruit 100 practices with unequal cluster size. The sample size was estimated with 90% power and a 5% level of confidence. According to a conservative estimate of a likely cluster effect of 16%, we needed to include 2,700 patients. Analyses were performed with Stata (IC version 13.1) (College Station, Texas, USA). The trial was registered at ClinicalTrials.gov (registration number NCT01699256).

CHAPTER 3. RESULTS

All intervention activities in this project fall into three categories: capability, opportunity, and motivation.

3.1. Content of implementation strategies

Use of screening tools could potentially identify patients with work-related or other social problems, however the GPs in the North Denmark Region did not, at that time, have a referral opportunity for these kinds of problems. We arranged for an opportunity to refer patients included in this project to the Department of Social Medicine in the North Denmark Region. This opportunity was offered to all participating practices. All practices were also offered guideline-concordant restructuring of medical record systems, financial incentives (MuIS, ~333 € or PaIS, ~200 €) per GP for participation, and trial-reminding activities (Table 2).

Table 2. Content of implementation strategies

Activities aimed at GPs	Capability	Opportunity	Motivation
Usual activities (offered to both groups)			
Regional information meetings	X		X
Regional website and written material	X		X
Small group continuing medical education	X		X
Passive supportive activities (offered to both groups)			
Social medicine referral opportunity		X	
Electronic medical record pop-ups	X		X
Financial incentives			X
Posters in the practices reminding of guidelines			X
Mouse pads guiding diagnosis coding, medical record procedures and reminders about guidelines	X		X
Pro-active supportive activities (offered to practices in the MuIS group)*			
Outreach visit	X		X
Feedback/quality assurance	X		X
Info-folder delivered at outreach visit	X		X
STart Back stratification tool*	X	X	
Social medical screening tool*	X	X	

Note: *MuIS = multifaceted implementation strategy.

3.2. Evaluation of the recruitment process

The recruitment process was evaluated by the Seven R factors (Table 3). Recruitment was performed from January 2013 to March 2014. During this time, the four recruiters spent an average of one working day per week with recruitment-related activities. Eligible practices had received between 2 and 12 personal contacts, in addition to study promotion at regional meetings with GPs, regional newsletters, local newspapers, and television.

The reasons non-participating practices gave for not signing up for the project were concerns about applying pop-ups and restructuring

their electronic medical record systems. Other reasons were related to the high work load in general practice. Practices often wanted to wait until they had more time to participate in research.

Table 3. Evaluation of the recruitment process

Design stage		*Recruitment stage*	
Components (R-factors)	Planned recruitment components	Barriers identified*	Adaptive changes to the recruitment strategy*
Relationship	This study was conducted in co-operation with the regional quality unit.	Lack of contact information for the main recruiter.	Include all contact information in postal and e-mail correspondence.
Reputation	The main recruiter was head of the research unit. Participation was recommended by the Committee of Multi-practice Studies in General Practice.		
Requirements	General practitioners had to enter a project database and fill out an online questionnaire to register as participants. Intervention group practices had to receive an outreach visit, use patient stratification tools, and access treatment quality reports.	Problems with logging in to the project database to sign up for participation.	E-mails containing a link to the project database replaced postal letters.
Rewards	Participation was an opportunity to get updates on the LBP guidelines. Incentive: 200-333 € per general practitioner. New opportunity to refer patients to the Department of Social Medicine.		
Reciprocity	Information on what was expected from participants and what participants could expect in return was provided. During the study, diagnosis coding would automatically trigger pop-ups. Pop-ups included	Problems with installing the pop-up software.	Contact information with free IT assistance was provided.
		Worries about the extra work related to pop-up	**A brief pop-up guide was sent to all practices and a more detailed explanation was**

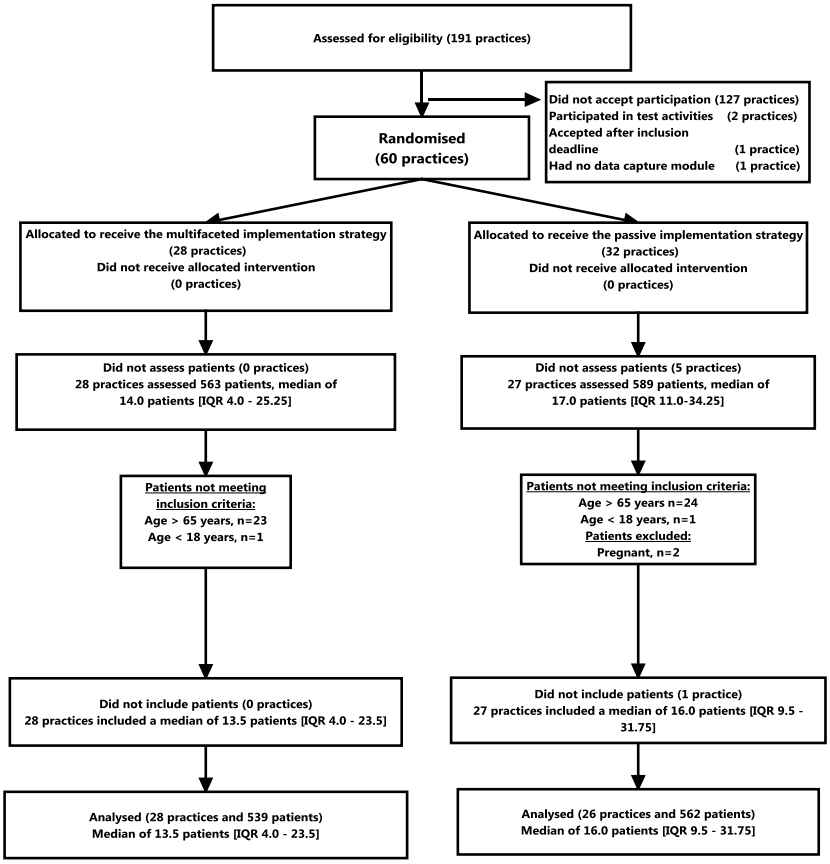
	questions relevant for evidence-based treatment.	**usage.** **Technical problems with pop-ups.**	**delivered upon request.** **Potential participants were given the opportunity to contact the main recruiter at any time.**
R-factors *Continued*	***Design stage***	***Recruitment stage***	
Resolution	Repeated project advocating through personal e-mails, postal letters, regional meetings with general practitioners, regional newsletters, local newspapers, and television.	**Difficulties with establishing the first contact with the general practices. More time than expected was needed to decide on participation.**	**Phone calls to potential participants were planned at weekly meetings of the recruitment group. During the initial contact, a follow-up appointment was made with a contact person in the practice.**
Respect	Aware of communicating our respect for arguments against participation and acknowledging the high workload in general practice. If the practice was to receive an outreach visit, the form and content should be established in co-operation between the outreach visitor and the practice.		

Note: *Empty boxes indicate absence of barriers; the specific R factors [33] were considered to be properly addressed in the planning stage. Boxes with normal text indicate barriers that were identified during recruitment but were successfully addressed by the end of recruitment, and boxes with bold text indicate identified barriers which were not fully addressed by the end of recruitment.

3.3. Flow of participants

We recruited 60 practices. Table 4 describes the participating and the non-participating general practices. Twenty-eight practices were allocated to the MuIS group, and 32 were allocated to the PaIS group. A total of 55 practices (28 MuIS, 27 PaIS) assigned 1,152 patients (566 MuIS, 586 PaIS) for assessment of eligibility. Fifty-four (90%) practices included 1,101 patients for the analysis of the referral of patients to secondary care. The follow-up rate was 100% (Figure 2).

Figure 2. Flow chart



Note: Sixty general practices were included in the study. A total of 55 practices (28 MuIS, 27 PaIS) assigned 1,152 patients (566 MuIS, 586 PaIS) for assessment of eligibility. Fifty-four practices included and contributed 1,101 patients for the analysis of the primary outcome.

3.4. Baseline characteristics

Baseline characteristics for MuIS and PaIS practices were similar (Table 3). Baseline characteristics for included practices, which contributed to the analysis, did not significantly differ from included practices which did not contribute to the analysis. In 2011 GPs in the MuIS group referred 4.99‰ (95% CI 3.51–6.61) of all their listed patients to secondary care with a LBP related diagnosis vs 4.80‰ (95% CI 4.24–5.20) in the PaIS group (p=0.961). However, 70% of the participating practices had a medical outreach visit in 2011, whereas 55% of non-participating practices had a medical outreach visit in 2011 (Table 4).

Table 4. Baseline characteristics for general practices

General practices in the North Denmark Region	Practices in the MuIS group N=28	Practices in the PaIS group N=32	Non-participants N=131	P value Participants vs Non-participants
Practice size (number of patients)	1,883 [IQR 1,602–3,475]	2,086 [IQR 1,649–3,876]	2,227 [IQR 1,642–3,888]	*0.957**
Medical outreach visit in 2011 (yes)	20 (71.4%)	22 (68.8%)	72 (55.0%)	*0.057†*
Referral rate to secondary care in 2011 (‰)	4.4 [IQR 3.0– 6.0]	4.9 [IQR 3.9– 6.5]	5.2 [IQR 3.1– 7.0]	*0.818**

Note: Data are median [IQR] or mean (SD). Referral rates to secondary health care were calculated as the number of patients referred to secondary health care with a LBP diagnosis in 2011 divided by the total number of listed patients in the practice.*Tested by Mann–Whitney U-test. † Tested by Fischer's exact test.

As part of the intervention, all practices in the MuIS group had at least one outreach visit with a median duration of 60 minutes [IQR 60–76.25]; the median time spent on follow-up (visits or phone calls) was 60 minutes [IQR 37.5–60]. At every initial visit, practices were represented by GPs, and in five cases (17.9%) GP trainees also participated. Discussion of clinical examination, triage, coding of patients with LBP, general advice, importance of making follow-up appointments, the STarT Back Tool, questions regarding psycho-social risk factors, referral in primary health care, and handing out of written material were performed at 28 initial visits (100%). Discussion

of patient history and referral to secondary health care was performed at 27 (96%) of the initial visits, whereas instruction in the use of the computer programme was given at 13 (46.4%) of the initial visits.

Patients had a mean age of 43 (SD 12.0) years and 550 (49.8%) were women. The two groups were very similar, except that patients in the MuIS group had an RMDQ score 1.15 points (95% CI 0.04–2.25; p=0.042) higher than the PaIS group (Table 5).

Table 5. Baseline characteristics of patients

Patient characteristics	***MuIS group (n=539)***	***PaIS group (n=562)***	***P value***
Age (years)*	43.8 (11.8)	42.6 (12.1)	0.102‡
Sex (male)*	282 (52.3%)	272 (48.1%)	0.167§
College level education (yes)†	58 (27.2%)	53 (21.3%)	0.156§
Co-morbidity (yes)†	85 (39.9%)	86 (35.5%)	0.383§
Employed or self-employed (yes)†	159 (74.0%)	187 (75.1%)	0.831§
Sick leave with LBP, last 14 days (yes)†	100 (56.2%)	118 (54.4%)	0.761§
RMDQ score (0–23 points)†	14.2 (5.5)	13.0 (5.8)	0.042‡
Back pain intensity (0–10 points)†	6.2 (2.1)	6.1 (2.2)	0.543‡
EQ VAS (0–100 points)†	54.4 (22.8)	55.6 (22.4)	0.559‡
STarT Back Tool score (low risk)†	51 (25.0%)	73 (30.8%)	0.263§
STarT Back Tool score (medium risk)†	89 (43.6%)	87 (36.7%)	
STarT Back Tool score (high risk)†	64 (31.4%)	77 (32.5%)	

Note: Data are mean score (SD) or number (%). * Data collected by the GP at the initial consultation (n=1,101). †Data collected via questionnaires after the initial consultation (n=475). ‡Tested by the two-sample t-test. §Tested by Fisher's Exact Test.

3.5. Missing data from GPs

GPs were planned to contribute with data from the electronic medical record system and from questionnaires (Table 6).

Table 6. Data completeness on the practice level

Question	Completeness
Satisfied with own competences	46 (76.7%)
Would like to improve skills (text)*	30 (50%)
Agreement with guideline	46 (76.7%)
Referral rate to secondary care in relation to STarT Back group (SBT filled in by GP)	0 (0%)
Referral rate to secondary care in relation to STarT Back group (SBT filled in by GP)	0 (0%)
Advised supplementary treatment in relation to STarT Back group (SBT filled in by GP)	0 (0%)

Note: *In the 16 cases where GPs replied with a single word or a minus mark, the response was coded as missing.

3.6. Missing data from patients

All patients contributed to the primary outcome but for the secondary and tertiary outcomes, missing data were an issue (Table 7).

Table 7. Data completeness on the patient level

	Base-line	Week 4	Week 8	Week 12	Week 16	Week 52
Primary outcome						
Referral to secondary care	NA	NA	1,101 (100%)	1,101 (100%)	1,101 (100%)	1,101 (100%)
Secondary outcomes						
Roland Morris Disability score	406 (36.9%)	278 (25.2%)	291 (26.4%)	NA	NA	274 (24.9%)
Numerical Pain Rating	457 (41.5%)	309 (28.1%)	321 (29.2%)	NA	NA	310 (28.2%)
EQ-5D VAS	464 (42.1%)	313 (28.4%)	322 (29.2%)	NA	NA	311 (28.2%)
Employment status	466 (42.3%)	314 (28.5%)	321 (29.2%)	NA	NA	312 (28.3%)
Sick leave	395 (35.9%)	258 (23.4%)	272 (24.7%)	NA	NA	252 (22.9%)
Satisfaction with treatment	NA	303 (27.5%)	307 (27.9%)	NA	NA	300 (27.2%)
Satisfaction with treatment outcomes	NA	295 (26.8%)	303 (27.5%)	NA	NA	299 (27.2%)
Tertiary outcomes						
Advised to stay active	438 (39.8%)	NA	NA	NA	NA	NA
Advised pain medication	456 (41.4%)	NA	NA	NA	NA	NA
RMDQ q9	NA	NA	NA	NA	NA	NA
RMDQ q23	NA	NA	NA	NA	NA	NA
Diagnosis coding	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
STarT (filled in by GP)	0 (0.0%)	NA	NA	NA	NA	NA
Triage (GP)	0 (0.0%)	NA	NA	NA	NA	NA
Duration of pain	0 (0.0%)	NA	NA	NA	NA	NA
Improving	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA
Recommended supplementary treatment	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	NA

3.7. Primary outcome

Twenty-seven patients (5.0%) in the MuIS group were referred to hospital care within 12 weeks vs 59 patients (10.5%) in the PaIS group (AOR 0.52, 95% CI 0.30–0.90; p=0.020) (Table 8). In a sensitivity analysis with follow-up after 8, 16, and 52 weeks, estimates had not significantly changed. The intra-class correlation for the primary outcome after 12 weeks was 0.015 (approximate 95% CI 0.011–0.069).

Table 8. Results for the primary outcome

Follow-up period	**MuIS group***	**PaIS group***	**OR †**	**P value**	**AOR †**	**P value**
Referral to secondary health care (y)						
8 weeks	21 (3.9%)	48 (8.5%)	0.52 (0.28-0.97)	0.039	0.51 (0.28-0.93)	0.029
12 weeks	27 (5.0%)	59 (10.5%)	0.52 (0.29-0.93)	0.027	0.52 (0.30-0.90)	0.020
16 weeks	31 (5.8%)	64 (11.4%)	0.56 (0.32-0.98)	0.041	0.55 (0.32-0.96)	0.034
52 weeks	45 (8.4%)	75 (13.4%)	0.63 (0.39-1.01)	0.056	0.62 (0.39-0.98)	0.040

Note: *Referral data (n=1,101) from registries. Data are numbers (%). †Estimates are unadjusted odds ratios (OR 95% CI) and adjusted odds ratios (AOR 95% CI). Adjustments were made for patients' age, patients' sex, and practice size.

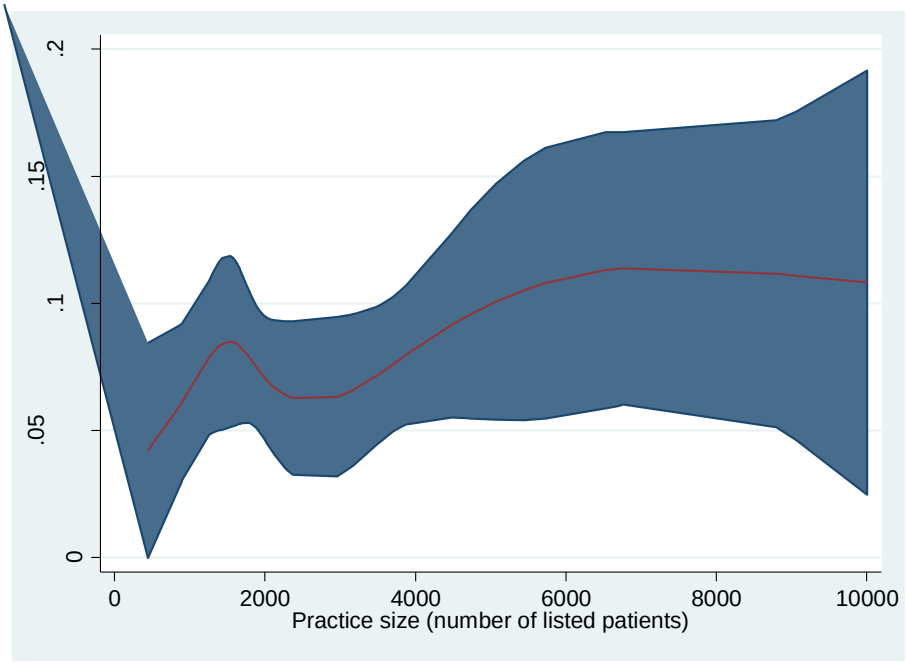
Description: Data were collected from regional registries.

Important changes compared to protocol: By protocol data was planned to be collected from the electronic medical record and validate data with registry data. This study was powered to detect a difference between referral rates of 5% and was powered to recruit

2,700 patients from 100 practices. However, the recruitment for this project unfortunately coincided with a conflict between the Danish regions and the Organisation of General Practitioners in Denmark, and this affected GPs' willingness to participate. Consequently, after 15 months, the inclusion of 60 practices and approximately 1,200 patients were accepted. The decision to change data source was made because the data from the medical records were stored in the DAMD and thus not available. The decision to change data source was made before data was collected (37).

Evaluation: In all models, possible clustering of data was taken into account. Estimates were calculated as both raw and adjusted for practice size, patients' gender, and patients' age. Practices were allocated to intervention groups in random permuted blocks, stratified by practice size. This balancing of treatment arms violates the assumption of independence, introduces correlation between intervention groups, and may introduce type I error if the balancing factor is not properly adjusted for.[50] The association between practice size and the primary outcome is illustrated below in a flexible model using splines (Figure 3).

Figure 3. Association between practice size and referrals



Note: Flexible fitting of referral rates by practice sizes using splines. The 95% confidence interval is illustrated by the shaded area.

Models which allowed for adjustment of practice size in splines were found to better fit data than regression models without this adjustment opportunity. Patients' age was likewise adjusted for using splines. Gender was adjusted for in two categories.

The model (.xtset Ydernummer .xtgee henvist i.group i.gender spline_age* spline_Patienter* , link(logit) family(binomial) corr(exchangeable) eform) in Stata was used to estimate the primary outcome.

Use of registry data might have rendered the measurement unreliable, since data on referral could have been related to later GP consultations for LBP. Given the short period of follow-up (12 weeks), this risk was considered minimal. However, some referrals after 52 weeks may be caused by later episodes of LBP. A sensitivity analysis with follow-up after 8, 16, and 52 weeks was performed to study possible changes in estimates. The results for the primary outcome were not sensitive to changes in the follow-up period.

3.8. Secondary outcomes

Employment status, sick leave, RMDQ, and EQ VAS had a non-significant tendency in favour of the MuIS group, whereas patients in the PaIS group were significantly more satisfied with treatment than patients in the MuIS group (Table 9).

Table 9. Results for the secondary outcomes

	MuIS group*	**PaIS group***	**OR †**	**P value**	**AOR †**	**P value**
Employment status (y)						
after 4 weeks	113 (74.8%)	117 (73.1%)	1.18 (0.67-2.08)	0.563	1.26 (0.71-2.24)	0.424
after 8 weeks	111 (77.1%)	124 (72.1%)	1.36 (0.76-2.43)	0.297	1.42 (0.89-2.26)	0.141
after 52 weeks	101 (71.1%)	109 (71.2%)	1.02 (0.60-1.74)	0.947	0.95 (0.55-1.63)	0.850
Sick leave within 14 days (y)						
after 4 weeks	54 (42.9%)	60 (46.2%)	0.87 (0.55-1.40)	0.577	0.90 (0.57-1.43)	0.658
after 8 weeks	32 (25.4 %)	43 (29.5%)	0.82 (0.44-1.53)	0.533	0.84 (0.44-1.61)	0.605
after 52 weeks	17 (13.7%)	19 (14.8%)	1.00 (0.59-1.73)	0.981	0.97 (0.52-1.82)	0.922
Satisfaction with treatment received (y)						
after 4 weeks	83 (56.5%)	99 (64.3%)	0.72 (0.48-1.07)	0.105	0.75 (0.53-1.07)	0.112
after 8 weeks	81 (57.9%)	114 (68.3%)	0.64 (0.41-0.99)	0.046	0.66 (0.43-1.02)	0.061
after 52 weeks	85 (57.8%)	105 (68.6%)	0.62 (0.39-0.98)	0.040	0.61 (0.39-0.95)	0.029
Satisfaction with treatment results (y)						
after 4 weeks	71 (48.3%)	82 (56.2%)	0.68 (0.47-0.98)	0.037	0.72 (0.51-1.00)	0.050
after 8 weeks	69 (49.3%)	98 (60.1%)	0.64 (0.39-1.04)	0.073	0.66 (0.42-1.05)	0.081
after 52 weeks	75 (51.0%)	102 (67.1%)	0.51 (0.32-0.84)	0.007	0.50 (0.31-0.81)	0.004
RMDQ (0-23 points)			**Unadjusted difference**		**Adjusted difference**	
dif 4 weeks - baseline	-4.23	-2.81	-1.42 (-2.88-0.39)	0.056	-1.34 (2.77-0.09)	0.067
dif 8 weeks - baseline	-5.73	-4.59	-1.14 (-2.59-0.30)	0.121	-1.26 (-2.68-0.16)	0.083
dif 52 weeks - baseline	-7.16	-6.50	-0.67 (-2.13-0.80)	0.373	-0.74 (-2.18-0.70)	0.316
Back pain intensity (0-10 points)						

dif 4 weeks - baseline	-1.96	-1.54	-0.42 (-1.02-0.19)	0.176	-0.53 (-1.12-0.69)	0.083
dif 8 weeks - baseline	-2.29	-2.31	0.03 (-0.57-0.63)	0.931	0.01 (-0.57-0.60)	0.972
dif 52 weeks - baseline	-2.43	-2.77	0.33 (-0.27- 0.93)	0.282	0.29 (-0.30-0.89)	0.328
EQ VAS (0-100 points)						
dif 4 weeks - baseline	10.57	8.78	1.79 (-4.13-7.71)	0.553	2.96 (-2.51-8.43)	0.288
dif 8 weeks - baseline	15.90	13.84	2.06 (-3.83-7.95)	0.493	2.46 (-2.95-7.87)	0.374
dif 52 weeks - baseline	15.46	14.89	0.58 (-5.34-6.50)	0.848	1.25 (-4.20-6.70)	0.653

Note: *Questionnaire data representing 50 practices and 475 patients. Data are number (%) or differences (follow-up – baseline). †Estimates are unadjusted odds ratios (OR 95% CI), adjusted odds ratios (AOR 95% CI), unadjusted mean differences (95% CI), or adjusted mean differences (95% CI). Adjustments were made for patients' age, patients' sex, and practice size.

All secondary outcomes were collected via patient questionnaires. In total 475 (43.1%) patients, representing 50 (83.3%) practices, participated in the questionnaires. Patients participating with questionnaires for the secondary outcomes were on average 3.5 years older and had a tendency to have a higher referral rate than patients not contributing to the secondary outcomes (Table 10). This may have harmed the internal validity of the secondary outcomes.

Table 10. Participated in questionnaires

Characteristics	Yes (n=475)	No (n=626)	P value
Age*	45.2 (*sd* 11.3)	41.7 (*sd* 12.3)	0.001
Gender (male) †	225 (47.4%)	328 (52.4%)	0.101
Secondary care referral†	46 (9.7%)	40 (6.4%)	0.053

Note: * Tested with the two-sample t-test. † Tested with Fischer's exact test.

Employment status

Description: Patients' self-reported their employment status. Data were collected from questionnaires after 4, 8, and 52 weeks. Patients were asked whether or not they had a job. The outcome was coded as a binary variable (yes / no) and analysed using logistic regression models for weeks 4, 8, and 52, with respect to the cluster effect. Estimates were calculated as both raw and adjusted for practice size, patients' gender, and patients' age.

Important change compared to protocol: None.

Evaluation: The data were analysed as planned.

Sick leave

Description: Patients' self-reported their sick leave. Data were collected from questionnaires after 4, 8, and 52 weeks. Patients were asked to fill in the number of hours on sick leave during the last 28 days. The outcome was coded as a binary variable (sick leave / no sick leave) and analysed using logistic regression models for weeks 4, 8, and 52, with respect to the cluster effect. Estimates were calculated as both raw and adjusted for practice size, patients' gender, and patients' age.

Important change compared to protocol: The outcome was originally planned to be analysed as continuous for the number of days on sick leave. The distribution of answers was right-skewed, therefore, this outcome was dichotomised. This was decided while the assessors were blinded to allocation, but familiar with a dummy variable for the outcome.

Evaluation: By dichotomising this outcome, information regarding the duration of sick leave was lost. Hence the outcome measure gave no information about sick leave duration.

Satisfaction with treatment received

Description: Patients' self-reported their satisfaction with treatment received. Data were collected from questionnaires after 4, 8, and 52 weeks. Patients were asked to report their satisfaction from 0-10 on a numerical rating scale. The outcome was coded as a binary variable (0-5 / 6-10) and analysed using logistic regression models for weeks 4, 8, and 52, with respect to the cluster effect. Estimates were calculated as both raw and adjusted for practice size, patients' gender, and patients' age.

Important change compared to protocol: The distribution of answers was not normally distributed, hence the outcome was dichotomised.

Evaluation: Patients often replied on the satisfied end of the scale (8-10) or on the unsatisfied end of the scale (0-2). This supports dichotomising the outcome, since most patients may interpret satisfaction as either yes or no. The use of a non-validated outcome measure may weaken the interpretation of patients' satisfaction with treatment received.

Satisfaction with treatment results

Description: Patients' self-reported their satisfaction with treatment results. Data were collected from questionnaires after 4, 8, and 52 weeks. Patients were asked to report their satisfaction from 0-10 on a numerical rating scale. The outcome was coded as a binary variable (0-5 / 6-10) and analysed using logistic regression models for weeks 4, 8, and 52, with respect to the cluster effect. Estimates were calculated as both raw and adjusted for practice size, patients' gender, and patients' age.

Important change compared to protocol: The distribution of answers was not normally distributed, hence the outcome was dichotomised.

Evaluation: Patients often replied on the satisfied end of the scale (8-10) or on the unsatisfied end of the scale (0-2). This supports dichotomising the outcome, since most patients may interpret satisfaction as either yes or no. The use of a non-validated outcome measure may weaken the interpretation of patients' satisfaction with treatment outcome.

Functional disability

Description: Patients' self-reported their functional disability on questionnaires at baseline and after 4, 8, and 52 weeks. Patients replied to 23 questions related to back pain disability and received a score between 0-23 points. A three point difference was considered clinically relevant. The outcome was calculated as the change from baseline to the score after 4, 8, and 52 weeks. The outcome was analysed in linear regression models with respect to the cluster effect. Estimates were calculated as both raw and adjusted for practice size, patients' gender, and patients' age.

Important change compared to protocol: None.

Evaluation: The data were analysed as planned.

Back pain intensity

Description: Patients' self-reported their back pain on questionnaires at baseline and after 4, 8, and 52 weeks. Patients answered on a 0-10 numerical rating scale. The outcome was calculated as the change from baseline to the score after 4, 8, and 52 weeks. A 30% change was considered clinically relevant. The outcome was analysed in linear regression models with respect to the cluster effect. Estimates were calculated as both raw and adjusted for practice size, patients' gender, and patients' age.

Important change compared to protocol: None.

Evaluation: The data were analysed as planned.

EQ VAS (0-100 points)

Description: Patients' self-reported their health on questionnaires at baseline and after 4, 8, and 52 weeks. Patients answered on a 0-100 numerical rating scale. The outcome was calculated as the change from baseline to the score after 4, 8, and 52 weeks. The outcome was analysed in linear regression models with respect to the cluster effect. Estimates were calculated as both raw and adjusted for practice size, patients' gender, and patients' age.

Important change compared to protocol: It was decided only to include the VAS component in this thesis.

Evaluation: The data were analysed partly as planned. Analysis of the second part of the EQ-5D (the five dimensions) will be included in Cathrine Elgaard Jensen's PhD thesis.

3.9. Tertiary outcomes

Change in beliefs and behaviour

Description: The intervention in this project was expected to change referral rates and patient reported outcomes through several steps. The first step was to change GPs' beliefs and behaviours. If the intervention was effective in changing GPs' behaviour, the next casual step involved a change in patients' beliefs and behaviours (Table11).

Table 11. Results for the tertiary outcomes

Process	**Measure**	MuIS	PaIS	**MuIS vs. PaIS**	**P value (Non adjusted)**
GPs' skills	Satisfied with own abilities[a]	20 (83.3%)	20 (91.0%)	↓	0.667
GPs' beliefs	Agreement with guidelines[a]	135 (93.8%)	123 (93.2%)	↑	1.000
GPs; behaviour	Have recommended to stay active[b]	135 (65.9%)	137 (58.8%)	↑	0.139
	Have recommended pain reducing medicine[c]	147 (69.3%)	167 (68.4%)	↑	0.840
Patients´ beliefs	Fear avoidance[d]	61 (40.1%)	74 (42.8%)	↑	0.653
Patients´ behaviour	Worried about what is happening with my health[e]	41 (27.3%)	36 (20.7%)	↓	0.191

Note: Process evaluation. [a]GP questionnaire, [b-c]questions in patient questionnaire at week 0, [d]Roland Morris Patrick question 9 at week 8,[e]Roland Morris Patrick question 23 at week 8. Tests are performed with Fishers' exact test.

Important change compared to protocol: GPs were also asked for areas in which they would like to improve their abilities for treating LBP. Responses were very short and therefore difficult to interpret. The majority of responses were related to the examination of patients

with LBP and to improve their ability to provide exercise instructions. Information on diagnosis coding, triage, STarT Back filled in by the GP, and information regarding improvements in patients' symptoms were lost with the DAMD.

Evaluation: The interpretation of the process evaluation was impaired by the low response rate in GP questionnaires and patient questionnaires, combined with the ceiling effect in the GP questionnaires and lost data. Results in Table 11 should be interpreted with caution.

Delivery of intended intervention

Table 12. Delivered intervention

Outreach visit	**N=28 (100%)**
Duration initial visit (median, iqr)	60 [60-76.25]
Duration follow-up (median, iqr)	60 [37.5-60]
Number of visits including medical candidates under training	5 (18%)
Number of visits including other clinical staff members	0 (0%)
Discussion of taking the patient's history	27 (96%)
Discussion of clinical examination	28 (100%)
Discussion of triage	28 (100%)
Discussion of coding of LBP diagnosis	28 (100%)
Discussion of general advices	28 (100%)
Discussion of making new appointments	28 (100%)
Discussion of STarT Back Tool	28 (100%)
Discussion of screening for social issues	28 (100%)
Discussion of referral in primary care	28 (100%)
Discussion of referral to hospital care	27 (96%)
Handed out written material	28 (100%)
Instruction in pop-up usage (only verbally delivered)	15 (54%)
Instruction in pop-up usage (at a computer screen)	13 (46%)

Description: The intervention delivered was planned to be measured for outreach visits (Table 12), follow-up contacts, use of STarT & SOS, and access to quality reports.

Important change compared to protocol: Due to loss of access to the DAMD, use of STarT & SOS and quality reports could not be reported.

Evaluation: Outreach visits and follow-up contacts were delivered with high fidelity. We do not know the fidelity of the other intervention components. Probably 50-75% of intervention practices had accessed quality reports once or several times and probably between 20-40% of the patients in the intervention group has been scored with STarT & SOS by the GP. However quality reports and STarT & SOS were discussed during every initial outreach visit (Table 12).

CHAPTER 4. DISCUSSION

The MuIS reduced the 12-week referral to secondary health care from 10.5% to 5.0%, without significantly changing patients' functional levels, pain levels, or self-rated health, whereas patients' satisfaction was significantly reduced compared with the PaIS group. A sensitivity analysis with follow-up after 8, 16, and 52 weeks did not change the conclusions.

This was a large randomised trial including 60 general practices and 1,101 patients. However, recruitment was lower than the expected 100 practices. The need to involve end-users in the development of or otherwise gain GPs' acceptance of new software and the amount of time needed to conduct recruitment were underestimated. Participating practices were generally more likely to have an outreach visit from the regional quality unit in 2011 compared with the 131 non-participating general practices. Otherwise, baseline characteristics regarding practice size and referral rates of patients with an LBP-specific diagnosis were similar.

Data for the primary outcome (referral to secondary care) were expected to be collected from the DAMD and validated with data from a regional registry. Since data from the DAMD were not used, the regional registry was the only provider of data for the primary outcome. This change in data source may have introduced concerns regarding reliability, since referrals may be related to later incidences of LBP. This risk was, however, expected to be small for referrals after 12 weeks, but the risk could be higher at follow-up after 52 weeks. If reliability was an issue after 52 weeks, it would be expected

to influence the two groups equally, hence not expected to introduce bias. Data collection from the regional registries enabled a 100% follow-up on referrals. Data on excluded patients, diagnosis coding, duration of pain, and assessment by GPs could have strengthened the analysis.

Patients were told that they could participate in the study without filling out questionnaires; this may have affected the response rate. The response rate for the secondary outcomes was low with 475 (43.1%) responders representing 50 (83.3%) of the practices and responders were older than non-responders. Hence, the validity of the secondary outcomes may be reduced.

We used a combined set of outcomes recommended for studies on LBP.[51] The patient-reported outcomes were evaluated using validated measures, whereas questions regarding satisfaction with treatment received and satisfaction with treatment outcomes were tailored to fit our setting. Hence, the questions had not been validated by us or anyone else. This weakened the interpretation of the two outcomes on satisfaction. For both outcome measures on satisfaction, less satisfaction was found among patients in the MuIS group. This discrepancy between better functional outcome measures and less patient satisfaction has been reported before; RMDQ was not correlated with patient satisfaction, but high general health perception measured by Shortform 12 was associated with satisfaction with health status.[52] This was also found by Henschke and colleagues, where poor general health could determine patient dissatisfaction one year after the initial visit to primary health care.[53] Self-rated health was measured with the EQ VAS. Even though

patients in the MuIS group at baseline were an average of 1.15 points on RMDQ below the PaIS group, the MuIS group had larger improvements in EQ VAS. Hence, dissatisfaction cannot be explained by poor health status in our setting. Other reasons in our study could be related to GPs' advice to stay active regardless of pain, or that patients with low risk were recommended minimum treatment, or it could be related to unfulfilled expectations induced by GPs' information of an expected good prognosis. However, we do not know why patients in the MuIS group were more dissatisfied than patients in the PaIS group.

We had planned a comprehensive process evaluation of the change in beliefs and behaviour of the GPs and the patients. This evaluation should have been based on data regarding improvements in patients' condition and SOS and STarT scores from the GPs' medical record systems. The data were stored in the DAMD. Therefore, the data were not available for research. This loss of data weakened the interpretation of our results of the tertiary outcomes compared to the protocol.[36]

4.1. Implementation of guidelines

A few randomised trials have studied implementation of LBP clinical guidelines in general practice using different strategies.[54-58] The use of physiotherapists as facilitators in general practice was distinctive for our project. In a randomised study from the UK with outreach visits and triage service to implement guidelines did not change clinical behaviour.[54] In another large cluster randomised

trial, an implementation strategy including four basic education modules and flyers for patients, was not found to be effective compared with postal dissemination of the guidelines. However, when motivational counselling of patients was added (each patient had up to three counselling sessions each lasting 10 to 15 minutes), a small but significant difference in patients' functional level was found.[55] Similar to our project, the two studies included outreach visits at GPs' work environments, which in our setting typically took place during an extended lunch break. Other studies have used workshops to implement LBP guidelines.[56-57] A Dutch guideline implementation study included a two-hour educational and clinical practice workshop in addition to a screening tool for patients with LBP and a tool for patient education. The intervention reduced inappropriate referrals from general practice to therapists (physical, exercise, or manual therapists).[56] In the IMPLEMENT study, the authors found a change in clinician behaviour (knowledge, attitudes, and intentions), but the change in attitude was not reflected in differences in the actual referral rate to X-ray or CT scan.[57] A study consisting of passive transfer of knowledge by postal letters with guidelines and reminders was unsuccessful in improving concordance with Canadian LBP guideline recommendations.[58] The use of a clinical decision support system, as part of a multifaceted strategy, together with quality reports and peer-to-peer consultations was studied in a large cohort study with 1,200 GPs and 23,685 patients. The multifaceted strategy was found to be effective in reducing MRI referrals from 5.3% to 3.7%.[59] The present project also found a high effect size on clinical behaviour (referral rate), but only following a broader intervention that included both clinical decision support, feedback (statistics regarding

LBP patients), and outreach visits. Compared with the other trials aimed at GPs, we estimate that our intervention dose in terms of GP-time spent together with outreach visitors, peers, or others taking part in an intervention, was slightly below average.

4.2. STarT Back Tool

STarT Back Tool was part of a combined intervention to the MuIS group. The STarT Back Tool was discussed at the outreach visits and integrated in the medical record systems at the MuIS practices. In addition STarT Back Tool was included in the patients' questionnaire at baseline; information from the patients' questionnaires was not available for the GPs.

The regional guideline does not specifically recommend the STarT Back Tool but mentions it as an opportunity for better subgrouping patients with LBP. The inclusion of STarT Back Tool as part of the intervention in this study was based on the assumption that the STarT Back score was predictive of patients' risk of complexity in our setting and that the recommended pathway for supplementary treatment (y/n) would benefit patients.

A previous study has found STarT Back Tool able to predict improvements in the RMDQ score in a Danish primary care setting (RR 2.4 for low-risk vs medium-risk and RR 2.8 for low-risk vs high-risk).[60] Lower predictive ability has been found in Danish secondary care (RR 1.5 for low-risk vs medium-risk and RR 1.7 for low-risk vs high-risk).[61] The STarT Backs' ability to identify patients at risk of higher levels of disability has furthermore been supported in a study

recruiting from a university community in Canada. Where participants were recruited by an advertisement in a local newspaper for screening of LBP in a chiropractic clinic.[62] However, STarT Back was not able to predict outcomes in two studies of patients seeking care at chiropractic clinics in Denmark and the UK.[63-64] A study in Florida recruited 146 patients from physiotherapy clinics. In that study, subgrouping by STarT Back could identify distinctive patterns between the low-risk group and the high-risk group, but not when comparing the medium-risk group with the other two groups.[65] The STarT Back Tool's ability to predict outcomes could therefore be dependent on the setting. Inclusion of an analysis to estimate the predictive value of STarT Back Tool has been considered. However, this analysis required a transformation of the study design to a cohort study. This was found out of scope of this thesis and would have involved methodological challenges since the STarT Back Tool was a part of the intervention in this randomised trial.

Treating patients according to their STarT Back group has been found to be both effective in improving patients' Roland Morris disability score and cost saving (annual £34.39 per patient) in a large study published in the Lancet.[42] These findings have been supported in a prospective study in English general practice (IMPaCT Back), where the use of STarT led to significant improvements in patient disability, without increasing health care costs.[66] The targeted treatments for patients seen in general practice include a minimal intervention delivered by GPs (for patients at low-risk of persistent symptoms), a referral to primary care supplementary treatment addressing pain and disability (for patients at medium-risk of persistent symptoms), or additional cognitive-behavioural

approaches to help address psychological and social obstacles for recovery (for patients at high-risk of persistent symptoms).[67] In our setting we did not provide a specific education for the physiotherapists in the region or other clinicians aimed at addressing psychological and social obstacles to recovery for patients at high-risk – like in the large STarT Back trial.[42] The effect in our study could probably have been optimised by an education programme aimed at the physiotherapist delivering the treatment to the patients. However, the fact that the STarT Back Tool is included in an intervention package with other guideline supporting initiatives may on the other hand have strengthened the effect of the STarT Back Tool. In this study the STarT Back Tool was integrated in the medical record system at the MuIS practices and could be filled in by the GP. This use of STarT Back Tool is not consistent with how the STarT Back Tool has been validated and found effective.[60,42]

The use of the STarT Back Tool is increasing and as of March 2016 it has been translated into Danish and 21 other languages.[68-69] A project in two other Danish regions is currently studying the efficiency of the STarT Back Tool in Danish primary care. [70] This project provides an education programme to the primary care physiotherapists similar to the intervention in the large STarT Back study from 2011.[42]

4.3. Perspectives

The results of this project supported applying a multifaceted implementation strategy instead of a more passive implementation

strategy when introducing guidelines for LBP in general practice. Even though the MuIS was effective in reducing referrals, it seems to have drawbacks in relation to patients' satisfaction. Future research may provide suggestions for optimising the strategy. Therefore, it could be advisable for policy makers to consider this kind of guideline implementation strategy when delivering guidelines and maybe combine implementation with routine or ad hoc monitoring of the processes of implementation. Performing a cost-effectiveness analysis and monitoring procedures are also in line with recommendations following a successful intervention and is the next stage following randomised controlled trials: stage four in the ChiPP model.[34]

Researchers are conducting more high-quality studies on new treatment methods than ever before, however, new evidence-based treatments are often slowly implemented into clinical practice. This leaves a gap between what we know and what we do in public healthcare.[69] We are entering what has been called the era of implementation;[71] hopefully this new era will bring further knowledge on how to support clinicians, reduce research waste, and advance public health outcomes. [72]

CHAPTER 5. CONCLUSION

The MuIS reduced the 12-week referral to secondary health care from 10.5% to 5.0%. After 52 weeks, the estimates were 13.4% and 8.4%. The MuIS did not significantly change patients' functional levels, pain levels, or self-rated health, whereas patients' satisfaction with treatment was significantly lower in the MuIS group compared with patients in the PaIS group.

REFERENCES

(1) Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, et al. A systematic review of the global prevalence of low back pain. Arthritis Rheum. 2012 Jun;64(6):2028-2037.

(2) Hayes VS, Chritoffanini SL, Kraemer SRJ, Johnsen SR, Vinding AL. Health Profile 2013: Trivsel, sundhed og sygdom i Nordjylland. The North Denmark Region. 2014 March. Danish. Available at: http://www.rn.dk/~/media/Rn_dk/Sundhed/Til%20sundhedsfaglige%20og%20samarbejdspartnere/Sundhedsfremme%20og%20forebyggelse/Sundhedsprofil/Sundhedsprofil_2013_final.ashx. Accessed November 9, 2015.

(3) Flachs EM, Eriksen L, Koch MB, Ryd JT, Dibba E, Skov-Ettrup L, Juel K. National Institute of Public Health. University of Southern Denmark. Sygdomsbyrden i Danmark – sygdomme (The burden of disease in Denmark). Copenhagen; Danish Health Authority; Oct 2015. Available from: https://sundhedsstyrelsen.dk/da/nyheder/2015/~/media/00C6825B11BD46F9B064536C6E7DFBA0.ashx.

(4) Newton JN, Briggs AD, Murray CJ, Dicker D, Foreman KJ, Wang H, et al. Changes in health in England, with analysis by English regions and areas of deprivation, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet. 2015 Sep; 14.

(5) Hartvigsen J, Frederiksen H, Christensen K. Back and neck pain in seniors-prevalence and impact. Eur Spine. J 2006 Jun;15(6):802-806.

(6) Hoy D, March L, Brooks P, Woolf A, Blyth F, Vos T, et al. Measuring the global burden of low back pain. Best Pract Res Clin Rheumatol. 2010 Apr;24(2):155-165.

(7) Meucci RD, Fassa AG, Faria NM. Prevalence of chronic low back pain: systematic review. Rev Saude Publica. 2015;49:1-10.

(8) Manchikanti L, Singh V, Falco FJ, Benyamin RM, Hirsch JA. Epidemiology of low back pain in adults. Neuromodulation. 2014 Oct;17 Suppl 2:3-10.

(9) Lemeunier N, Leboeuf-Yde C, Gagey O. The natural course of low back pain: a systematic critical literature review. Chiropr Man Therap. 2012 Oct 17;20(1):20-33.

(10) Chen SM, Liu MF, Cook J, Bass S, Lo SK. Sedentary lifestyle as a risk factor for low back pain: a systematic review. Int Arch Occup Environ Health. 2009 Jul;82(7):797-806.

(11) Bohman T, Alfredsson L, Jensen I, Hallqvist J, Vingard E, Skillgate E. Does a healthy lifestyle behaviour influence the prognosis of low back pain among men and women in a general population? A population-based cohort study. BMJ Open. 2014 Dec 30;4(12):e005713-2014-005713.

(12) Hancock MJ, Maher CG, Laslett M, Hay E, Koes B. Discussion paper: what happened to the 'bio' in the bio-psycho-social model of low back pain? Eur Spine J. 2011 Dec;20(12):2105-2110.

(13) Nicholas MK, Linton SJ, Watson PJ, Main CJ, "Decade of the Flags" Working Group. Early identification and management of psychological risk factors ("yellow flags") in patients with low back pain: a reappraisal. Phys Ther. 2011 May;91(5):737-753.

(14) Cook CE, Taylor J, Wright A, Milosavljevic S, Goode A, Whitford M. Risk factors for first time incidence sciatica: a systematic review. Physiother Res Int. 2014 Jun;19(2):65-78.

(15) Somerville S, Hay E, Lewis M, Barber J, van der Windt D, Hill J, et al. Content and outcome of usual primary care for back pain: a systematic review. Br J Gen Pract. 2008 Nov;58(556):790-7, i-vi.

(16) Davis D, Evans M, Jadad A, Perrier L, Rath D, Ryan D, et al. The case for knowledge translation: shortening the journey from evidence to effect. BMJ. 2003 Jul 5;327(7405):33-35.

(17) Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581-629.

(18) Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. CMAJ. 1995 Nov 15;153(10):1423-1431.

(19) Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technol Assess. 2004 Feb;8(6):iii-iv, 1-72.

(20) Squires JE, Sullivan K, Eccles MP, Worswick J, Grimshaw JM. Are multifaceted interventions more effective than single-component interventions in changing health-care professionals' behaviours? An overview of systematic reviews. Implement Sci. 2014 Oct 6;9:152-014-0152-6.

(21) Prior M, Guerin M, Grimmer-Somers K. The effectiveness of clinical guideline implementation strategies--a synthesis of systematic review findings. J Eval Clin Pract. 2008 Oct;14(5):888-897.

(22) Glasziou P, Haynes B. The paths from research to improved health outcomes. Evid Based Nurs. 2005 Apr;8(2):36-38.

(23) Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci. 2011 Apr 23;6:42.

(24) McDonald AM, Knight RC, Campbell MK, Entwistle VA, Grant AM, Cook JA, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Trials. 2006 Apr 7;7:9.

(25) Hysong SJ, Smitham KB, Knox M, Johnson KE, Sorelle R, Haidet P. Recruiting clinical personnel as research participants: a framework for assessing feasibility. Implement Sci. 2013 Oct 24;8(1):125.

(26) Goodyear-Smith F, York D, Petousis-Harris H, Turner N, Copp J, Kerse N, et al. Recruitment of practices in primary care research: the long and the short of it. Fam Pract. 2009 Apr;26(2):128-136.

(27) McBride PE, Massoth KM, Underbakke G, Solberg LI, Beasley JW, Plane MB. Recruitment of private practices for primary care research: experience in a preventive services clinical trial. J Fam Pract. 1996 Oct;43(4):389-395.

(28) Clarke C, Hartery L, Worrall G. Recruiting family doctors for research studies. Can Fam Physician. 1998 Mar;44:472-3, 479-81.

(29) Johnston S, Liddy C, Hogg W, Donskov M, Russell G, Gyorfi-Dyke E. Barriers and facilitators to recruitment of physicians and practices for primary care health services research at one centre. BMC Med Res Methodol. 2010 Dec 13;10:109.

(30) Asch S, Connor SE, Hamilton EG, Fox SA. Problems in recruiting community-based physicians for health services research. J Gen Intern Med. 2000 Aug;15(8):591-599.

(31) Cave A, Ahmadi E, Makarowski C. Recruiting issues in community-based studies: some advice from lessons learned. Can Fam Physician. 2009 May;55(5):557-558.

(32) Carey TS, Kinsinger L, Keyserling T, Harris R. Research in the community: recruiting and retaining practices. J Community Health. 1996 Oct;21(5):315-327.

(33) Solberg LI. Recruiting medical groups for research: relationships, reputation, requirements, rewards, reciprocity, resolution, and respect. Implement Sci. 2006 Oct; 26;1:25.

(34) Bro F, Rowlands G. Interventions to change physician performance: the ChiPP (Change in professional performance) statement. Quality in Primary Care. 2006;14:65-70.

(35) The North Denmark Region. Regional low back pain guidelines. Available from. https://www.sundhed.dk/sundhedsfaglig/praksisinformation/almen-praksis/nordjylland/patientforloeb/forloebsbeskrivelser/l-muskel-skelet-system/laendesmerter. Danish, 2013.

(36) Riis A, Jensen CE, Bro F, Maindal HT, Petersen KD, Jensen MB. Enhanced implementation of low back pain guidelines in general practice: study protocol of a cluster randomised controlled trial. Implement Sci. 2013 Oct 20;8:124.

(37) Jensen CE, Riis A, Pedersen KM, Jensen MB, Petersen KD. Study protocol of an economic evaluation of an extended implementation strategy for the treatment of low back pain in general practice: a cluster randomised controlled trial. Implement Sci. 2014 Oct 8;9:140.

(38) Danish Quality Unit of General Practice. About DAK-E. 2015; Available at: http://www.dak-e.dk/flx/english/dak_e_it/about_dak_e_it/.

(39) Okkes IM, Becker HW, Bernstein RM, Lamberts H: The March 2002 update of the electronic version of ICPC-2. A step forward to the use of ICD-10 as a nomenclature and a terminology for ICPC-2. Fam Pract. 2002; 19(5):543-546.

(40) Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet. 2003 Oct 11;362(9391):1225-1230.

(41) Gagliardi AR, Marshall C, Huckson S, James R, Moore V. Developing a checklist for guideline implementation planning: review and synthesis of guideline development and implementation advice. Implement Sci. 2015 Feb 12;10(1):19-015-0205-5.

(42) Hill JC, Whitehurst DG, Lewis M, Bryan S, Dunn KM, Foster NE, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet. 2011 Oct 29;378(9802):1560-1571.

(43) Roland MO, Morris RW. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. Spine. 1983; 8(2):141-144.

(44) Farrar JT, Young JP,Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain. 2001 Nov;94(2):149-158.

(45) Cortes J, Blanco JF, Pescador D, Asensio N, Castro C, Herrera JM. New model to explain the EQ-5D VAS in patients who have undergone spinal fusion. Qual Life Res. 2010 Dec;19(10):1541-1550.

(46) Det Centrale Personregister. Registry for the Danish personal identification number. Available from: https://cpr.dk/in-english.

(47) Korendijk EJ, Hox JJ, Moerbeek M, Maas CJ. Robustness of parameter and standard error estimates against ignoring a contextual effect of a subject-level covariate in cluster-randomized trials. Behav Res Methods. 2011 Dec;43(4):1003-1013.

(48) Wu S, Crespi CM, Wong WK. Comparison of methods for estimating the intraclass correlation coefficient for binary responses in cancer prevention cluster randomized trials. Contemp Clin Trials. 2012 Sep;33(5):869-880.

(49) Harrell FE. Regression Modeling Strategies. With application to linear Models, Logistic and Ordinal Regressions, and Survival Analysis. 2nd ed. Springer. Cham. 2015.

(50) Kahan BC, Morris TP. Reporting and analysis of trials using stratified randomisation in leading medical journals: review and reanalysis. BMJ. 2012;345:e5840.

(51) Bombardier C. Outcome assessments in the evaluation of treatment of spinal disorders. Introduction. Spine (Phila Pa 1976). 2000 Dec 15;25(24):3097-3099.

(52) Takeyachi Y, Konno S, Otani K, et al. Correlation of low back pain with functional status, general health perception, social

participation, subjective happiness, and patient satisfaction. Spine. 2003; 28:1461,6–7.

(53) Henschke N, Wouda L, Maher CG, Hush JM, van Tulder MW. Determinants of patient satisfaction 1 year after presenting to primary care with acute low back pain. Clin J Pain. 2013; 29:512–517.

(54) Dey P, Simpson CW, Collins SI, et al. Implementation of RCGP guidelines for acute low back pain: a cluster randomised controlled trial. Br J Gen Pract. 2004;54(498):33-37.

(55) Becker A, Leonhardt C, Kochen MM, Keller S, Wegscheider K, Baum E, et al. Effects of two guideline implementation strategies on patient outcomes in primary care: a cluster randomized controlled trial. Spine (Phila Pa 1976). 2008 Mar 1;33(5):473-480.

(56) Engers AJ, Wensing M, van Tulder MW, Timmermans A, Oostendorp RA, Koes BW, et al. Implementation of the Dutch low back pain guideline for general practitioners: a cluster randomized controlled trial. Spine (Phila Pa 1976). 2005 Mar 15;30(6):559-600.

(57) French SD, McKenzie JE, O'Connor DA, Grimshaw JM, Mortimer D, Francis JJ, et al. Evaluation of a theory-informed implementation intervention for the management of acute low back pain in general medical practice: the IMPLEMENT cluster randomised trial. PLoS One. 2013 Jun 13;8(6):e65471.

(58) Bishop PB, Wing PC. Knowledge transfer in family physicians managing patients with acute low back pain: a prospective randomized control trial. Spine J. 2006 May-Jun;6(3):282-288.

(59) Ip IK, Gershanik EF, Schneider LI, Raja AS, Mar W, Seltzer S, et al. Impact of IT-enabled intervention on MRI use for back pain. Am J Med. 2014 Jun;127(6):512-8.e1.

(60) Morso L, Kent P, Albert HB, Hill JC, Kongsted A, Manniche C. The predictive and external validity of the STarT Back Tool in Danish primary care. Eur Spine J. 2013 Aug;22(8):1859-1867.

(61) Morso L, Kent P, Manniche C, Albert HB. The predictive ability of the STarT Back Screening Tool in a Danish secondary care setting. Eur Spine J. 2014 Jan;23(1):120-128.

(62) Page I, Abboud J, O Shaughnessy J, Laurencelle L, Descarreaux M. Chronic low back pain clinical outcomes present higher associations with the STarT Back Screening Tool than with physiologic measures: a 12-month cohort study. BMC Musculoskelet Disord. 2015 Aug 19;16:201-015-0669-0.

(63) Kongsted A, Andersen CH, Hansen MM, Hestbaek L. Prediction of outcome in patients with low back pain - A prospective cohort study comparing clinicians' predictions with those of the Start Back Tool. Man Ther. 2015 Jun 23;

(64) Newell D, Field J, Pollard D. Using the STarT Back Tool: Does timing of stratification matter? Man Ther. 2015 Aug;20(4):533-539.

(65) Beneciuk JM, Robinson ME, George SZ. Subgrouping for patients with low back pain: a multidimensional approach incorporating cluster analysis and the STarT Back Screening Tool. J Pain. 2015 Jan;16(1):19-30.

(66) Foster NE, Mullis R, Hill JC, Lewis M, Whitehurst DG, Doyle C, et al. Effect of stratified care for low back pain in family practice (IMPaCT Back): a prospective population-based sequential comparison. Ann Fam Med. 2014 Mar-Apr;12(2):102-111.

(67) Sowden G, Hill JC, Konstantinou K, Khanna M, Main CJ, Salmon P, et al. Targeted treatment in primary care for low back pain: the treatment system and clinical training programmes used in the IMPaCT Back study (ISRCTN 55174281). Fam Pract. 2012 Feb;29(1):50-62.

(68) Morso L, Albert H, Kent P, Manniche C, Hill J. Translation and discriminative validation of the STarT Back Screening Tool into Danish. Eur Spine J. 2011 Dec;20(12):2166-2173.

(69) The STarT Back Group. Keele University. Available from: https://www.keele.ac.uk/sbst/startbacktool/translatiotions.

(70) Morsoe L. Low Back Pain - What's Next? Stratified Care Compared to Current Practice. Available from: https://clinicaltrials.gov/ct2/show/NCT02612467?term=STarT+Back+Tool&rank=1.

(71) Horton R. Public health research in the UK: the era of implementation. Lancet 2015 Nov 13;386 Suppl 2:S1-6736.

(72) Al-Shahi Salman R, Beller E, Kagan J, Hemminki E, Phillips RS, Savulescu J, et al. Increasing value and reducing waste in biomedical research regulation and management. Lancet. 2014 Jan 11;383(9912):176-185.

ISSN (online): 2246-1302
ISBN (online): 978-87-7112-429-3

AALBORG UNIVERSITY PRESS