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Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025921
Article Type:	Research
Date Submitted by the Author:	14-Aug-2018
Complete List of Authors:	Jensen, Morten; Centre for Quality, Region of Southern Denmark; The Institute of Regional Health Research, University of Southern Denmark Olsen, Kim; DaCHE, Institute of Public Health, University of Southern Denmark Morsø, Lars; Centre for Quality, Region of Southern Denmark; Institute of Public Health, University of Southern Denmark, DaCHE Søndergaard, Jens; Research Unit of General Practice, Institute of Public Health, University of Southern Denmark Schiøttz-Christensen, Berit; Institute of Regional Health Research, University of Southern Denmark., Centre of Southern Denmark, Middelfart Hospital, a part of Hospital Lillebaelt,
Keywords:	Magnetic resonance imaging < RADIOLOGY & IMAGING, PUBLIC HEALTH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Low Back Pain

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Titel:

Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data

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Key Words:

Keywords: MRI-rate, lumbar MRI, Direct Referral to MRI, Registry Data, Statistics Denmark, Low Back Pain , Organisational Changes

Word Count

3284

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Abstract

Objectives:

This study reports lumbar MRI referral patterns in Region of Southern Denmark (RSD) and investigate the hypothesis that we will see an increase in lumbar magnetic resonance imaging rates (MRI-rates) in RSD in comparison with the other regions in Denmark from 2010-2013.

Design:

A difference-in-difference (DD) analysis, using GPs in other Regions as control, was used to test if the new referral options had an effect on the MRI rates.

Setting:

In 2010, RSD introduced organisational changes to the referral options for lumbar MRI. Firstly, the possibility for direct referral to lumbar MRI was introduced to General practitioner's (GP), and secondly the region gathered all local spine departments into one specialist hospital called the Spine Centre.

Participants:

We retrieved all lumbar MRIs performed on patients aged 18+ performed on Danish hospitals from 2008-2013 using the registries from Statistics Denmark. We use socio-demographic information from all Danish citizens aged 18+ aggregated to GP level.

Primary and secondary outcome measures:

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Lumbar MRI scans per 1.000 capita enlisted with a GP (MRI-rates) were calculated based on GP's patient list. Four referral types were made to describe changes in referral patterns.

Results:

In total 183.389 patients received 240.760 lumbar MRIs in the period. The use of the direct referral option by GPs in the RSD increased by 115% in the period from 2010 to 2013 and accounted for 34% of all referrals (N = 6,545) in 2013. MRI-rates were significantly higher in RSD following the organisational changes (DD 1.389 [0.925,1.852] lumbar MRI per 1.000 enlisted with a GP).

Conclusions:

Introduction of organisational changes in RSD as direct referral to MRI from GPs and Chiropractors as well as establishing a Spine Centre increase the lumbar MRI rate in comparison with other regions in Denmark.

Strengths and limitations of this study:

- Registry study relying on a natural experiment
- Nation-wide registry data including socio-demographic information on all citizens aged 18+
- Use of a Difference-in-Difference design for possible causal inference
- The study might underestimate the lumbar MRIs from private hospitals

Background

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The number of lumbar magnetic resonance imaging (MRI) undertaken in the United States (US) Medicare population increased substantially from 1994 to 2006, despite guidelines which discourages routine use of MRI [1-3]. It was estimated that the use of MRI and other imaging modalities accounted for 7% of the direct treatment costs of LBP in 1998 [4].

The factors associated with the increased use of MRI in the diagnostics of low back pain have been investigated. Research shows that the substantial geographic differences in use of spinal MRI across states in the US [5-8] can be explained by differences in local clinical practices [6], physician ownership of specialty hospitals [9], fee-for-service schemes [10], MRI-scanner availability [11] and state median income per capita [12]. However, these studies were undertaken in a US-setting among populations that had limited access to health care providers and where a fee-for service incentive affected doctors' wages. Consequently, more studies are needed on factors impacting the use of lumbar MRI, in other health care settings [13-15].

In this study we have the opportunity of using nation-wide data and hence evaluating a natural experiment. In 2010, Region of Southern Denmark (RSD), made two organisational changes. These included, centralisation of regional spine specialist departments across regional hospitals in one spine specialist hospital. Further, General Practitioners (GPs) and chiropractors were given the possibility to directly refer LBP patients for lumbar MRI without prior referral to the Spine Centre or to office-based specialist doctors. In the support of the organisational changes, RSD implemented a LBP Disease Management Programme (DMP). These changes were unique in Denmark as two of four other regions maintained decentralised spine departments and did not allow for direct referral. Hence these regions act as a good indicator of the counterfactual RSD.

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Like GPs in RSD, GPs in the Capitol Region (CR) and Central Denmark Region (CD) were given the possibility to directly refer LBP patients for a lumbar MRI in 2010 and 2011, respectively. This allow GPs from CD to act as controls from 2008-2010, while GPs from CR are excluded. To date, the effect of these organisational changes in RSD have not been investigated.

The study investigates the effect of the organisational changes on use of lumbar MRI in the diagnostics of LBP patients in RSD. Specifically, we describe yearly lumbar MRI rates (lumbar MRI per 1,000 enlisted with a GP) for all individuals aged 18+. We hypothesised that the yearly lumbar MRI rates from 2010 to 2013 would increase significantly in RSD compared to the other regions.

Methods

Design

A longitudinal register-based study covering the Danish population aged 18+ from 2008 to 2013.

Setting

In Denmark, five decentralised administrative regions, including 98 municipalities, manage the tax founded health care system [16]. Each region has a public elected council and is autonomously managing the secondary care sector. All services provided at hospitals and office-based physician are free of charge, while services at physiotherapist and chiropractors involve co-payments from the patient. GPs' in Denmark have a unique patient list (GP list) of citizens, to whom the GP solely provided services for. The GP list size is on average 1.600 patients, and 98% of all Danes are enlisted at one of the 2.200 GP clinics in Denmark [16].

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Data sources

The study used data from the registries at Statistics Denmark (DST), a governmental institution providing data for research purposes[17]. All registries are linkable at the individual level, using the personal civil registration number (CPR-number), which are given to Danish citizens at birth [18 19]. The study includes data from the following registries:

The Danish National Patient Registry (NPR) [20 21], includes information on diagnosis coded according to the International Classification of Disease (ICD-10), and procedure and surgery codes (Health Care Classification System (SKS codes)). All NPR records are unique, due to a NPR serial numbers (unique to each patient's continuum of care at a hospital) and patients' CPR-numbers.

The Danish National Health Service Register for Primary Care (DNHR) [22], includes all contacts to the primary sector health care providers including GPs, Chiropractors, Physiotherapists, and office-based specialist doctors. The GP list and GP list size were generated by combining the unique GP id with the CPR-number from patients receiving most of their services from the GP id[23]. GPs' with patient list size less than 300 patients were deleted as they are hypothesised to be GPs either starting up or closing down the practice. Those citizens with no information of GP id in one of the study years, were allocated to a hypothetical GP id generated for each region.

Danish National Prescription Registry (DNPR) includes information on all prescription based analgesic drugs sold at Danish primacies[24]. We identified analgesic drugs according to the Anatomical Therapeutic Chemical classification (ATC) code[25]. Analgesic drugs included ATC code

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NN02A and NN02B; tablet cans with >100 pills of paracetamol and ibuprofen, synthetic opioids, and opioids.

Statistics Denmark (DST) as an umbrella includes information from other registers and we retrieved information on income[26], education[27], job- and socio-economic status[28], civil status[18], and demographics [18].

Definition of lumbar MRI

This study included data for lumbar MRI (SKS code: UXME30)[21]. Each MRI scan performed at a public hospital is recorded in NPR. Lumbar MRI performed on a private hospital are recorded in the NPR if they are subsidised by the government. Patients with multiple spine MRI registrations on the same NPR serial number were identified and the UXME30 code was retained for analysis. If patients showed two or more UXME30 codes for the same day only one were kept.

Definition of referral mode

A referral mode variable was defined based on two variables from the NPR; Referral directly from the GP (1), directly from the Chiropractor or initiated by private insurance (2), directly from the office-based specialist doctors (3), and from the hospital department (4). In the dataset we observe registrations with referral directly from the GP, before 2010. These are recoded into hospital registrations.

Primary outcome

The primary outcome is lumbar MRI rate per 1,000 enlisted with a GP

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Analyses strategy

The impact on MRI-rates of the well-defined organisational changes in 2010 in RSD, is analysed as a natural experiment. The change in the other regions are used as control under the assumption that the development of MRI rates in the control regions are a good indicator of how the MRI rates would have developed in RSD in absence of the organizational changes.

We hypothesise that the two referral options (direct GP referral and referral to the Spine Centre) drives any change in use of lumbar MRI. As patients have not chosen to live in RSD based on the access to MRI, the assumption behind our analyses strategy is that we can interpret patients as randomly assigned to a GP who by construct of the natural experiment happen to have access to the organizational changes (RSD) or not (control regions). We therefor included GPs from the Zealand Region (ZR) and the North Denmark Region (NR) as controls for all years in the analysis. GPs from the CR are included from 2008 to 2010, as they had the possibility to directly refer LBP patients for a lumbar MRI in 2011. GPs from the CR were excluded as controls.

The DD model estimates the effect of organisational changes by assuming that the counterfactual development in the lumbar MRI rates in the treatment group (i.e, RSD) could be approximated by the development in the lumbar MRI rates of the other regions [29]. For the control group to match the approximation of the counterfactual development in lumbar MRI rates in RSD the model, we rely on an assumption that there was a common trend in lumbar MRI rates before the interventions. The common trend assumption was visually inspected for unadjusted analyses (see Figure 2). The DD approach by definition control for all time constant heterogeneity between GPs

in RSD and the controls but if we expect time varying differences occurring over time we need to add covariates. Hence, second assumption behind our approach is that there were no time-varying unobservable covariates, that could explain differences in selection into a referral to lumbar MRI between GPs, and between regions. [29]. Hence, we generally assume that citizens need for MRI are identical among regions after controlling for observable patients' characteristics and supply factors related to LBP treatment did not change over time on the regional level,

Statistics

The study used difference-in-difference (DD) in a parametric Ordinary Least Squares (OLS) regression model using robust standard errors and clustering for GP id. We aggregated the individual level socio demographic data to GP level. This allowed for analysis using information from the socio demographic composition of the GPs' lists to account for any time varying patient characteristics, that is associated with LBP, and therefor explain differences in GPs' referral to lumbar MRI. A supplementary advantage of using the GP as analytical level is that we in this way obtain an unbalanced panel data structure of our dataset, with one observation per unique GP per year.

To show dynamic year effects of the models, 2009 was used as pre-intervention and each intervention year was used as the post-intervention year, in four DD regression models– one for each post treatment year (2010, 2011, 2012 and 2013). To test if the trend in MRI rates were not different between RSD and controls before the programme we tested for a treatment effect in 2009 using 2008 as base year. The five models used the variables as in the adjusted models and

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were analysed using both control groups. The DD estimates and the 95% confidence intervals [CI ;] were graphed (the control regions were the x-axis) in Figure 3. Tables reported number (N), means, standard deviations (SD), unpaired t-test, and percentages (%). The changes in referral modes were graphed for RSD (see Figure 1). All analyses were performed using STATA Release 13 (STATACorp, College Station, TX, USA) and graphics and tables were performed in Microsoft Excel 2010 (©Microsoft Corporation).

Covariates

The unadjusted models included the following variables: pre- and post-2009 (0 = 2008–2009, 1 = 2010–2013) and intervention and control regions (1 = RSD and 0 =ZR, NR, CD).

The adjusted models add time varying covariates to the above variables. This is done to avoid that any observed change in RSD after the change is simply due to changes in the characteristics of the citizens over time – for example that citizens in RSD over time becomes more prevalent to LBP than control regions All covariates included, except GP list size, were made as proportions of enlisted patients with characteristic X divided with the GP list size. Patients characteristics X included; age 18-59, citizens in a full-time job, income DKK 0-399.000 or missing, women, citizens living as singles, and Charlson comorbidity index score[30] 2+, patients with vocational education, patients using a prescription on an analgesic drug at a pharmacists, patients having a visit at a physiotherapist, patients having a visit a chiropractor, and patients visiting an office-based specialist doctors (rheumatologist, neurologist, orthopaedics, and radiologist). Covariates are seen in table 1.

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Patient and Public Involvement

Patients were not involved in the making of the study

Ethics

The Danish Data Protection Agency approved this study (Journal number 15/14594). The study is based on registry data, which does not require ethics approval in Denmark (Act on Research Ethics Review of Health Research Projects § 14, sec. 2 http://www.nvk.dk/english/act-on-research 10.02.2017).

Results

During the study period 183.389 patients were assessed with 240.760 lumbar MRIs. Of those 27% (63.982 lumbar MRIs) were performed on private hospitals.

(insert figure 1)

Figure 1 shows changes in the rates of referrals for lumbar MRI in the RSD. MRI referrals directly from GPs accounted for 18% (N = 3,044) of all referrals in 2010. In the subsequent three years, the rate of MRI referrals directly from the GP increased 115% to (N = 6,545) and accounted for 34% of all of the MRI referrals in 2013.

(insert figure 2)

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The common trend was visually inspected using figure 2, showing unadjusted average regional lumbar MRI rates for GPs in RDS and the control regions. Figure 2 implies common support for the unadjusted models. To capture any differences in time-varying trends we included characteristics of the GP patient list, seen in Table 1. The table show that there are statistical differences for 8 of the 12 included covariates between GPs' in RSD and control group regions in the pre-intervention years. However, the differences are small between the patient characteristics of the GPs' lists in RSD and GPs' lists in control group regions.

Table 1: Differences in proportions of patients enlisted at a GP from either intervention or control regions for pre-intervention years (2008 and 2009 combined)

	RSD's GPs (N=832)		Control regions' GPs (N=1878)$		
	Mean	SD	Mean	SD	T-test§
Comorbidity score 2+	0.031	0.008	0.031	0.010	*
Full time job	0.565	0.060	0.570	0.064	*
Vocationel education	0.443	0.029	0.450	0.038	*
Marital status single	0.318	0.064	0.323	0.076	*
Income DKK 0-399.999	0.899	0.028	0.888	0.039	*
Gender (women)	0.509	0.063	0.509	0.066	
18-59 year of age	0.674	0.076	0.679	0.082	
GP ids' list size	2265.060	3197.228	2212.976	3440.372	
Visits to Physiotherapist	0.086	0.022	0.096	0.026	*
Visits to Chiropractor	0.079	0.024	0.072	0.023	*
Visits to Office based specialists	0.035	0.022	0.037	0.027	*
Use of pain medication	0.153	0.037	0.150	0.040	

Abbreviations: ** p<0.05, § t-test by group with unequal variance; N number of observations; RSD Region of Southern Denmark, GP general practitioner, SD Standard Deviation. $ Including general practitioners from Zealand Region, Central Denmark Region and North Denmark Region*

The results of the two DD analyses of the lumbar MRI rates per 1,000 enlisted with GPs RSD compared to GPs' in the control group, are shown in Table 2. After the organisational changes in RSD, the lumbar MRI rates increased significantly compared to control groups, for both models ranging from 1.389 [CI 0.925;1.852] to 1.831 [CI 1.369;2.292] lumbar MRIs per 1,000 enlisted with a GP.

Table 2: Difference in Difference estimates from unadjusted and adjusted models with Region of Southern Denmark and the control regions

	Lumbar MRI rates	
	Unadjusted	Adjusted model§
DD (RSD*Post treatment)	1.831*** [1.369,2.292]	1.389*** [0.925,1.852]
Constant	9.043*** [8.854,9.233]	2.600 [-5.284,10.484]

*§ Adjusted model include covariates for; Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at Physiotherapist, visits at Chiropractor, visits at office-based spine specialist, use of pain medication. Standardized beta coefficients; 95% confidence interval [,], * p<0.05, ** p<0.01, *** p<0.001, DD Difference in Difference, RSD Region of Southern Denmark, Post treatment, years from 2010-2013.*

The dynamic year effects, for both models are seen in figure 3. Figure 3 indicates that the common trend assumption support is fulfilled as a hypothesised treatment effect before the treatment occurred is insignificant. Dynamic year effects for post-intervention years were positive and significant for all years, with an observed increase positive trend of the estimates, indicating that the effect of the organisational changes increases over time.

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(Insert figure 3)

Discussion

This study showed that establishing a Spine Centre in the RSD and introducing direct referrals for lumbar MRI by GPs was associated with an increase in the use of lumbar MRI (compared to that of other regions) in the years following the 2010 changes. On average the increase was between 1.389 to 1.832 lumbar MRI per 1.000 enlisted with GPs in RSD involving an increase in lumbar MRI of between 1.400 and 1.800 additional scans compared to the other regions. The use of the direct referral option by GPs in the RSD increased by 115% in the period from 2010 to 2013.

As in other studies from the US[7], we find geographical variation in the use of lumbar MRI among the regions in Denmark. The reason for the difference in use of lumbar MRI among the regions is still unclear. Some points towards a special interest in back pain by specialist doctors in RSD, which relates to different regional clinical practices, which have been found in US studies[6 11]. The relationship between MRI usages and physician incentives[9 10], is unlikely to explain the differences in a Danish setting; Firstly, physicians at public hospital receive a fixed yearly salary, thereby not having incentives to refer patients. Secondly, the public hospitals undertook 74 % of all scans.

The increase in referrals for lumbar MRI following the change in GP referral access to lumbar MRI in the RSD in 2010 is noteworthy. GPs in the RSD clearly began to use the new referral option immediately, as it accounted for 36% of the increase in new lumbar MRI referrals between 2009 and 2010. This change might indicate a lowering in the threshold for a MRI referral. There could be

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numerous reasons for the use of direct referrals to lumbar MRI, including patient demands[31 32] and physicians' wish to provide quick reassurances to LBP patients[32]. Providing quick reassurance to patients could prevent further costly visits to specialist doctors and reduce future treatment costs. However, previous studies have shown that lumbar MRI referrals from GPs are inappropriate in up to 50% of the cases when judged against the guidelines [10 33-35]. Further, the inappropriate use of lumbar MRI has been shown to be associated with an increased use of opioids, higher health care costs and has a low impact on pain relief or functional recovery after 6 months in non-specific LBP patients, without serious pathologies such as cancer, nerve root compression, cauda equina, radiculopathy and sciatica [3 5 36-42]. Further studies are needed to investigate if the same associations are found in this setting.

Strengths and Limitations

This study used DD estimates to capture the effect of the organisational changes and LBP DMP in RSD. Difference in difference is a popular design for evaluation of policy changes, as is widely used in social science[29]. DD relies on the assumption of a common trend in the pre-treatment period for the outcomes of interest. This assumption seems to be fulfilled in the current study.

Referrals from chiropractors and GPs are seen from 2008 to 2009 are recoded to hospital referrals, as they did not have the opportunity to refer LBP patients for a lumbar MRI. There might be several explanations for these registrations; Firstly, registrations with referrals from GP in 2009 may be test of the electronic referral system, used in the communication of between GPs and hospitals. Secondly, referrals from GPs can be interpreted in relation to GPs referring LBP patients

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for a consult in secondary care, where the GP refer the patient for a lumbar MRI on the same day as the consult. This allows the hospital-based specialist doctor to assess the lumbar MRI at the consult on the hospital, and to reduce visits at the hospital for the patient.

The study relied on data from the newly 2018 update of the NPR at Statistics Denmark[43]. This allowed for data from all individuals aged 18+ of the population of Denmark, leaving an unseen precision of analyses performed on country level.

Conclusions

Following RSD' introduction of organisational changes in 2010, the lumbar MRI rate increased significantly in comparison with the other regions in Denmark. The issue of whether the increased usage of lumbar MRI is beneficial for the RSD's LBP patients (compared to that of other regions) requires further investigations.

Figure Legends:

Figure 1: Changes in the referral patterns to lumbar MRI in Region of Southern Denmark from 2008-2013 using a 100% stacked curve diagram.

Abbreviations: MRI, magnetic resonance imaging, GP general practitioners

Figure 2: Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013

Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.

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Figure 3: Dynamic year effects using the adjusted model, with multiple difference in difference estimates with 2009 as the pre-intervention period and all post intervention years for Region of Southern Denmark and the control regions.

Abbreviations b, Beta estimates from the difference in difference analysis; min95, Lower bound of the 95%confidence interval of the beta estimate; max95, upper bound of the 95% confidence interval of the beta estimate

Declarations

Acknowledgements

Not applicable

Ethics approval and consent to participate

The study is based on registry data, which does not require ethics approval in Denmark (Act on Research Ethics Review of Health Research Projects § 14, sec. 2 http://www.nvk.dk/english/act-on-research 10.02.2017). The study group did however send the study protocol for an ethic assessment to the regional ethics committee in Region of Southern Denmark. The committee found that the study did not need ethic approval. The Danish Data Protection Agency approved this study (Journal number 15/14594).

Consent for publication

All authors' consent to publish this document

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Availability of data and material

The data that support the findings of this study are available from national databases at Statistics Denmark (Sejrøgade 11, DK-2100 København Ø, Phone +45 39 17 31 30, E-Mail forskningsservice@dst.dk), a governmental institution, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Statistics Denmark and The Danish Data Protection Agency (Borgergade 28, DK-1300 Copenhagen, Phone +45 3319 3200, E-Mail dt@datatilsynet.dk).

Competing interests

The authors declare that they have no competing interests

Funding

The study is a part of a three year PhD grant with contributions from Centre for Quality, Region of Southern Denmark, The Institute of Regional Health Research, University of Southern Denmark and Region of Southern Denmark. The Study further received a grant from the Regional Research Fund of Southern Denmark, Region of Southern Denmark. All grant givers had no saying in the design and interpretation of the study.

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Authors' contributions

MS and KO made the dataset at Statistics Denmark and analysed the data. MS wrote the manuscript, made figures and tables with contributions from KO, LM, JS and BC. All authors read and approved the final manuscript."

List of abbreviations

magnetic resonance imaging (MRI), ow back pain (LBP), United States (US), Region of Southern Denmark (RSD), General Practitioners (GPs), Disease Management Programme (DMP), Capitol Region (CR), the Danish National Patient Registry (NPR), Health Care Classification System (SKS codes), civil registration numbers (CPR), Difference-In-Difference (DD), Ordinary Least Squares (OLS), number (N), 95% Confidence Intervals [CI ,] and percentages (%)

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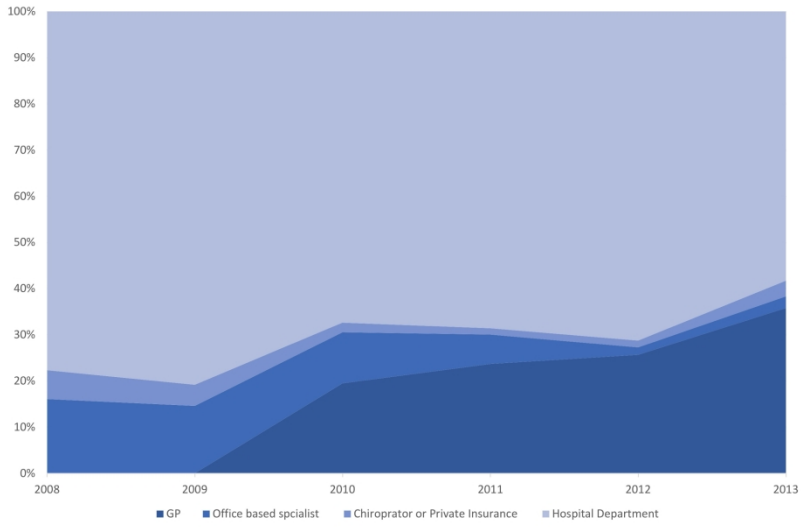

Figure 1: Changes in the referral patterns to lumbar MRI in Region of Southern Denmark from 2008-2013 using a 100% stacked curve diagram. Abbreviations: MRI, magnetic resonance imaging, GP general practitioners

296x166mm (300 x 300 DPI)

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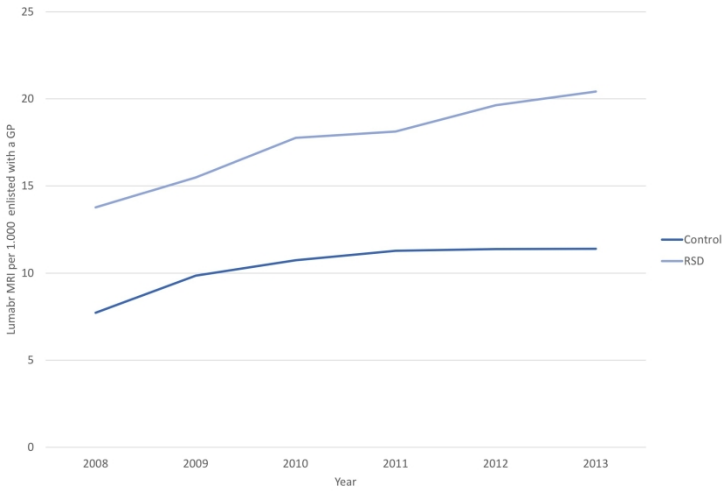

Caption : Figure 2: Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.

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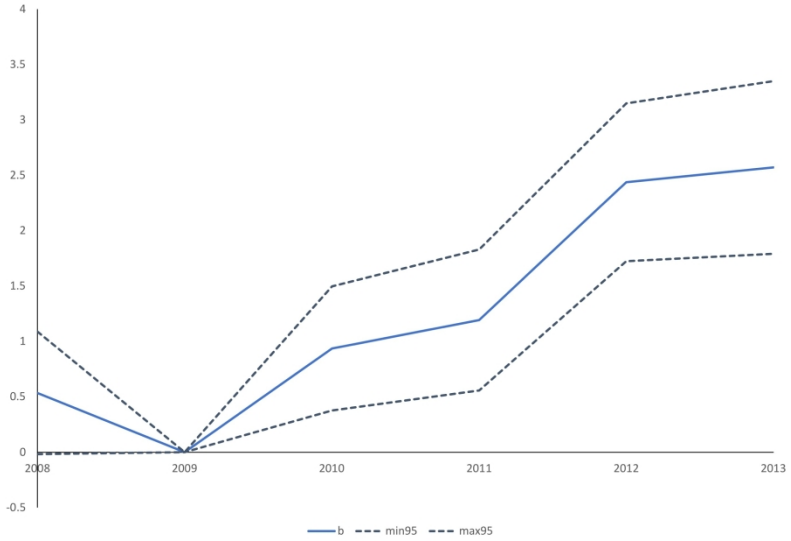

Figure 3: Dynamic year effects using the adjusted model, with multiple difference in difference estimates with 2009 as the pre-intervention period and all post intervention years for Region of Southern Denmark and the control regions. Abbreviations b, Beta estimates from the difference in difference analysis; min95, Lower bound of the 95%confidence interval of the beta estimate; max95, upper bound of the 95% confidence interval of the beta estimate

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6, 7, 9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	N/A
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7,8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	5
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	N/A

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		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	12
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11,12
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14, 15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14, 15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025921.R1
Article Type:	Research
Date Submitted by the Author:	26-Dec-2018
Complete List of Authors:	Jensen, Morten; Centre for Quality, Region of Southern Denmark; The Institute of Regional Health Research, University of Southern Denmark Olsen, Kim; DaCHE, Institute of Public Health, University of Southern Denmark Morsø, Lars; Centre for Quality, Region of Southern Denmark; The Institute of Regional Health Research, University of Southern Denmark Søndergaard, Jens; Research Unit of General Practice, Institute of Public Health, University of Southern Denmark Schiøttz-Christensen, Berit; The Institute of Regional Health Research, University of Southern Denmark; Lillebaelt Hospital, Region of Southern Denmark, Spine Centre of Southern Denmark
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Diagnostics, Health policy, Radiology and imaging, Sports and exercise medicine, Public health
Keywords:	Magnetic resonance imaging < RADIOLOGY & IMAGING, PUBLIC HEALTH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Low Back Pain

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Title:
Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data

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Key Words:

Keywords: MRI-rate, lumbar MRI, Direct Referral to MRI, Registry Data, Statistics Denmark, Low Back Pain , Organisational Changes

Word Count

3284

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Abstract

Objectives:

This study reports lumbar magnetic resonance imaging (MRI) referral patterns in Region of Southern Denmark (RSD) and investigate the hypothesis that we will see an increase in imaging rates (MRI-rates) following new referral options to lumbar MRI in RSD in comparison with the other regions in Denmark from 2010-2013.

Design:

A difference-in-difference (DD) analysis, using GPs in other Regions as control, was used to test if the new referral options had an effect on the MRI rates.

Setting:

In 2010, RSD introduced organisational changes affecting the referral options for lumbar MRI. Firstly, the possibility for direct referral to lumbar MRI was introduced to General practitioner's (GP), and secondly the region gathered all local spine departments into one specialist hospital called the Spine Centre.

Participants:

We retrieved all lumbar MRIs performed on patients aged 18+ performed on Danish hospitals from 2008-2013 using the registries from Statistics Denmark. We use socio-demographic information from all Danish citizens aged 18+ aggregated to GP level.

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Primary and secondary outcome measures:

Lumbar MRI scans per 1.000 capita enlisted with a GP (MRI-rates) were calculated based on GP's patient list. Four referral types were made to describe changes in referral patterns.

Results:

In total 183.389 patients received 240.760 lumbar MRIs in the period. The use of the direct referral option by GPs in the RSD increased by 115% in the period from 2010 to 2013 and accounted for 34% of all referrals (N = 6,545) in 2013. MRI-rates were significantly higher in RSD following the organisational changes (DD 1.389 [0.925,1.852] lumbar MRI per 1.000 enlisted with a GP).

Conclusions:

Introduction of organisational changes in RSD as direct referral to MRI from GPs and Chiropractors as well as establishing a Spine Centre increase the lumbar MRI rate in comparison with other regions in Denmark.

Strengths and limitations of this study:

- Nation-wide registry data including socio-demographic information on all citizens aged 18+
- Use of a Difference-in-Difference design for possible causal inference
- The study might underestimate the lumbar MRIs from private hospitals

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Background

The number of lumbar magnetic resonance imaging (MRI) undertaken in the United States (US) Medicare population increased substantially from 1994 to 2006, despite guidelines which discourages routine use of MRI [1-3]. It was estimated that the use of MRI and other imaging modalities accounted for 7% of the direct treatment costs of LBP in 1998 [4].

The factors associated with the increased use of MRI in the diagnostics of low back pain have been investigated. Research shows that the substantial geographic differences in use of spinal MRI across states in the US [5-8] can be explained by differences in local clinical practices [6], physician ownership of specialty hospitals [9], fee-for-service schemes [10], MRI-scanner availability [11] and state median income per capita [12]. However, these studies were undertaken in a US-setting among populations that had limited access to health care providers and where a fee-for service incentive affected doctors' wages. Consequently, more studies are needed on factors impacting the use of lumbar MRI, in other health care settings [13-15].

In this study we have the opportunity of using nation-wide data and hence evaluating a natural experiment. In 2010, Region of Southern Denmark (RSD), made two organisational changes. These included, centralisation of regional spine specialist departments across regional hospitals in one spine specialist hospital. Further, General Practitioners (GPs) and chiropractors were given the possibility to directly refer LBP patients for lumbar MRI without prior referral to the Spine Centre or to office-based specialist doctors. In the support of the organisational changes, RSD implemented a LBP Disease Management Programme (DMP). The centralisation of the hospital

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occurred over months in the beginning of 2010, and the hospital were fully operational in mid 2010. The direct referral access was available for the GPs in the first months of 2010. These changes were unique in Denmark as two of four other regions maintained decentralised spine departments and did not allow for direct referral. To date, the effect of these organisational changes in RSD have not been investigated.

The study investigates the effect of the organisational changes on use of lumbar MRI in the diagnostics of LBP patients in RSD. Primary outcome is defined as yearly lumbar MRI rates for all individuals aged 18+, We hypothesised that the yearly lumbar MRI rates from 2010 to 2013 would increase significantly in RSD compared to the other regions.

Methods

Design

A longitudinal register-based study covering the Danish population aged 18+ from 2008 to 2013. The study relies on a natural experiment using RSD as the intervention group. Two regions, Zealand Region (ZR) and the North Denmark Region (NR), maintained their organisation in the study period from 2008 to 2013. Hence these two regions can act as good indicators of the counterfactual RSD. GPs in RSD, GPs in the Capitol Region (CR) and Central Denmark Region (CD) were given the possibility to directly refer LBP patients for a lumbar MRI in 2010 and 2011, respectively. This allow GPs from CD to act as controls from 2008-2010, while GPs from CR are excluded, as they allow referrals from GPs at the same time as RSD, why they cannot act as good indicators of the counterfactual development in RSD if RSD had not made the organisational changes.

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Primary outcome

The primary outcome is yearly lumbar MRI per 1,000 enlisted with a GP.

Setting

In Denmark, five decentralised administrative regions, including 98 municipalities, manage the tax founded health care system [16]. Each region has a public elected council and is autonomously managing the secondary care sector. All services provided at hospitals and office-based physician are free of charge, while services at physiotherapist and chiropractors involve co-payments from the patient. GPs' in Denmark have a unique patient list (GP list) of citizens, to whom the GP solely provided services for. The GP list size is on average 1.600 patients, and 98% of all Danes are enlisted at one of the 2.200 GP clinics in Denmark [16].

Data sources

The study used data from the registries at Statistics Denmark (DST), a governmental institution providing data for research purposes[17]. All registries are linkable at the individual level, using the personal civil registration number (CPR-number), which are given to Danish citizens at birth [18 19]. The study includes data from the following registries:

The Danish National Patient Registry (NPR) [20 21], includes information on diagnosis coded according to the International Classification of Disease (ICD-10), and procedure and surgery codes (Health Care Classification System (SKS codes)). All NPR records are unique, due to a NPR serial numbers (unique to each patient's continuum of care at a hospital) and patients' CPR-numbers.

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The Danish National Health Service Register for Primary Care (DNHR) [22], includes all contacts to the primary sector health care providers including GPs, Chiropractors, Physiotherapists, and office-based specialist doctors. The GP list and GP list size were generated by combining the unique GP id with the CPR-number from patients receiving most of their services from the GP id[23]. GPs' with patient list size less than 300 patients were deleted as they are hypothesised to be GPs either starting up or closing down the practice. Those citizens with no information of GP id in one of the study years, were allocated to a hypothetical GP id generated for each region.

Danish National Prescription Registry (DNPR) includes information on all prescription based analgesic drugs sold at Danish primacies[24]. We identified analgesic drugs according to the Anatomical Therapeutic Chemical classification (ATC) code[25]. Analgesic drugs included ATC code NN02A and NN02B; tablet cans with >100 pills of paracetamol and ibuprofen, synthetic opioids, and opioids.

Statistics Denmark (DST) as an umbrella includes information from other registers and we retrieved information on income[26], education[27], job- and socio-economic status[28], civil status[18], and demographics [18].

Definition of lumbar MRI

This study included data for lumbar MRI (SKS code: UXME30)[21]. Each MRI scan performed at a public hospital is recorded in NPR. Lumbar MRI performed on a private hospital are recorded in the NPR if they are subsidised by the government. Patients with multiple spine MRI registrations

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on the same NPR serial number were identified and the UXME30 code was retained for analysis. If patients showed two or more UXME30 codes for the same day only one were kept.

Definition of referral mode

A referral mode variable was defined based on two variables from the NPR; Referral directly from the GP (1), directly from the Chiropractor or initiated by private insurance (2), directly from the office-based specialist doctors (3), and from the hospital department (4). In the dataset we observe registrations with referral directly from the GP, before 2010. These are recoded into hospital registrations.

Analyses strategy

The impact on MRI-rates of the well-defined organisational changes in 2010 in RSD, is analysed as a natural experiment. The change in the other regions are used as control under the assumption that the development of MRI rates in the control regions are a good indicator of how the MRI rates would have developed in RSD in absence of the organizational changes.

We hypothesise that the two referral options (direct GP referral and referral to the Spine Centre) drives any change in use of lumbar MRI. As patients have not chosen to live in RSD based on the access to MRI, the assumption behind our analyses strategy is that we can interpret patients as randomly assigned to a GP who by construct of the natural experiment happen to have access to the organizational changes (RSD) or not (control regions). We therefore included GPs from the Zealand Region (ZR) and the North Denmark Region (NR) as controls for all years in the analysis.

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GPs from the CR are included from 2008 to 2010, as they had the possibility to directly refer LBP patients for a lumbar MRI in 2011. GPs from the CR were excluded as controls.

The DD model estimates the effect of organisational changes by assuming that the counterfactual development in the lumbar MRI rates in the treatment group (i.e, RSD) could be approximated by the development in the lumbar MRI rates of the other regions [29]. For the control group to match the approximation of the counterfactual development in lumbar MRI rates in RSD the model, we rely on an assumption that there was a common trend in lumbar MRI rates before the interventions. The common trend assumption was visually inspected for unadjusted analyses. The DD approach by definition control for all time constant heterogeneity between GPs in RSD and the controls but if we expect time varying differences occurring over time we need to add covariates. Hence, second assumption behind our approach is that there were no time-varying unobservable covariates, that could explain differences in selection into a referral to lumbar MRI between GPs, and between regions. [29]. Hence, we generally assume that citizens need for MRI are identical among regions after controlling for observable patients' characteristics and supply factors related to LBP treatment did not change over time on the regional level,

Statistics

The study used difference-in-difference (DD) in a parametric Ordinary Least Squares (OLS) regression model using robust standard errors and clustering for GP id. We aggregated the individual level socio demographic data to GP level. This allowed for analysis using information from the socio demographic composition of the GPs' lists to account for any time varying patient

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characteristics, that is associated with LBP, and therefore explain differences in GPs' referral to lumbar MRI. A supplementary advantage of using the GP as analytical level is that we in this way obtain an unbalanced panel data structure of our dataset, with one observation per unique GP per year.

The changes in referral modes were graphed for RSD (see Figure 1). To show dynamic year effects of the models, 2009 was used as pre-intervention and each intervention year was used as the post-intervention year, in four DD regression models– one for each post treatment year (2010, 2011, 2012 and 2013). To test if the trend in MRI rates were not different between RSD and controls before the programme we tested for a treatment effect in 2009 using 2008 as base year. The five models used the variables as in the adjusted models and were analysed using both control groups. The DD estimates and the 95% confidence intervals [CI;] were graphed (the control regions were the x-axis). Tables reported number (N), means, standard deviations (SD), unpaired t-test, and percentages (%). All analyses were performed using STATA Release 13 (STATACorp, College Station, TX, USA) and graphics and tables were performed in Microsoft Excel 2010 (©Microsoft Corporation).

Covariates

The unadjusted models included the following variables: pre- and post-2009 (0 = 2008–2009, 1 = 2010–2013) and intervention and control regions (1 = RSD and 0 =ZR, NR, CD).

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The adjusted models add time varying covariates to the above variables. This is done to avoid that any observed change in RSD after the change is simply due to changes in the characteristics of the citizens over time – for example that citizens in RSD over time becomes more prevalent to LBP than control regions. All covariates included, except GP list size, were made as proportions of enlisted patients with characteristic X divided with the GP list size. Patients characteristics X included; age 18-59, citizens in a full-time job, income DKK 0-399.000 or missing, women, citizens living as singles, and Charlson comorbidity index score[30] 2+, patients with vocational education, patients using a prescription on an analgesic drug at a pharmacists, patients having a visit at a physiotherapist, patients having a visit a chiropractor, and patients visiting an office-based specialist doctors (rheumatologist, neurologist, orthopaedics, and radiologist). Covariates are seen in table 1.

Patient and Public Involvement

Patients were not involved in the making of the study

Ethics

The Danish Data Protection Agency approved this study (Journal number 15/14594). The study is based on registry data, which does not require ethics approval in Denmark (Act on Research Ethics Review of Health Research Projects § 14, sec. 2 http://www.nvk.dk/english/act-on-research 10.02.2017).

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Results

During the study period 183.389 patients were assessed with 240.760 lumbar MRIs. Of those 27% (63.982 lumbar MRIs) were performed on private hospitals.

(insert figure 1)

Figure 1 shows changes in the rates of referrals for lumbar MRI in the RSD. MRI referrals directly from GPs accounted for 18% (N = 3,044) of all referrals in 2010. In the subsequent three years, the rate of MRI referrals directly from the GP increased 115% to (N = 6,545) and accounted for 34% of all of the MRI referrals in 2013. MRI referrals from office-based specialist (rheumatologist or orthopaedics) decreased from 2008 (N = 1,916, 16%) to 2013 (N = 464, 2% MRI referrals from office-based chiropractors or from a private insurance increased from 2011 (N=220, 1%) to 2008 (N=748, 6%). MRI referrals from hospital-based doctors increased from 2008 (N=9,262, 77%) to 2012 (N=12,487,71%).

(insert figure 2)

The common trend was visually inspected using figure 2, showing unadjusted average regional lumbar MRI rates for GPs in RDS and the control regions. Lumbar MRI rates for RSD increased each year starting from 14.29 lumbar MRI per 1,000 enlisted with a GP in 2008 to 21.13 lumbar MRI per 1,000 enlisted with a GP in 2013. The average lumbar MRI rates for three control regions increased from 7.79 lumbar MRI per 1,000 enlisted with a GP in 2008 to 11.48 lumbar MRI per

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1,000 enlisted with a GP in 2012 and 2013. Figure 2 implies common support for the unadjusted models. To capture any differences in time-varying trends we included characteristics of the GP patient list, seen in Table 1. The table show that there are statistical differences for 8 of the 12 included covariates between GPs' in RSD and control group regions in the pre-intervention years. However, the differences are small between the patient characteristics of the GPs' lists in RSD and GPs' lists in control group regions.

Table 1: Differences in proportions of patients enlisted at a GP from either intervention or control regions for pre-intervention years (2008 and 2009 combined)

	RSD's GPs (N=832)		Control regions' GPs (N=1878)$		
	Mean	SD	Mean	SD	T-test§
Comorbidity score 2+	0.031	0.008	0.031	0.010	*
Full time job	0.565	0.060	0.570	0.064	*
Vocational education	0.443	0.029	0.450	0.038	*
Marital status single	0.318	0.064	0.323	0.076	*
Income DKK 0-399.999	0.899	0.028	0.888	0.039	*
Gender (women)	0.509	0.063	0.509	0.066	
18-59 year of age	0.674	0.076	0.679	0.082	
GP ids' list size	2265.060	3197.228	2212.976	3440.372	
Visits to Physiotherapist	0.086	0.022	0.096	0.026	*
Visits to Chiropractor	0.079	0.024	0.072	0.023	*
Visits to Office based specialists	0.035	0.022	0.037	0.027	*
Use of pain medication	0.153	0.037	0.150	0.040	

*Means reflect proportions of patients divided by the GP list size. Abbreviations: * p<0.05, § t-test by group with unequal variance; N number of observations; RSD Region of Southern Denmark, GP general practitioner, SD Standard Deviation. $ Including general practitioners from Zealand Region, Central Denmark Region and North Denmark Region.*

The results of the two DD analyses of the lumbar MRI rates per 1,000 enlisted with GPs RSD compared to GPs' in the control group, are shown in Table 2. After the organisational changes in RSD, the lumbar MRI rates increased significantly compared to control groups, for both models

ranging from 1.389 [CI 0.925;1.852] to 1.831 [CI 1.369;2.292] lumbar MRIs per 1,000 enlisted with a GP.

Table 2: Difference in Difference estimates from unadjusted and adjusted models with Region of Southern Denmark and the control regions

	Lumbar MRI rates	
	Unadjusted	Adjusted model§
DD (RSD*Post treatment)	1.83***	1.39***
	[1.37,2.29]	[0.93,1.85]
Constant	9.04***	2.60
	[8.85,9.23]	[-5.28,10.48]

*§ Adjusted model include covariates for; Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at Physiotherapist, visits at Chiropractor, visits at office-based spine specialist, use of pain medication. Standardized beta coefficients; 95% confidence interval [,], * p<0.05, ** p<0.01, *** p<0.001, DD Difference in Difference, RSD Region of Southern Denmark, Post treatment, years from 2010-2013.*

The dynamic year effects, for both models are seen in figure 3. Figure 3 indicates that the common trend assumption support is fulfilled as a hypothesised treatment effect before the intervention occurred is insignificant. Dynamic year effects for post-intervention years were positive and significant for all years, with an observed increase positive trend of the estimates, indicating that the effect of the organisational changes increases over time.

(Insert figure 3)

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Discussion

This study showed that establishing a Spine Centre in the RSD and introducing direct referrals for lumbar MRI by GPs was associated with an increase in the use of lumbar MRI (compared to that of other regions) in the years following the 2010 changes. On average the increase was between 1.389 to 1.832 lumbar MRI per 1.000 enlisted with GPs in RSD involving an increase in lumbar MRI of between 1.400 and 1.800 additional scans compared to the other regions. The use of the direct referral option by GPs in the RSD increased by 115% in the period from 2010 to 2013, indicating that the GP adopted the new referral option.

As in other studies from the US[7], we find geographical variation in the use of lumbar MRI among the regions in Denmark. The reason for the difference in use of lumbar MRI among the regions is still unclear. Some points towards a special interest in back pain by specialist doctors in RSD, which relates to different regional clinical practices, which have been found in US studies[6 11]. The relationship between MRI usages and physician incentives[9 10], is unlikely to explain the differences in a Danish setting; Firstly, physicians at public hospital receive a fixed yearly salary, thereby not having incentives to refer patients. Secondly, the public hospitals undertook 74 % of all scans.

The increase in referrals for lumbar MRI following the change in GP referral access to lumbar MRI in the RSD in 2010 is noteworthy. GPs in the RSD clearly began to use the new referral option immediately and the use of the referral option increase by 115% from 2010 to 2013. This change might indicate a lowering in the threshold for a MRI referral. There could be numerous reasons for the use of direct referrals to lumbar MRI, including patient demands[31 32] and physicians' wish to provide quick reassurances to LBP patients[32]. Providing quick reassurance to patients could

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prevent further costly visits to specialist doctors and reduce future treatment costs. However, previous studies have shown that lumbar MRI referrals from GPs are inappropriate in up to 50% of the cases when judged against the guidelines [10 33-35]. Further, the inappropriate use of lumbar MRI has been shown to be associated with an increased use of opioids, higher health care costs and has a low impact on pain relief or functional recovery after 6 months in non-specific LBP patients, without serious pathologies such as cancer, nerve root compression, cauda equina, radiculopathy and sciatica [3 5 36-42]. Further studies are needed to investigate if the same associations are found in this setting.

Strengths and Limitations

This study used DD estimates to capture the effect of the organisational changes and LBP DMP in RSD. Difference in difference is a popular design for evaluation of policy changes, as is widely used in social science[29]. DD relies on the assumption of a common trend in the pre-treatment period for the outcomes of interest. This assumption seems to be fulfilled in the current study, even though we have a short pre-treatment period.

Referrals from GPs is seen from 2008 to 2009 and are recoded to hospital referrals, as they did not have the opportunity to refer LBP patients for a lumbar MRI. There might be several explanations for these registrations; Firstly, registrations with referrals from GP in 2009 may be test of the electronic referral system, used in the communication of between GPs and hospitals. Secondly, referrals from GPs can be interpreted in relation to GPs referring LBP patients for a consult in secondary care, where the GP refer the patient for a lumbar MRI on the same day as the consult.

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This allows the hospital-based specialist doctor to assess the lumbar MRI at the consult on the hospital, and to reduce visits at the hospital for the patient.

The study relied on data from the newly 2018 update of the NPR at Statistics Denmark[43]. This allowed for the newest data from all individuals aged 18+ of the population of Denmark. The granularity of the data allows for an unseen precision of analyses performed on country level.

Conclusions

Following RSD' introduction of organisational changes in 2010, the lumbar MRI rate increased significantly in comparison with the other regions in Denmark. The issue of whether the increased usage of lumbar MRI is beneficial for the RSD's LBP patients (compared to that of other regions) requires further investigations.

Figure Legends:

Figure 1: Changes in the referral patterns to lumbar MRI in Region of Southern Denmark from 2008-2013 using a 100% stacked curve diagram. Abbreviations: MRI, magnetic resonance imaging, GP general practitioners

Figure 2: Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.

Figure 3: Dynamic year effects using the adjusted model, with multiple difference in difference estimates with 2009 as the pre-intervention period and all post intervention years for Region of Southern Denmark and the control regions. Abbreviations b, Beta estimates from the difference in

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difference analysis; min95, Lower bound of the 95% confidence interval of the beta estimate; max95, upper bound of the 95% confidence interval of the beta estimate

Declarations

Acknowledgements

Not applicable

Ethics approval and consent to participate

The study is based on registry data, which does not require ethics approval in Denmark (Act on Research Ethics Review of Health Research Projects § 14, sec. 2 http://www.nvk.dk/english/act-on-research 10.02.2017). The study group did however send the study protocol for an ethic assessment to the regional ethics committee in Region of Southern Denmark. The committee found that the study did not need ethic approval. The Danish Data Protection Agency approved this study (Journal number 15/14594).

Consent for publication

All authors' consent to publish this document

Availability of data and material

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The data that support the findings of this study are available from national databases at Statistics Denmark (Sejrøgade 11, DK-2100 København Ø, Phone +45 39 17 31 30, E-Mail forskningsservice@dst.dk), a governmental institution, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Statistics Denmark and The Danish Data Protection Agency (Borgergade 28, DK-1300 Copenhagen, Phone +45 3319 3200, E-Mail dt@datatilsynet.dk).

Competing interests

The authors declare that they have no competing interests

Funding

The study is a part of a three year PhD grant with contributions from Centre for Quality, Region of Southern Denmark, The Institute of Regional Health Research, University of Southern Denmark and Region of Southern Denmark. The Study further received a grant from the Regional Research Fund of Southern Denmark, Region of Southern Denmark. All grant givers had no saying in the design and interpretation of the study.

Authors' contributions

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MS and KO made the dataset at Statistics Denmark and analysed the data. MS wrote the manuscript, made figures and tables with contributions from KO, LM, JS and BC. All authors read and approved the final manuscript."

List of abbreviations

magnetic resonance imaging (MRI), ow back pain (LBP), United States (US), Region of Southern Denmark (RSD), General Practitioners (GPs), Disease Management Programme (DMP), Capitol Region (CR), the Danish National Patient Registry (NPR), Health Care Classification System (SKS codes), civil registration numbers (CPR), Difference-In-Difference (DD), Ordinary Least Squares (OLS), number (N), 95% Confidence Intervals [CI ,] and percentages (%)

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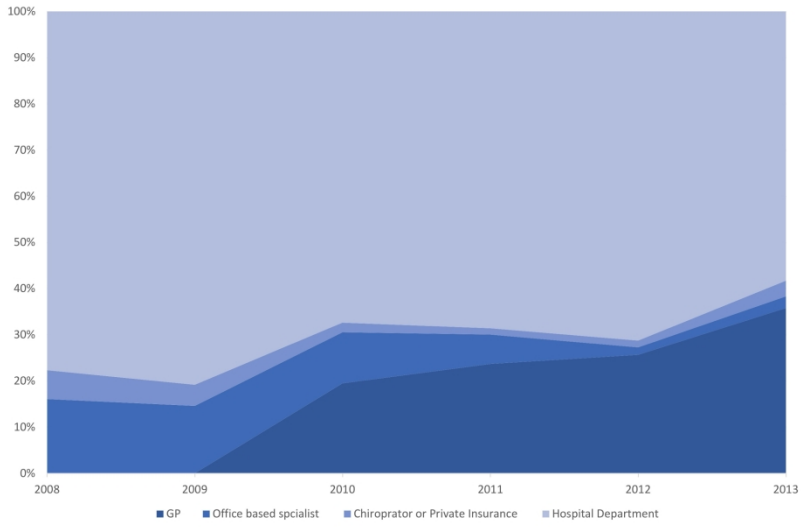

Figure 1: Changes in the referral patterns to lumbar MRI in Region of Southern Denmark from 2008-2013 using a 100% stacked curve diagram. Abbreviations: MRI, magnetic resonance imaging, GP general practitioners

296x166mm (300 x 300 DPI)

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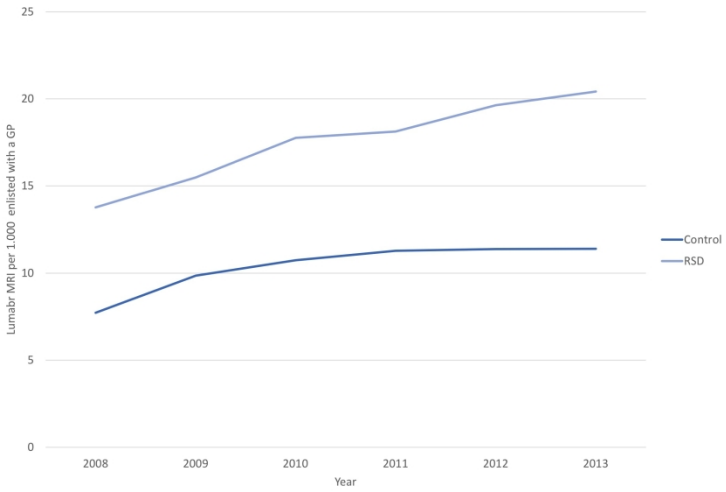

Caption : Figure 2: Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.

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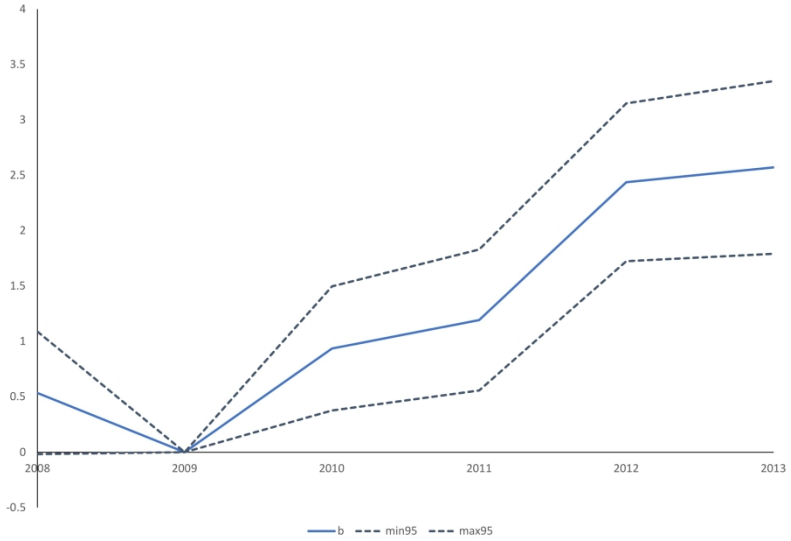

Figure 3: Dynamic year effects using the adjusted model, with multiple difference in difference estimates with 2009 as the pre-intervention period and all post intervention years for Region of Southern Denmark and the control regions. Abbreviations b, Beta estimates from the difference in difference analysis; min95, Lower bound of the 95%confidence interval of the beta estimate; max95, upper bound of the 95% confidence interval of the beta estimate

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6, 7, 9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	N/A
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7,8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	5
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	N/A

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		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	12
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11,12
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14, 15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14, 15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025921.R2
Article Type:	Research
Date Submitted by the Author:	03-Apr-2019
Complete List of Authors:	Jensen, Morten; Centre for Quality, Region of Southern Denmark; The Institute of Regional Health Research, University of Southern Denmark Olsen, Kim; DaCHE, Institute of Public Health, University of Southern Denmark Morsø, Lars; Centre for Quality, Region of Southern Denmark; The Institute of Regional Health Research, University of Southern Denmark Søndergaard, Jens; Research Unit of General Practice, Institute of Public Health, University of Southern Denmark Schiøttz-Christensen, Berit; The Institute of Regional Health Research, University of Southern Denmark; Lillebaelt Hospital, Region of Southern Denmark, Spine Centre of Southern Denmark
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Diagnostics, Health policy, Radiology and imaging, Public health
Keywords:	Magnetic resonance imaging < RADIOLOGY & IMAGING, PUBLIC HEALTH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Low Back Pain, MRI

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Title:
Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data

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Key Words:

Keywords: MRI-rate, lumbar MRI, Direct Referral to MRI, Registry Data, Statistics Denmark, Low Back Pain , Organisational Changes

Word Count

3968

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Abstract

Objectives:

This study reports lumbar magnetic resonance imaging (MRI) referral patterns in Region of Southern Denmark (RSD) and investigate the hypothesis that we will see an increase in imaging rates (MRI-rates) following new referral options to lumbar MRI in RSD in comparison with the other regions in Denmark from 2010-2013.

Design:

A difference-in-difference (DD) analysis, using GPs in other Regions as control, was used to test if the new referral options had an effect on the MRI rates.

Setting:

In 2010, RSD introduced organisational changes affecting the referral options for lumbar MRI. Firstly, the possibility for direct referral to lumbar MRI was introduced to General practitioner's (GP), and secondly the region gathered all local spine departments into one specialist hospital called the Spine Centre.

Participants:

We retrieved all lumbar MRIs performed on patients aged 18+ performed on Danish hospitals from 2008-2013 using the registries from Statistics Denmark. We use socio-demographic information from all Danish citizens aged 18+ aggregated to GP level.

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Primary and secondary outcome measures:

Lumbar MRI scans per 1.000 capita enlisted with a GP (MRI-rates) were calculated based on GP's patient list. Four referral types were made to describe changes in referral patterns.

Results:

In total 183.389 patients received 240.760 lumbar MRIs in the period. The use of the direct referral option by GPs in the RSD increased by 115% in the period from 2010 to 2013 and accounted for 34% of all referrals (N = 6,545) in 2013. MRI-rates were significantly higher in RSD following the organisational changes (DD 1.389 [0.925,1.852] lumbar MRI per 1.000 enlisted with a GP).

Conclusions:

Introduction of organisational changes in RSD as direct referral to MRI from GPs and Chiropractors as well as establishing a Spine Centre increase the lumbar MRI rate in comparison with other regions in Denmark.

Strengths and limitations of this study:

- Nation-wide registry data including socio-demographic information on all citizens aged 18+
- Use of a Difference-in-Difference design for possible causal inference
- The study might underestimate the lumbar MRIs from private hospitals

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Background

The number of lumbar magnetic resonance imaging (MRI) undertaken in the United States (US) Medicare population increased substantially from 1994 to 2006, despite guidelines which discourages routine use of MRI [1-3]. It was estimated that the use of MRI and other imaging modalities accounted for 7% of the direct treatment costs of LBP in 1998 [4].

The factors associated with the increased use of MRI in the diagnostics of low back pain have been investigated. Research shows that the substantial geographic differences in use of spinal MRI across states in the US [5-8] can be explained by differences in local clinical practices [6], physician ownership of specialty hospitals [9], fee-for-service schemes [10], MRI-scanner availability [11] and state median income per capita [12]. However, these studies were undertaken in a US-setting among populations that had limited access to health care providers and where a fee-for service incentive affected doctors' wages. Consequently, more studies are needed on factors impacting the use of lumbar MRI, in other health care settings [13-15].

In this study we have the opportunity of using nation-wide data and hence evaluating a natural experiment. In 2010, Region of Southern Denmark (RSD), made two organisational changes. These included, centralisation of regional spine specialist departments across regional hospitals in one spine specialist hospital. Further, General Practitioners (GPs) and chiropractors were given the possibility to directly refer LBP patients for lumbar MRI without prior referral to the Spine Centre or to office-based specialist doctors. In the support of the organisational changes, RSD implemented a LBP Disease Management Programme (DMP). The centralization of the hospital occurred in the beginning of 2010, and the hospital were fully operational in mid 2010. The direct

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referral access was available for the GPs in the first months of 2010. Hence we expect effects of the reform to be modest in 2010 and to increase in the following years. These changes were unique in Denmark as two of four other regions maintained decentralised spine departments and did not allow for direct referral. To date, the effect of these organisational changes in RSD have not been investigated.

The study investigates the effect of the organisational changes on use of lumbar MRI in the diagnostics of LBP patients in RSD. Primary outcome is defined as yearly lumbar MRI rates for all individuals aged 18+. As the reform increased the possibilities to refer to lumbar MRI we hypothesised that the yearly lumbar MRI rates from 2010 to 2013 would increase significantly in RSD compared to the other regions.

Methods

Design

A longitudinal register-based study covering the Danish population aged 18+ from 2008 to 2013. The study relies on a natural experiment using RSD as the intervention group. Two regions, Zealand Region (ZR) and the North Denmark Region (NR), maintained their organisation in the study period from 2008 to 2013. Hence these two regions can act as good indicators of the counterfactual RSD. GPs in RSD, GPs in the Capitol Region (CR) and Central Denmark Region (CD) were given the possibility to directly refer LBP patients for a lumbar MRI in 2010 and 2011, respectively. This allows GPs from CD to act as controls from 2008-2010, while GPs from CR are excluded, as they allow referrals from GPs at the same time as RSD, which is why they cannot act

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as good indicators of the counterfactual development in RSD if RSD had not made the organisational changes.

Primary outcome

The primary outcome is yearly lumbar MRI per 1,000 enlisted with a GP.

Setting

In Denmark, five decentralised administrative regions, including 98 municipalities, manage the tax founded health care system [16]. Each region has a public elected council and is autonomously managing secondary healthcare services. All services provided at hospitals and office-based physician are free of charge, while services at physiotherapist and chiropractors involve co-payments from the patient. GPs in Denmark have a unique patient list (GP list) of citizens, to whom the GP solely provided services. The GP list size is on average 1.600 patients, and 98% of all Danes are enlisted at one of the 2.200 GP clinics in Denmark [16].

Data sources

The study used data from the registries at Statistics Denmark (DST), a governmental institution providing data for research purposes[17]. All registries are linkable at the individual level, using the personal civil registration number (CPR-number), which are given to all Danish citizens at birth [18] [19]. The study includes data from the following registries:

The Danish National Patient Registry (NPR) [20] [21], includes information on diagnosis coded according to the International Classification of Disease (ICD-10), and procedure and surgery codes

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(Health Care Classification System (SKS codes)). All NPR records are unique, due to a NPR serial numbers (unique to each patient's continuum of care at a hospital) and patients' CPR-numbers.

The Danish National Health Service Register for Primary Care (DNHR) [22], includes all contacts to the primary sector health care providers including GPs, Chiropractors, Physiotherapists, and office-based specialist doctors. The GP list and GP list size were generated by combining the unique GP id with the CPR-number from patients receiving most of their services from the GP id[23]. GPs with patient list size less than 300 patients were deleted as they are hypothesised to be GPs either starting up or closing down the practice. Those citizens with no information of GP id in one of the study years, were allocated to a hypothetical GP id generated for each region.

Danish National Prescription Registry (DNPR) includes information on all prescription based analgesic drugs sold at Danish primacies[24]. We identified analgesic drugs according to the Anatomical Therapeutic Chemical classification (ATC) code[25]. Analgesic drugs included ATC code NN02A and NN02B; tablet cans with >100 pills of paracetamol and ibuprofen, synthetic opioids, and opioids.

We further retrieved registers on income[26], education[27], job- and socio-economic status[28], civil status[18], and demographics [18] from DST.

Definition of lumbar MRI

This study included data for lumbar MRI (SKS code: UXME30)[21]. Each MRI scan performed at a public hospital is recorded in NPR. Lumbar MRIs performed on a private hospital are recorded in

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the NPR if they are subsidised by the government. Patients with multiple spine MRI registrations on the same NPR serial number were identified and the UXME30 code was retained for analysis. If patients showed two or more UXME30 codes for the same day only one remained.

Definition of referral mode

A referral mode variable was defined based on two variables from the NPR; Referral directly from the GP (1), directly from the Chiropractor or initiated by private insurance (2), directly from the office-based specialist doctors (3), and from the hospital department (4). In the dataset we observe registrations with referral directly from the GP, before 2010. These are recoded into hospital registrations.

Analyses strategy

The impact on MRI-rates of the well-defined organisational changes in 2010 in RSD, is analysed as a natural experiment. The change in the other regions are used as control under the assumption that the development of MRI rates in the control regions are a good indicator of how the MRI rates would have developed in RSD in absence of the organizational changes.

We hypothesise that the two referral options (direct GP referral and referral to the Spine Centre) drives any change in use of lumbar MRI. As patients have not chosen to live in RSD based on the access to MRI, the assumption behind our analyses strategy is that we can interpret patients as randomly assigned to a GP who by construct of the natural experiment happen to have access to the organizational changes (RSD) or not (control regions). We therefore included GPs from the Zealand Region (ZR) and the North Denmark Region (NR) as controls for all years in the analysis.

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GPs from the CR are included from 2008 to 2010, as they had the possibility to directly refer LBP patients for a lumbar MRI in 2011. GPs from the CR were excluded as controls.

We use a difference in difference (DD) model to analyse the effect of the reform. The DD model estimates the effect of organisational changes by assuming that the counterfactual development in the lumbar MRI rates in the treatment group (i.e., RSD) could be approximated by the development in the lumbar MRI rates of the other regions [29]. For the control group to match the approximation of the counterfactual development in lumbar MRI rates in RSD the model, we rely on an assumption that there was a common trend in lumbar MRI rates before the interventions. The common trend assumption was visually inspected. Furthermore we estimated the effects of the reform year by year for 2010, 2011, 2012 and 2013 and made a placebo test by testing for an effect of the reform before it was implemented – i.e. testing for an increase in MRI from 2008 to 2009. This placebo test is an indirect test of the common trend. The DD approach by definition control for all time constant heterogeneity between GPs in RSD and the controls but if we expect time varying differences occurring over time we need to add covariates. Hence, second assumption behind our approach is that there were no time-varying unobservable covariates, that could explain differences in selection into a referral to lumbar MRI between GPs, and between regions [29]. Hence, we generally assume that citizens' need for MRI are identical among regions after controlling for observable patients' characteristics and supply factors related to LBP treatment did not change over time on the regional level. A limitation of our dataset is that we only have two years of observation before the organizational changes, which makes the validation of the common trend assumption hard to assess. As a consequence we supplemented the DD analysis with two robustness checks. First, we made a replication of the analysis using quarterly

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data instead of annual data. This gives eight pre-treatment observations, which allow for a better assessment of the common trend. Second, we estimate the treatment effect using propensity score matching (PSM) – an approach that does not rely on the common trend assumption but on common support[30-32].

Statistics

The DD model is implemented using a parametric Ordinary Least Squares (OLS) regression model with robust standard errors and clustering for GP id. We aggregated the individual level socio demographic data to GP level. This allowed for analysis using information from the socio demographic composition of the GPs' lists to account for any time varying patient characteristics, that is associated with LBP, and therefore explain differences in GPs' referral to lumbar MRI. A supplementary advantage of using the GP as analytical level is that we in this way obtain an unbalanced panel data structure of our dataset, with one observation per unique GP per year. As a robustness check we organise data in quarterly observations and re-assess the DD model using 24 quarterly observations rather than 7 annual observations per GP. We further use PSM with nearest neighbour with caliper equal to ¼ of the standard deviation on the propensity scores. The supplementary material gives detailed information on the robustness check using quarterly data and PSM.

The changes in referral modes were graphed for RSD (see Figure 1). To show dynamic year effects of the models, 2009 was used as pre-intervention and each intervention year was used as the post-intervention year, in four DD regression models– one for each post treatment year (2010,

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2011, 2012 and 2013). To test if the trend in MRI rates were not different between RSD and controls before the programme we tested for a treatment effect in 2009 using 2008 as base year. The five models used the variables as in the adjusted models and were analysed using both control groups. The DD estimates and the 95% confidence intervals [CI;] were graphed (the control regions were the x-axis). Tables reported number (N), means, standard deviations (SD), unpaired t-test, and percentages (%). All analyses were performed using STATA Release 13 (STATACorp, College Station, TX, USA) and graphics and tables were performed in Microsoft Excel 2010 (©Microsoft Corporation).

Covariates

The unadjusted models included the following variables: pre- and post 2009 (0 = 2008–2009, 1 = 2010–2013) and intervention and control regions (1 = RSD and 0 =ZR, NR, CD).

The adjusted models add time varying covariates to the above variables. This is done to avoid that any observed change in RSD after the change is simply due to changes in the characteristics of the citizens over time – for example that citizens in RSD over time becomes more prevalent to LBP than control regions. All covariates included, except GP list size, were made as proportions of enlisted patients with characteristic X divided with the GP list size. Patients characteristics X included; age 18-59, citizens in a full-time job, income DKK 0-399.000 or missing, women, citizens living as singles, and Charlson comorbidity index score[33] 2+, patients with vocational education, patients using a prescription on an analgesic drug at a pharmacists, patients having a visit at a physiotherapist, patients having a visit at a chiropractor, and patients visiting an office-based

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specialist doctors (rheumatologist, neurologist, orthopaedics, and radiologist). Covariates are seen in table 1.

Patient and Public Involvement

Patients were not involved in the study

Ethics

The Danish Data Protection Agency approved this study (Journal number 15/14594). The study is based on registry data, which does not require ethics approval in Denmark (Act on Research Ethics Review of Health Research Projects § 14, sec. 2 http://www.nvk.dk/english/act-on-research 10.02.2017).

Results

During the study period 183.389 patients were assessed with 240.760 lumbar MRIs. Of those 27% (63.982 lumbar MRIs) were performed on private hospitals.

(insert figure 1)

Figure 1 shows changes in the rates of referrals for lumbar MRI in the RSD. MRI referrals directly from GPs accounted for 18% (N = 3,044) of all referrals in 2010. In the subsequent three years, the rate of MRI referrals directly from the GP increased 115% to (N = 6,545) and accounted for 34% of all of the MRI referrals in 2013. MRI referrals from office-based specialist (rheumatologist or orthopaedics) decreased from 2008 (N = 1,916, 16%) to 2013 (N = 464, 2% MRI referrals from

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office-based chiropractors or from a private insurance increased from 2011 (N=220, 1%) to 2008 (N=748, 6%). MRI referrals from hospital-based doctors increased from 2008 (N=9,262, 77%) to 2012 (N=12,487,71%).

(insert figure 2*)*

The common trend was visually inspected using figure 2, showing unadjusted average regional lumbar MRI rates for GPs in RDS and the control regions. Lumbar MRI rates for RSD increased each year starting from 14.29 lumbar MRI per 1,000 enlisted with a GP in 2008 to 21.13 lumbar MRI per 1,000 enlisted with a GP in 2013. The average lumbar MRI rates for three control regions increased from 7.79 lumbar MRI per 1,000 enlisted with a GP in 2008 to 11.48 lumbar MRI per 1,000 enlisted with a GP in 2012 and 2013. To capture any differences in time-varying trends we included characteristics of the GP patient list, seen in Table 1. The table show that there are statistical differences for 8 of the 12 included covariates between GPs in RSD and control group regions in the pre-intervention years. However, the differences are small between the patient characteristics of the GPs' lists in RSD and GPs' lists in control group regions.

Table 1: Differences in proportions of patients enlisted at a GP from either intervention or control regions for pre-intervention years (2008 and 2009 combined)

	RSD's GPs (N=832)		Control regions' GPs (N=1878)$		
	Mean	SD	Mean	SD	T-test§
Comorbidity score 2+	0.031	0.008	0.031	0.010	*
Full time job	0.565	0.060	0.570	0.064	*
Vocational education	0.443	0.029	0.450	0.038	*
Marital status single	0.318	0.064	0.323	0.076	*
Income DKK 0-399.999	0.899	0.028	0.888	0.039	*
Gender (women)	0.509	0.063	0.509	0.066	

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18-59 year of age	0.674	0.076	0.679	0.082	
GPs' id list size	2265.060	3197.228	2212.976	3440.372	
Visits to Physiotherapist	0.086	0.022	0.096	0.026	*
Visits to Chiropractor	0.079	0.024	0.072	0.023	*
Visits to Office based specialists	0.035	0.022	0.037	0.027	*
Use of pain medication	0.153	0.037	0.150	0.040	

Means reflect proportions of patients divided by the GP list size. Abbreviations: ** p<0.05, § t-test by group with unequal variance; N number of observations; RSD Region of Southern Denmark, GP general practitioner, SD Standard Deviation. $ Including general practitioners from Zealand Region, Central Denmark Region and North Denmark Region.*

The results of the DD analyses of the lumbar MRI rates per 1,000 enlisted with GPs RSD compared to GPs in the control group, are shown in Table 2. After the organisational changes in RSD, the lumbar MRI rates increased significantly compared to control groups, for both models ranging from 1.39 [CI 0.93;1.85] to 1.83 [CI 1.37;2.29] lumbar MRIs per 1,000 enlisted with a GP.

Table 2: Difference in Difference and propensity score matching estimates from unadjusted and adjusted models with Region of Southern Denmark and the control regions

	Lumbar MRI rates			
	Difference in difference			PSM[c]
	Unadjusted	Adjusted model[a]	Quarterly data[b]	
DD (RSD*Post treatment)	1.83***	1.39***	0.43***	3.80***
	[1.37,2.29]	[0.93,1.85]	[0.32,0.53]	[2.67 ; 4.94]
Constant	9.04***	2.60	2.24***	-
	[8.85,9.23]	[-5.28,10.48]		

[a] Adjusted model include covariates for; Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at Physiotherapist, visits at Chiropractor, visits at office-based spine specialist, use of pain medication. [b] The DD model with quarterly data use the same covariates. However, in addition we included quarter dummies (Q1, Q2 Q3 and Q4) to take a way the obvious seasonality shown in figure A1 in the supplementary material[c]. The PSM model use conventional options; nearest neighbour with (caliper = ¼ of the standard deviation on the propensity scores). We use the same covariates as in the DD model, but include the MRI rates in 2008 and 2009 as matching covariates to control for unobservable selection[31 32]. Furthermore, we control for clustering at GP level[34].Abbriviations; 95% confidence

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*interval [,], * p<0.05, ** p<0.01, *** p<0.001, DD Difference in Difference, RSD Region of Southern Denmark, Post treatment, years from 2010-2013, PSM Propensity Score Matching.*

Table 2 also present the robustness checks using DD with quarterly data and PSM (see table A1 for DD results and A2 for PSM results in the supplementary material). The model with quarterly data shows a significant increase in quarterly MRI of 0.43, which is at a comparable level as the model using annual data when multiplying with four. The PSM model however, shows quite higher effects. This may rest on the fact that RSD generally is at a higher level of MRI throughout the period of observation and that the PSM approach is less effective in taking this into account. The PSM result indicates that the DD makes a conservative estimate of the effect. We refer to the table A3 for bias reductions of PSM model and figure A2 for common support in supplementary material.

The dynamic year effects, for both models are seen in figure 3. Figure 3 indicates that the common trend assumption support is fulfilled, as a hypothesised treatment effect before the intervention (i.e. in 2009) occurred (placebo effect) is insignificant. This test is also insignificant in the model using quarterly data and hence eight pre-treatment observations (see table A1 in supplementary material).

Dynamic year effects for post-intervention years were positive and significant for all years, with an observed increase positive trend of the estimates, indicating that the effect of the organisational changes increases over time (figure 3).

(Insert figure 3)

Discussion

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This study showed that establishing a Spine Centre in the RSD and introducing direct referrals for lumbar MRI by GPs was associated with an increase in the use of lumbar MRI (compared to that of other regions) in the years following the 2010 changes. On average the increase was between 1.39 to 1.83 lumbar MRI per 1.000 enlisted with GPs in RSD involving an increase in lumbar MRI of between 1.400 and 1.800 additional scans compared to the other regions. The use of the direct referral option by GPs in the RSD increased by 115% in the period from 2010 to 2013, indicating that the GP adopted the new referral option.

As in other studies from the US[7], we find geographical variation in the use of lumbar MRI among the regions in Denmark. The reason for the difference in use of lumbar MRI among the regions is still unclear. Some points towards a special interest in back pain by specialist doctors in RSD, which relates to different regional clinical practices, which have been found in US studies[6 11]. The relationship between MRI usages and physician incentives[9 10], is unlikely to explain the differences in a Danish setting; Firstly, physicians at public hospital receive a fixed yearly salary, thereby not having incentives to refer patients. Secondly, the public hospitals undertook 74 % of all scans.

The increase in referrals for lumbar MRI following the change in GP referral access to lumbar MRI in the RSD in 2010 is noteworthy. GPs in the RSD clearly began to use the new referral option immediately and the use of the referral option increase by 115% from 2010 to 2013. This change might indicate a lowering in the threshold for a MRI referral. There could be numerous reasons for the use of direct referrals to lumbar MRI, including patient demands[35 36] and physicians' wish to provide quick reassurances to LBP patients[36]. Providing quick reassurance to patients could prevent further costly visits to specialist doctors and reduce future treatment costs. However,

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previous studies have shown that lumbar MRI referrals from GPs are inappropriate in up to 50% of the cases when judged against the guidelines [10 37-39]. Further, the inappropriate use of lumbar MRI has been shown to be associated with an increased use of opioids, higher health care costs and has a low impact on pain relief or functional recovery after 6 months in non-specific LBP patients, without serious pathologies such as cancer, nerve root compression, cauda equina, radiculopathy and sciatica [3 5 40-46]. Further studies are needed to investigate if the same associations are found in this setting.

Strengths and Limitations

This study used DD estimates to capture the effect of the organisational changes and LBP DMP in RSD. Difference in difference is a popular design for evaluation of policy changes, as is widely used in social science[29]. DD relies on the assumption of a common trend in the pre-treatment period for the outcomes of interest. This assumption seems to be fulfilled in the current study. However, a clear limitation of our dataset is that we have a short pre-treatment period. As a consequence we have used DD on quarterly data as well as PSM analysis to check the robustness of the results. Both analyses support the findings and as we believe the DD approach to be the most conservative we stick to this model as our base case. Details on the robustness model are to be found in supplementary material.

Referrals from GPs are seen from 2008 to 2009 and are recoded to hospital referrals, as they did not have the opportunity to refer LBP patients for a lumbar MRI. There might be several explanations for these registrations; Firstly, registrations with referrals from GP in 2009 may be test of the electronic referral system, used in the communication of between GPs and hospitals.

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Secondly, referrals from GPs can be interpreted in relation to GPs referring LBP patients for a consult in secondary care, where the GP refer the patient for a lumbar MRI on the same day as the consult. This allows the hospital-based specialist doctor to assess the lumbar MRI at the consult on the hospital, and to reduce visits at the hospital for the patient.

The study relied on data from the newly 2018 update of the NPR at Statistics Denmark[47]. This allowed for the newest data from all individuals aged 18+ of the population of Denmark. The granularity of the data allows for an unseen precision of analyses performed on country level.

Conclusions

Following RSD' introduction of organisational changes in 2010, the lumbar MRI rate increased significantly in comparison with the other regions in Denmark. The issue of whether the increased usage of lumbar MRI is beneficial for the RSD's LBP patients (compared to that of other regions) requires further investigations.

Figure Legends:

Figure 1: Changes in the referral patterns to lumbar MRI in Region of Southern Denmark from 2008-2013 using a 100% stacked curve diagram. Abbreviations: MRI, magnetic resonance imaging, GP general practitioners

Figure 2: Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.

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Figure 3: Dynamic year effects using the adjusted model, with multiple difference in difference estimates with 2009 as the pre-intervention period and all post intervention years for Region of Southern Denmark and the control regions. Abbreviations b, Beta estimates from the difference in difference analysis; min95, Lower bound of the 95% confidence interval of the beta estimate; max95, upper bound of the 95% confidence interval of the beta estimate

Declarations

Acknowledgements

Not applicable

Ethics approval and consent to participate

The study is based on registry data, which does not require ethics approval in Denmark (Act on Research Ethics Review of Health Research Projects § 14, sec. 2 http://www.nvk.dk/english/act-on-research 10.02.2017). The study group did however send the study protocol for an ethic assessment to the regional ethics committee in Region of Southern Denmark. The committee found that the study did not need ethic approval. The Danish Data Protection Agency approved this study (Journal number 15/14594).

Consent for publication

All authors' consent to publish this document

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Availability of data and material

The data that support the findings of this study are available from national databases at Statistics Denmark (Sejrøgade 11, DK-2100 København Ø, Phone +45 39 17 31 30, E-Mail forskningsservice@dst.dk), a governmental institution, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Statistics Denmark and The Danish Data Protection Agency (Borgergade 28, DK-1300 Copenhagen, Phone +45 3319 3200, E-Mail dt@datatilsynet.dk).

Competing interests

The authors declare that they have no competing interests

Funding

The study is a part of a three-year PhD grant with contributions from Centre for Quality, Region of Southern Denmark, The Institute of Regional Health Research, University of Southern Denmark and Region of Southern Denmark. The Study further received a grant from the Regional Research Fund of Southern Denmark, Region of Southern Denmark. All grant givers had no saying in the design and interpretation of the study.

Authors' contributions

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MS and KO made the dataset at Statistics Denmark and analysed the data. MS and KO wrote the manuscript, made figures and tables with contributions from LM, JS and BC. All authors read and approved the final manuscript."

List of abbreviations

magnetic resonance imaging (MRI), ow back pain (LBP), United States (US), Region of Southern Denmark (RSD), General Practitioners (GPs), Disease Management Programme (DMP), Capitol Region (CR), the Danish National Patient Registry (NPR), Health Care Classification System (SKS codes), civil registration numbers (CPR), Difference-In-Difference (DD), Ordinary Least Squares (OLS), number (N), 95% Confidence Intervals [CI ,] and percentages (%)

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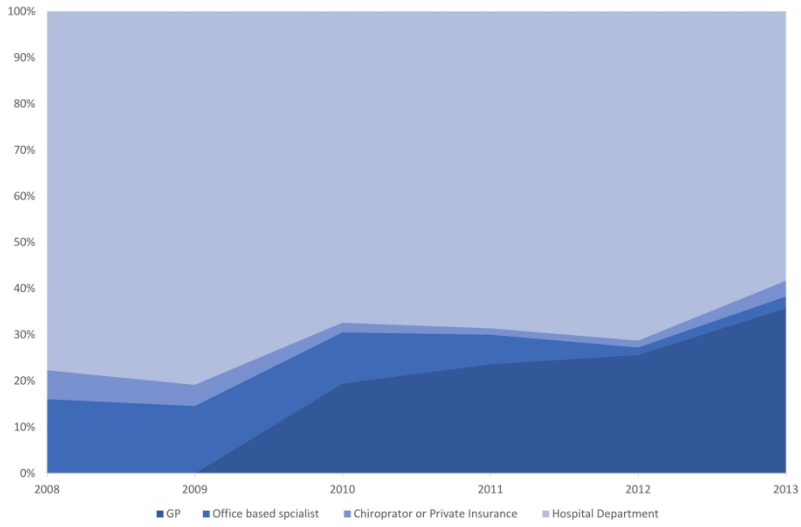

Figure 1: Changes in the referral patterns to lumbar MRI in Region of Southern Denmark from 2008-2013 using a 100% stacked curve diagram. Abbreviations: MRI, magnetic resonance imaging, GP general practitioners

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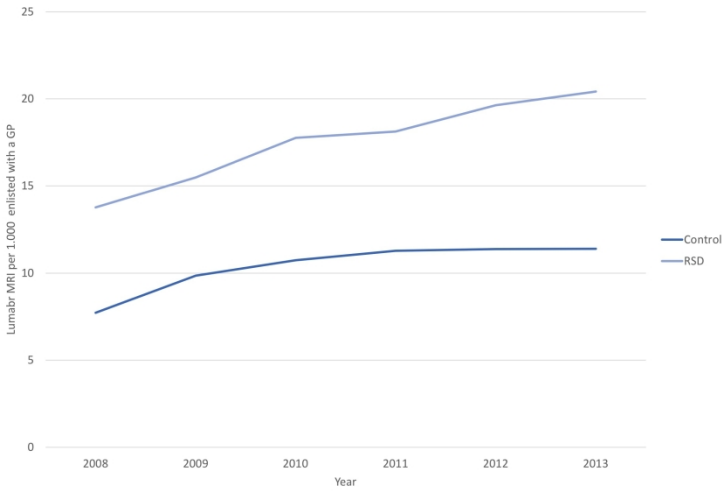

Caption : Figure 2: Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.

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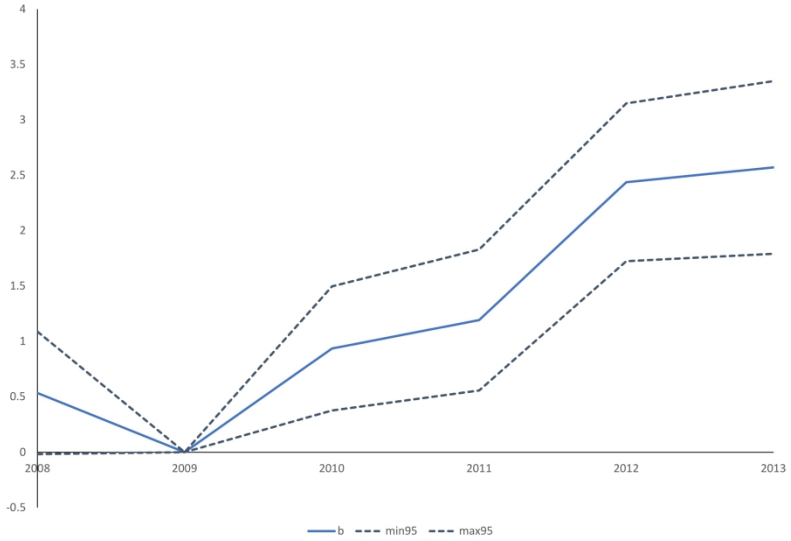

Figure 3: Dynamic year effects using the adjusted model, with multiple difference in difference estimates with 2009 as the pre-intervention period and all post intervention years for Region of Southern Denmark and the control regions. Abbreviations b, Beta estimates from the difference in difference analysis; min95, Lower bound of the 95%confidence interval of the beta estimate; max95, upper bound of the 95% confidence interval of the beta estimate

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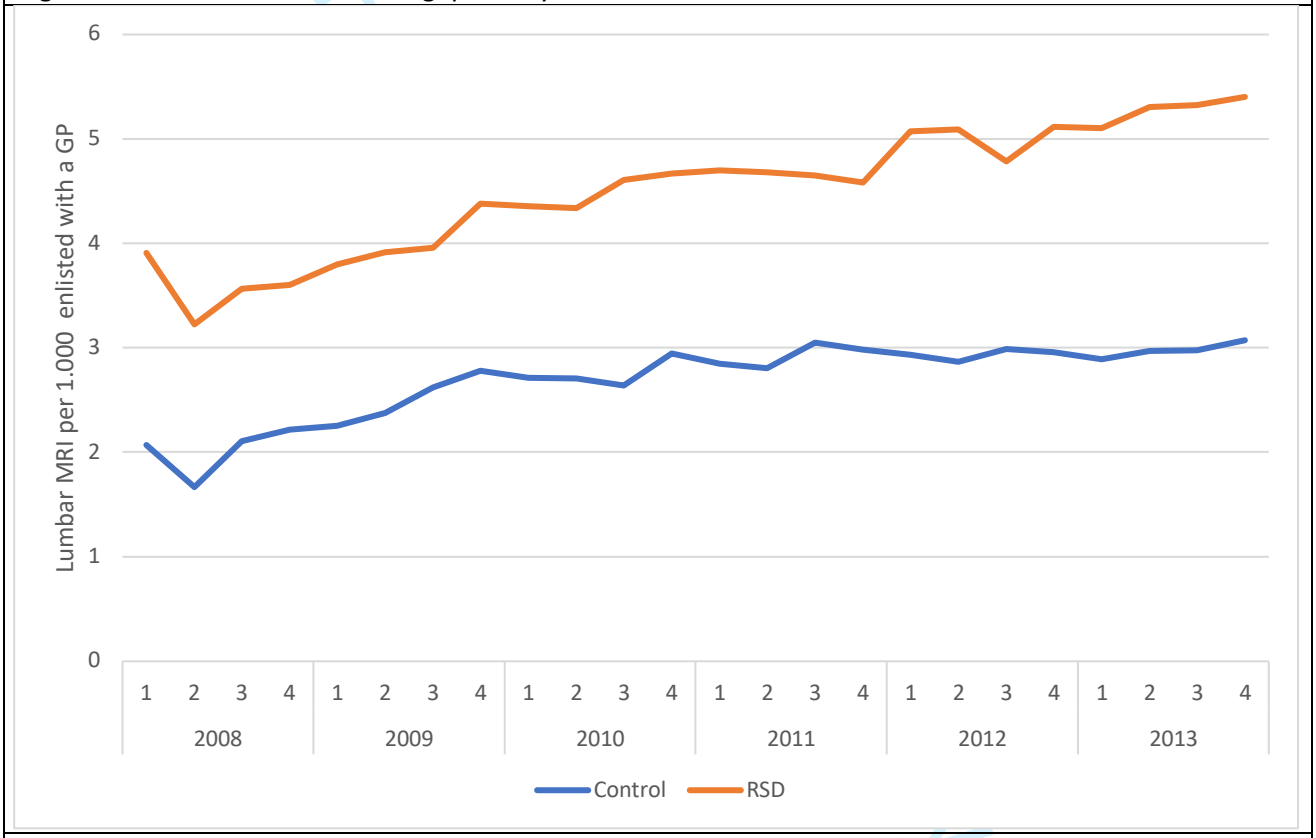
Supplementary material: Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data.

In this supplementary material we report the details of the robustness checks of the DD model in the paper. First we present results of reorganising data to quarterly levels and re-assessment of the DD model. Second we present the PSM model and assess the assumptions behind this model.

DD model using quarterly level

The results are presented below. Figure A.1 show the trends in MRI using quarterly data, and table A.1 show the DD results where we in addition to the covariates in the paper have included quarter dummies (Q1, Q2 Q3 and Q4) to take away the obvious seasonality that shows up in figure A.1.

Figure A.1: Lumbar MRI rates using quarterly data



Notes: *Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.*

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Table A.1: DD estimates using quarterly data

	Model (1) 2010-13 vs 2008-9	Model (2) 2010-13 vs 2008-9	Model (3) 2010-13 vs 2008-9	Placebo 2009 vs 2008
RSD	1.53***	1.53***	1.55***	1.56***
Post treatment	0.61***	0.61***	0.62***	0.49***
DD (RSD x Post treatment)	**0.46*** **	**0.46*** **	**0.43*** **	**-0.05**
Quarter 1	-	-0.20***	-0.20***	-0.27***
Quarter 2	-	-0.27***	-0.27***	-0.46***
Quarter 3	-	-0.13***	0.99***	-0.16***
Quarter 4	-	Omitted	Omitted	Omitted
Constant	2.26***	2.41***	2.42***	2.24***
Clustered error terms at GP level	Y	Y	N	Y
GP FE	N	N	Y	N
Quarterly time trend dummies (quarter 1-24)	N	N	Y	N

Figure A.1 show that the trends in MRI rates seem to be parallel even in the unadjusted rates. The common trend assumption is conditional on the covariates and the placebo test in column 4 in table A.1 confirms that the change in MRI rates in RSD, conditional on the covariates, is not significantly different from the control before 2010 (i.e. 2009 vs 2008). However the post-2010 effects are still positive and significant with levels between 0.43 and 0.46, which is close to ¼ of the treatment effects in the results based on annual data. Hence the robustness check using quarterly data confirms the results in the paper.

PSM model

The PSM approach requires that the common support assumption be fulfilled. Hence, covariates that describes the bias between the treatment and control group, is needed to produce propensity scores to weigh the MRI rates. A disadvantage of the PSM as compared to DD is that it does not control for unobserved variables causing bias – hence it is relying on a rich set of covariates. However, by using the MRI rate in 2008 and 2009 as matching covariates we indirectly control for unobservable variables. The reason is that it can be argued that any unobserved selection bias between treatment- and control groups may also be present in the outcome variable before the reform. Hence, including the historic MRI rates for 2008 and 2009 as matching variables is a way to control for unobserved heterogeneity between treatment and control GPs and this approach is generally believed to be very strong – also compared to DD (G.W. ; J.M. Wooldridge Imbens, 2009) and (Martin Huber et al., 2013).

Table A.2 show the treatment effect of the reform using PSM with various sets of covariates. It is evident that the effect is positive and significant but also that the magnitude of the effect is much higher than the DD estimates. We use Stata psmatch2 command with conventional options; nearest neighbour with (caliper = ¼ of the standard deviation on the propensity scores) and bootstrapped error terms. As the DD clusters at GP level we also tried to estimate the PSM treatment effect by simply running an OLS regression on the matched sample using the propensity scores as weights and then cluster at GP level in the OLS (B. Arpino and M. Cannas, 2016). This did not change the results.

Figure A.2 assesses the common support assumption, which is key to PSM. As the histograms are overlapping it shows that for any GP in RSD there exists a control GP with the same propensity score –

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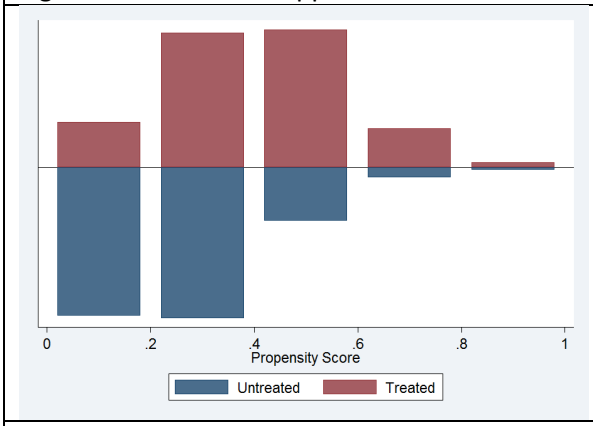
hence there exist a suitable match for all RSD GPs. Table A.3 show that the bias between treated and control GPs has been reduced substantially for most of the covariates. This indicates that comparison after matching is valid. Some covariates are not biased in the unmatched sample but turns biased in the matched sample and therefore we try to run the PSM model with the historic outcome variables only. Table 3 show that this change the magnitude of the effect but not the significance.

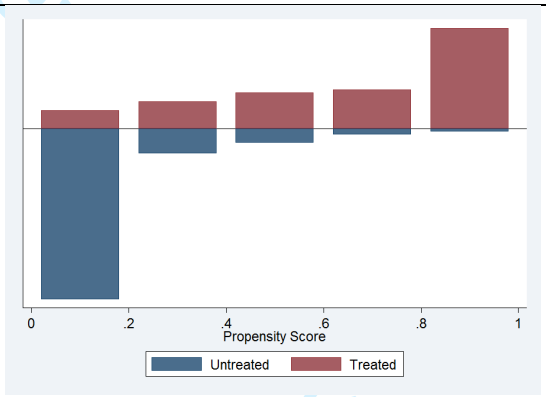
Table A.2: Average treatment effect of the treated using propensity score matching

	Model (1)	Model (2)	Model (3)
ATT	2.81***	8.01***	3.80***
CI	[1.87 ; 3.75]	[7.29 ; 8.84]	[2.67 ; 4.94]
Table 1 covariates	N	Y	Y
MRI rates in 2008 and 2009	Y	N	Y

Abbreviations: ATT Average treatment effect of the treated, CI 95% confidence interval, Table 1 covariates included, *Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at Physiotherapist, visits at Chiropractor, visits at office-based spine specialist, use of pain medication, MRI magnetic resonance imagining, Y yes, N no, *** p<0.001*

Figure A.2: Common support for two models





Propensity scores using covariates from table 1, which include; *Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at Physiotherapist, visits at Chiropractor, visits at office-based spine specialist, use of pain medication*

Propensity scores using covariates using covariates from table 1 in the manuscript, which include; *Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at Physiotherapist, visits at Chiropractor, visits at office-based spine specialist, use of pain medication* and MRI rates in 2008 and 2009.

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Table A.3: Bias reduction for the Propensity Score Matching model

Covariate		RSD (mean)	Control (mean)	% bias	% bias reduction	t	p
Charlson index	U	0.032	0.029	38.2		6.550	0.000
	M	0.032	0.031	11.3	71	1.560	0.118
Income	U	0.897	0.885	36.5		5.780	0.000
	M	0.897	0.889	23.2	36	4.060	0.000
Vocational education	U	0.444	0.451	-20.8		-3.340	0.001
	M	0.444	0.453	-27.3	-31	-4.560	0.000
Pain medication	U	0.153	0.151	6.3		1.040	0.296
	M	0.153	0.152	3.6	43	0.590	0.555
Single	U	0.320	0.326	-9.4		-1.530	0.126
	M	0.321	0.300	29.3	-213	4.690	0.000
Gender (women)	U	0.508	0.508	-0.2		-0.040	0.971
	M	0.508	0.491	27.1	12281	4.440	0.000
Full time job	U	0.552	0.558	-9.0		-1.490	0.136
	M	0.552	0.569	-29.7	-230	-4.500	0.000
Visits to physiotherapist	U	0.086	0.096	-42.8		-7.050	0.000
	M	0.086	0.100	-57.3	-34	-7.250	0.000
Visits to Office based specialists	U	0.037	0.037	-3.3		-0.540	0.591
	M	0.037	0.027	38.7	-1074	6.100	0.000
Visits to Chiropractor	U	0.079	0.072	29.7		5.040	0.000
	M	0.079	0.096	-73.9	-149	-6.880	0.000
MRI rate 2008	U	14.297	[a]8.068	136.7		25.540	0.000
	M	14.234	13.460	17.0	88	2.270	0.023
MRI rate 2009	U	16.059	10.032	130.1		23.770	0.000
	M	16.085	16.920	-18.0	86	-2.030	0.043

Abbreviations: *RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging, % percentage, t t-statistics, p p-value, U unmatched, M matched*

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6, 7, 9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	N/A
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7,8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	5
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	N/A

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		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	12
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11,12
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14, 15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14, 15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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BMJ Open

Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025921.R3
Article Type:	Research
Date Submitted by the Author:	30-May-2019
Complete List of Authors:	Jensen, Morten; The Institute of Regional Health Research, University of Southern Denmark; VIVE - The Danish Center of Social Science Research Olsen, Kim; DaCHE, Institute of Public Health, University of Southern Denmark Morsø, Lars; Centre for Quality, Region of Southern Denmark; The Institute of Regional Health Research, University of Southern Denmark Søndergaard, Jens; Research Unit of General Practice, Institute of Public Health, University of Southern Denmark Schiøttz-Christensen, Berit; The Institute of Regional Health Research, University of Southern Denmark; Lillebaelt Hospital, Region of Southern Denmark, Spine Centre of Southern Denmark
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Diagnostics, Health policy, Radiology and imaging, Public health
Keywords:	Magnetic resonance imaging < RADIOLOGY & IMAGING, PUBLIC HEALTH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Low Back Pain, MRI

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Title:
Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data

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Key Words:

Keywords: MRI-rate, lumbar MRI, Direct Referral to MRI, Registry Data, Statistics Denmark, Low Back Pain , Organisational Changes

Word Count

4,054

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Abstract

Objectives:

This study reports lumbar magnetic resonance imaging (MRI) referral patterns in the Region of Southern Denmark (RSD) and investigates the hypothesis that we will see an increase in imaging rates (MRI-rates) following new referral options to lumbar MRI in the RSD in comparison with the other regions in Denmark from 2010-2013

Design:

A difference-in-difference (DD) analysis, using general practitioner's (GP) in other regions as control, was used to test if the new referral options had an effect on the MRI rates.

Setting:

In 2010, RSD introduced organisational changes affecting the referral options for lumbar MRI. Firstly, the possibility for direct referral to lumbar MRI was introduced GPs, and secondly the region gathered all local spine departments into one specialist hospital called the Spine Centre.

Participants:

We retrieved all lumbar MRIs performed on patients aged 18+ performed on Danish hospitals from 2008-2013 using the registries from Statistics Denmark. We use socio-demographic information from all Danish citizens aged 18+ aggregated to GP level.

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Primary and secondary outcome measures:

Lumbar MRI scans per 1,000 capita enlisted with a GP (MRI-rates) were calculated based on GP's patient list. Four referral types were made to describe changes in referral patterns.

Results:

In total 183,389 patients received 240,760 lumbar MRIs in the period. The use of the direct referral option by GPs in the RSD increased by 115% in the period from 2010 to 2013 and accounted for 34% of all referrals (N = 6,545) in 2013. MRI-rates were significantly higher in RSD following the organisational changes (DD 1.389 [0.925,1.852] lumbar MRI per 1.000 enlisted with a GP).

Conclusions:

Introduction of organisational changes in RSD as direct referral to lumbar MRI from GPs and chiropractors as well as establishing a Spine Centre increase the lumbar MRI rate in comparison with other regions in Denmark.

Strengths and limitations of this study:

- Nation-wide registry data including socio-demographic information on all citizens aged 18+
- Use of a Difference-in-Difference design for possible causal inference
- The study might underestimate the lumbar MRIs from private hospitals

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Background

The number of lumbar magnetic resonance imaging (MRI) undertaken in the United States (US) Medicare population increased substantially from 1994 to 2006, despite guidelines which discourages routine use of MRI [1-3]. It was estimated that the use of MRI and other imaging modalities accounted for 7% of the direct treatment costs of LBP in 1998 [4].

The factors associated with the increased use of MRI in the diagnostics of low back pain have been investigated. Research shows that the substantial geographic differences in use of spinal MRI across states in the US [5-8] can be explained by differences in local clinical practices [6], physician ownership of specialty hospitals [9], fee-for-service schemes [10], MRI-scanner availability [11] and state median income per capita [12]. However, these studies were undertaken in a US-setting among populations that had limited access to health care providers and where a fee-for service incentive affected doctors' wages. Consequently, more studies are needed on factors impacting the use of lumbar MRI, in other health care settings [13-15].

In this study we have the opportunity of using nation-wide data and hence evaluating a natural experiment. In 2010, Region of Southern Denmark (RSD), made two organisational changes. These included, centralisation of regional spine specialist departments across regional hospitals in one spine specialist hospital. Further, general practitioners (GPs) and chiropractors (CP) were given the possibility to directly refer LBP patients for lumbar MRI without prior referral to the Spine Centre or to office-based specialist doctors. In the support of the organisational changes, RSD implemented a LBP Disease Management Programme (DMP). The centralization of the hospital occurred in the beginning of 2010, and the hospital were fully operational in mid 2010.

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The direct referral access was available for the GPs in the first months of 2010. Hence, we expect effects of the reform to be modest in 2010 and to increase in the following years. These changes were unique in Denmark as two of four other regions maintained decentralised spine departments and did not allow for direct referral. To date, the effect of these organisational changes in RSD have not been investigated.

The study investigates the effect of the organisational changes on use of lumbar MRI in the diagnostics of LBP patients in RSD. Primary outcome is defined as yearly lumbar MRI rates for all individuals aged 18+. As the reform increased the possibilities to refer to lumbar MRI we hypothesised that the yearly lumbar MRI rates from 2010 to 2013 would increase significantly in RSD compared to the other regions.

Methods

Design

A longitudinal register-based study covering the Danish population aged 18+ from 2008 to 2013. The study relies on a natural experiment using RSD as the intervention group. Two regions, Zealand Region (ZR) and the North Denmark Region (NR), maintained their organisation in the study period from 2008 to 2013. Hence these two regions can act as good indicators of the counterfactual RSD. GPs in RSD, GPs in the Capital Region of Denmark (CR) and the Central Denmark Region (CD) were given the possibility to directly refer LBP patients for a lumbar MRI in 2010 and 2011, respectively. This allows GPs from CD to act as controls from 2008-2010, while GPs from CR are excluded, as they allow referrals from GPs at the same time as RSD, which is why they

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cannot act as good indicators of the counterfactual development in RSD if RSD had not made the organisational changes.

Primary outcome

The primary outcome is yearly lumbar MRI per 1,000 enlisted with a GP.

Setting

In Denmark, five decentralised administrative regions, including 98 municipalities, manage the tax founded health care system [16]. Each region has a public elected council and is autonomously managing secondary healthcare services. All services provided at hospitals and office-based physicians are free of charge, while services at physiotherapists and CPs involve co-payments from the patient. GPs in Denmark have a unique patient list (GP list) of citizens, to whom the GP solely provided services. The GP list size is on average 1,600 patients, and 98% of all Danes are enlisted at one of the 2,200 GP clinics in Denmark [16].

Data sources

The study used data from the registries at Statistics Denmark (DST), a governmental institution providing data for research purposes[17]. All registries are linkable at the individual level, using the personal civil registration number (CPR-number), which are given to all Danish citizens at birth [18] [19]. The study includes data from the following registries:

The Danish National Patient Registry (NPR) [20] [21], includes information on diagnosis coded according to the International Classification of Disease (ICD-10), and procedure and surgery codes

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(Health Care Classification System (SKS codes)). All NPR records are unique, due to a NPR serial numbers (unique to each patient's continuum of care at a hospital) and patients' CPR-numbers.

The Danish National Health Service Register for Primary Care (DNHR) [22], includes all contacts to the primary sector health care providers including GPs, CP, physiotherapists, and office-based specialist doctors. The GP list and GP list size were generated by combining the unique GP id with the CPR-number from patients receiving most of their services from the GP id[23]. GPs with patient list size less than 300 patients were deleted as they are hypothesised to be GPs either starting up or closing down the practice. Those citizens with no information of GP id in one of the study years, were allocated to a hypothetical GP id generated for each region.

Danish National Prescription Registry (DNPR) includes information on all prescription based analgesic drugs sold at Danish primacies[24]. We identified analgesic drugs according to the Anatomical Therapeutic Chemical classification (ATC) code[25]. Analgesic drugs included ATC code NN02A and NN02B; tablet cans with >100 pills of paracetamol and ibuprofen, synthetic opioids, and opioids.

We further retrieved registers on income[26], education[27], job- and socio-economic status[28], civil status[18], and demographics [18] from DST.

Definition of lumbar MRI

This study included data for lumbar MRI (SKS code: UXME30)[21]. Each MRI scan performed at a public hospital is recorded in NPR. Lumbar MRIs performed on a private hospital are recorded in

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the NPR if they are subsidised by the government. Patients with multiple spine MRI registrations on the same NPR serial number were identified and the UXME30 code was retained for analysis. If patients showed two or more UXME30 codes for the same day only one remained.

Definition of referral mode

A referral mode variable was defined based on two variables from the NPR; Referral directly from the GP (1), directly from the CP or initiated by private insurance (2), directly from the office-based specialist doctors (3), and from the hospital department (4). Before 2010, we observe referrals to lumbar MRI from GPs. These are recoded into hospital registrations.

Analyses strategy

The impact on MRI-rates of the well-defined organisational changes in 2010 in RSD, is analysed as a natural experiment. The change in the other regions are used as control under the assumption that the development of MRI rates in the control regions are a good indicator of how the MRI rates would have developed in RSD in absence of the organizational changes.

We hypothesise that the two referral options (direct GP referral and referral to the Spine Centre) drives any change in use of lumbar MRI. As patients have not chosen to live in RSD based on the access to MRI, the assumption behind our analyses strategy is that we can interpret patients as randomly assigned to a GP who by construct of the natural experiment happen to have access to the organizational changes (RSD) or not (control regions). We therefore included GPs from the ZR and the NR as controls for all years in the analysis. GPs from the CD are included from 2008 to

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2010, as they had the possibility to directly refer LBP patients for a lumbar MRI in 2011. GPs from the CR were excluded as controls.

We use a difference in difference (DD) model to analyse the effect of the reform. The DD model estimates the effect of organisational changes by assuming that the counterfactual development in the lumbar MRI rates in the treatment group (i.e., RSD) could be approximated by the development in the lumbar MRI rates of the other regions [29]. For the control group to match the approximation of the counterfactual development in lumbar MRI rates in RSD the model, we rely on an assumption that there was a common trend in lumbar MRI rates before the interventions. The common trend assumption was visually inspected. Furthermore, we estimated the effects of the reform year by year for 2010, 2011, 2012 and 2013 and made a placebo test by testing for an effect of the reform before it was implemented – i.e. testing for an increase in lumbar MRI rates from 2008 to 2009. This placebo test is an indirect test of the common trend. The DD approach by definition control for all time constant heterogeneity between GPs in RSD and the controls but if we expect time varying differences occurring over time we need to add covariates. Hence, second assumption behind our approach is that there were no time-varying unobservable covariates, that could explain differences in selection into a referral to lumbar MRI between GPs, and between regions [29]. Hence, we generally assume that citizens' need for lumbar MRI are identical among regions after controlling for observable patients' characteristics and supply factors related to LBP treatment did not change over time on the regional level. A limitation of our dataset is that we only have two years of observation before the organizational changes, which makes the validation of the common trend assumption hard to assess. As a consequence we supplemented the DD analysis with two robustness checks. First, we made a replication of the analysis using quarterly

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data instead of annual data. This gives eight pre-treatment observations, which allow for a better assessment of the common trend. Second, we estimate the treatment effect using propensity score matching (PSM) – an approach that does not rely on the common trend assumption but on common support[30-32].

Statistics

The DD model is implemented using a parametric Ordinary Least Squares (OLS) regression model with robust standard errors and clustering for GP id. We aggregated the individual level socio demographic data to GP level. This allowed for analysis using information from the socio demographic composition of the GPs' lists to account for any time varying patient characteristics, that is associated with LBP, and therefore explain differences in GPs' referral to lumbar MRI. A supplementary advantage of using the GP as analytical level is that we in this way obtain an unbalanced panel data structure of our dataset, with one observation per unique GP per year. As a robustness check we organise data in quarterly observations and re-assess the DD model using 24 quarterly observations rather than 7 annual observations per GP. We further use PSM with nearest neighbour with caliper equal to ¼ of the standard deviation on the propensity scores. The supplementary material gives detailed information on the robustness check using quarterly data and PSM.

The changes in referral modes were graphed for RSD (see Figure 1). To show dynamic year effects of the models, 2009 was used as pre-intervention and each intervention year was used as the post-intervention year, in four DD regression models– one for each post treatment year (2010,

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2011, 2012 and 2013). To test if the trend in MRI rates were not different between RSD and controls before the programme we tested for a treatment effect in 2009 using 2008 as base year. The five models used the variables as in the adjusted models and were analysed using both control groups. The DD estimates and the 95% confidence intervals [CI;] were graphed (the control regions were the x-axis). Tables reported number (N), means, standard deviations (SD), unpaired t-test, and percentages (%). All analyses were performed using STATA Release 13 (STATACorp, College Station, TX, USA) and graphics and tables were performed in Microsoft Excel 2010 (©Microsoft Corporation).

Covariates

The unadjusted models included the following variables: pre- and post 2009 (0 = 2008–2009, 1 = 2010–2013) and intervention and control regions (1 = RSD and 0 =ZR, NR, CD).

The adjusted models add time varying covariates to the above variables. This is done to avoid that any observed change in RSD after the change is simply due to changes in the characteristics of the citizens over time – for example that citizens in RSD over time becomes more prevalent to LBP than citizens in control regions. All covariates included, except GP list size, were made as proportions of enlisted patients with characteristic X divided with the GP list size. Patients characteristics X included; age 18-59, citizens in a full-time job, income DKK 0-399,000 or missing, women, citizens living as singles, and Charlson comorbidity index score[33] 2+, patients with vocational education, patients using a prescription on an analgesic drug at a pharmacists, patients having a visit at a physiotherapist, patients having a visit at a CP, and patients visiting an office-

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based specialist doctor (rheumatologist, neurologist, orthopaedics, and radiologist). Covariates are seen in table 1.

Patient and Public Involvement

Patients were not involved in the study

Ethics

The Danish Data Protection Agency approved this study (Journal number 15/14594). The study is based on registry data, which does not require ethics approval in Denmark (Act on Research Ethics Review of Health Research Projects § 14, sec. 2 http://www.nvk.dk/english/act-on-research 10.02.2017).

Results

During the study period 183.389 patients were assessed with 240.760 lumbar MRIs. Of those 27% (63,982 lumbar MRIs) were performed on private hospitals.

(insert figure 1)

Figure 1 shows changes in the rates of referrals for lumbar MRI in the RSD. MRI referrals directly from GPs accounted for 18% (N = 3,044) of all referrals in 2010. In the subsequent three years, the rate of MRI referrals directly from the GP increased 115% to (N = 6,545) and accounted for 34% of all of the MRI referrals in 2013. MRI referrals from office-based specialists (rheumatologist or orthopaedics) decreased from 2008 (N = 1,916, 16%) to 2013 (N = 464, 2%). MRI referrals from CPs

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or from a private insurance decreased from 2008 (N=748, 6%) to 2011 (N=220, 1%). MRI referrals from hospital-based doctors increased from 2008 (N=9,262, 77%) to 2012 (N=12,487,71%).

(insert figure 2*)*

The common trend was visually inspected using figure 2, showing unadjusted average regional lumbar MRI rates for GPs in RDS and the control regions. Lumbar MRI rates for RSD increased each year starting from 14.29 lumbar MRI per 1,000 enlisted with a GP in 2008 to 21.13 lumbar MRI per 1,000 enlisted with a GP in 2013. The average lumbar MRI rates for three control regions increased from 7.79 lumbar MRI per 1,000 enlisted with a GP in 2008 to 11.48 lumbar MRI per 1,000 enlisted with a GP in 2012 and 2013. To capture any differences in time-varying trends we included characteristics of the GP patient list, seen in Table 1. The table show that there are statistical differences for 8 of the 12 included covariates between GPs in RSD and control group regions in the pre-intervention years. However, the differences are small between the patient characteristics of the GPs' lists in RSD and GPs' lists in control group regions.

Table 1: Differences in proportions of patients enlisted at a GP from either intervention or control regions for pre-intervention years (2008 and 2009 combined)

	RSD's GPs (N=832)		Control regions' GPs (N=1878)$		
	Mean	SD	Mean	SD	T-test§
Comorbidity score 2+	0.031	0.008	0.031	0.010	*
Full time job	0.565	0.060	0.570	0.064	*
Vocational education	0.443	0.029	0.450	0.038	*
Marital status single	0.318	0.064	0.323	0.076	*
Income DKK 0-399.999	0.899	0.028	0.888	0.039	*
Gender (women)	0.509	0.063	0.509	0.066	
18-59 year of age	0.674	0.076	0.679	0.082	
GPs' id list size	2,265.060	3,197.228	2,212.976	3,440.372	

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Visits to physiotherapist	0.086	0.022	0.096	0.026	*
Visits to chiropractor	0.079	0.024	0.072	0.023	*
Visits to office based specialists	0.035	0.022	0.037	0.027	*
Use of pain medication	0.153	0.037	0.150	0.040	

*Means reflect proportions of patients divided by the GP list size. Abbreviations: * p<0.05, § t-test by group with unequal variance; N number of observations; RSD Region of Southern Denmark, GP general practitioner, SD Standard Deviation. $ Including general practitioners from the Zealand Region, the Central Denmark Region and the North Denmark Region.*

The results of the DD analyses of the lumbar MRI rates per 1,000 enlisted with GPs RSD compared to GPs in the control group, are shown in Table 2. After the organisational changes in RSD, the lumbar MRI rates increased significantly compared to control groups, for both models ranging from 1.39 [CI 0.93;1.85] to 1.83 [CI 1.37;2.29] lumbar MRIs per 1,000 enlisted with a GP.

Table 2: Difference in Difference and propensity score matching estimates from unadjusted and adjusted models with Region of Southern Denmark and the control regions

	Lumbar MRI rates			
	Difference in difference			PSM[c]
	Unadjusted	Adjusted model[a]	Quarterly data[b]	
DD (RSD*Post treatment)	1.83***	1.39***	0.43***	3.80***
	[1.37,2.29]	[0.93,1.85]	[0.32,0.53]	[2.67 ; 4.94]
Constant	9.04***	2.60	2.24***	-
	[8.85,9.23]	[-5.28,10.48]		

*Four models showing the main outcome lumbar MRIs per 1,000 enlisted with a GP. [a] Adjusted model include covariates for; Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at physiotherapist, visits at chiropractor, visits at office-based spine specialist, use of pain medication. [b] The DD model with quarterly data use the same covariates. However, in addition we included quarter dummies (Q1, Q2 Q3 and Q4) to take a way the obvious seasonality shown in figure A1 in the supplementary materal. [c] The PSM model use conventional options; nearest neighbour with (caliper = ¼ of the standard deviation on the propensity scores). We use the MRI rates in 2008 and 2009 as matching covariates to control for unobservable selection[31 32]. Furthermore, we control for clustering at GP level[34]. Abbreviations; 95% confidence interval [,], * p<0.05, ** p<0.01, *** p<0.001, DD Difference in Difference, RSD Region of Southern Denmark, Post treatment, years from 2010-2013, PSM Propensity Score Matching, GP general practitioner.*

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Table 2 also present the robustness checks using DD with quarterly data and PSM (see table A.1 for DD results and table A.2 for PSM results in the supplementary material). The model with quarterly data shows a significant increase in quarterly MRI of 0.43, which is at a comparable level as the model using annual data when multiplying with four. The PSM model however, shows quite higher effects. This may rest on the fact that RSD generally is at a higher level of MRI throughout the period of observation and that the PSM approach is less effective in taking this into account. The PSM result indicates that the DD makes a conservative estimate of the effect. We refer to the table A3 for bias reductions of PSM model and figure A2 for common support in supplementary material.

The dynamic year effects, for both models are seen in figure 3. Figure 3 indicates that the common trend assumption support is fulfilled, as a hypothesised treatment effect before the intervention (i.e. in 2009) occurred (placebo effect) is insignificant. This test is also insignificant in the model using quarterly data and hence eight pre-treatment observations (see table A1 in supplementary material).

Dynamic year effects for post-intervention years were positive and significant for all years, with an observed increase positive trend of the estimates, indicating that the effect of the organisational changes increases over time (figure 3).

(Insert figure 3)

Discussion

This study showed that establishing a Spine Centre in the RSD and introducing direct referrals for lumbar MRI by GPs was associated with an increase in the use of lumbar MRI (compared to that of

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other regions) in the years following the 2010 changes. On average the increase was between 1.39 to 1.83 lumbar MRI per 1,000 enlisted with GPs in RSD involving an increase in lumbar MRI of between 1,400 and 1,800 additional scans compared to the other regions. The use of the direct referral option by GPs in the RSD increased by 115% in the period from 2010 to 2013, indicating that the GP adopted the new referral option.

As in other studies from the US[7], we find geographical variation in the use of lumbar MRI among the regions in Denmark. The reason for the difference in use of lumbar MRI among the regions is still unclear. Some points towards a special interest in back pain by specialist doctors in RSD, which relates to different regional clinical practices, which have been found in US studies[6 11]. The relationship between MRI usages and physician incentives[9 10], is unlikely to explain the differences in a Danish setting; Firstly, physicians at public hospital receive a fixed yearly salary, thereby not having incentives to refer patients. Secondly, the public hospitals undertook 74 % of all scans.

The increase in referrals for lumbar MRI following the change in GP referral access to lumbar MRI in the RSD in 2010 is noteworthy. GPs in the RSD clearly began to use the new referral option immediately and the use of the referral option increase by 115% from 2010 to 2013. This change might indicate a lowering in the threshold for a MRI referral. There could be numerous reasons for the use of direct referrals to lumbar MRI, including patient demands[35 36] and physicians' wish to provide quick reassurances to LBP patients[36]. Providing quick reassurance to patients could prevent further costly visits to specialist doctors and reduce future treatment costs. However, previous studies have shown that lumbar MRI referrals from GPs are inappropriate in up to 50% of the cases when judged against the guidelines [10 37-39]. Further, the inappropriate use of lumbar MRI

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has been shown to be associated with an increased use of opioids, higher health care costs and has a low impact on pain relief or functional recovery after 6 months in non-specific LBP patients, without serious pathologies such as cancer, nerve root compression, cauda equina, radiculopathy and sciatica [3 5 40-46]. Further studies are needed to investigate if the same associations are found in this setting.

Strengths and Limitations

This study used DD estimates to capture the effect of the organisational changes and LBP DMP in RSD. Difference in difference is a popular design for evaluation of policy changes, as is widely used in social science[29]. DD relies on the assumption of a common trend in the pre-treatment period for the outcomes of interest. This assumption seems to be fulfilled in the current study. However, a clear limitation of our dataset is that we have a short pre-treatment period. As a consequence we have used DD on quarterly data as well as PSM analysis to check the robustness of the results. Both analyses support the findings and as we believe the DD approach to be the most conservative we stick to this model as our base case. Details on the robustness model are to be found in supplementary material.

Referrals from GPs are seen from 2008 to 2009 and are recoded to hospital referrals, as they did not have the opportunity to refer LBP patients for a lumbar MRI. There might be several explanations for these registrations; Firstly, registrations with referrals from GP in 2009 may be test of the electronic referral system, used in the communication of between GPs and hospitals. Secondly, referrals from GPs can be interpreted in relation to GPs referring LBP patients for a consult in secondary care, where the GP refer the patient for a lumbar MRI on the same day as the

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consult. This allows the hospital-based specialist doctor to assess the lumbar MRI at the consult on the hospital, and to reduce visits at the hospital for the patient.

The study relied on data from the newly 2018 update of the NPR at Statistics Denmark[47]. This allowed for the newest data from all individuals aged 18+ of the population of Denmark. The granularity of the data allows for an unseen precision of analyses performed on country level.

Conclusions

Following RSD' introduction of organisational changes in 2010, the lumbar MRI rate increased significantly in comparison with the other regions in Denmark. The issue of whether the increased usage of lumbar MRI is beneficial for the RSD's LBP patients (compared to that of other regions) requires further investigations.

Figure Legends:

Figure 1: Changes in the referral patterns to lumbar MRI in Region of Southern Denmark from 2008-2013 using a 100% stacked curve diagram. Abbreviations: MRI, magnetic resonance imaging, GP general practitioners

Figure 2: Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (the Zealand Region, the Central Denmark Region and the North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.

Figure 3: Dynamic year effects using the adjusted model, with multiple difference in difference estimates with 2009 as the pre-intervention period and all post intervention years for Region of Southern Denmark and the control regions. Abbreviations b, Beta estimates from the difference in

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difference analysis; min95, Lower bound of the 95% confidence interval of the beta estimate; max95, upper bound of the 95% confidence interval of the beta estimate

Declarations

Acknowledgements

Not applicable

Ethics approval and consent to participate

The study is based on registry data, which does not require ethics approval in Denmark (Act on Research Ethics Review of Health Research Projects § 14, sec. 2 http://www.nvk.dk/english/act-on-research 10.02.2017). The study group did however send the study protocol for an ethic assessment to the regional ethics committee in Region of Southern Denmark. The committee found that the study did not need ethic approval. The Danish Data Protection Agency approved this study (Journal number 15/14594).

Consent for publication

All authors' consent to publish this document

Availability of data and material

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The data that support the findings of this study are available from national databases at Statistics Denmark (Sejrøgade 11, DK-2100 København Ø, Phone +45 39 17 31 30, E-Mail forskningsservice@dst.dk), a governmental institution, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Statistics Denmark and The Danish Data Protection Agency (Borgergade 28, DK-1300 Copenhagen, Phone +45 3319 3200, E-Mail dt@datatilsynet.dk).

Competing interests

The authors declare that they have no competing interests

Funding

The study is a part of a three-year PhD grant with contributions from Centre for Quality, Region of Southern Denmark, The Institute of Regional Health Research, University of Southern Denmark and Region of Southern Denmark. The Study further received a grant from the Regional Research Fund of Southern Denmark, Region of Southern Denmark. All grant givers had no saying in the design and interpretation of the study.

Authors' contributions

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MSJ and KRO made the dataset at Statistics Denmark and analysed the data. MSJ and KRO wrote the manuscript, made figures and tables with contributions from LM, JS and BC. All authors read and approved the final manuscript.

List of abbreviations

magnetic resonance imaging (MRI), ow back pain (LBP), United States (US), Region of Southern Denmark (RSD), general practitioners (GPs), Disease Management Programme (DMP), Chiropractor (CP), the Zealand Region (ZR), the North Denmark Region (ND), the Central Denmark Region (CD), the Capital Region of Denmark (CR), the Danish National Patient Registry (NPR), Health Care Classification System (SKS codes), civil registration numbers (CPR), Difference-In-Difference (DD), Propensity Score Matching (PSM) Ordinary Least Squares (OLS), number (N), 95% Confidence Intervals [CI ,] and percentages (%)

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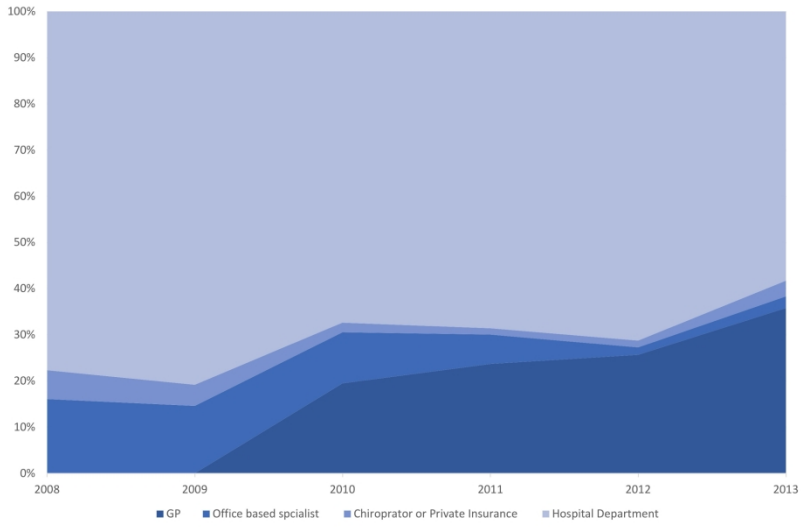

Figure 1: Changes in the referral patterns to lumbar MRI in Region of Southern Denmark from 2008-2013 using a 100% stacked curve diagram. Abbreviations: MRI, magnetic resonance imaging, GP general practitioners

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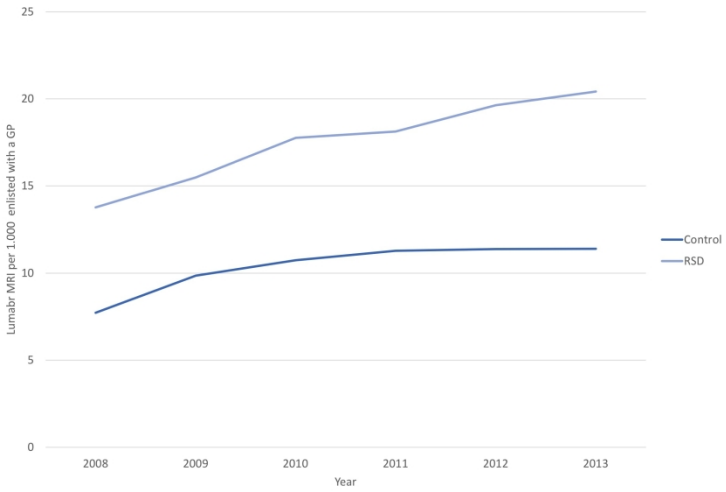

Caption : Figure 2: Lumbar MRI rates for Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.

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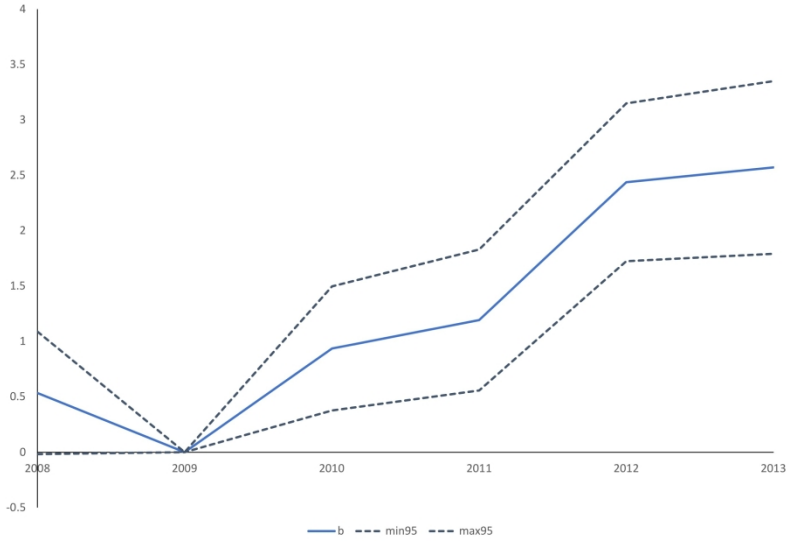

Figure 3: Dynamic year effects using the adjusted model, with multiple difference in difference estimates with 2009 as the pre-intervention period and all post intervention years for Region of Southern Denmark and the control regions. Abbreviations b, Beta estimates from the difference in difference analysis; min95, Lower bound of the 95%confidence interval of the beta estimate; max95, upper bound of the 95% confidence interval of the beta estimate

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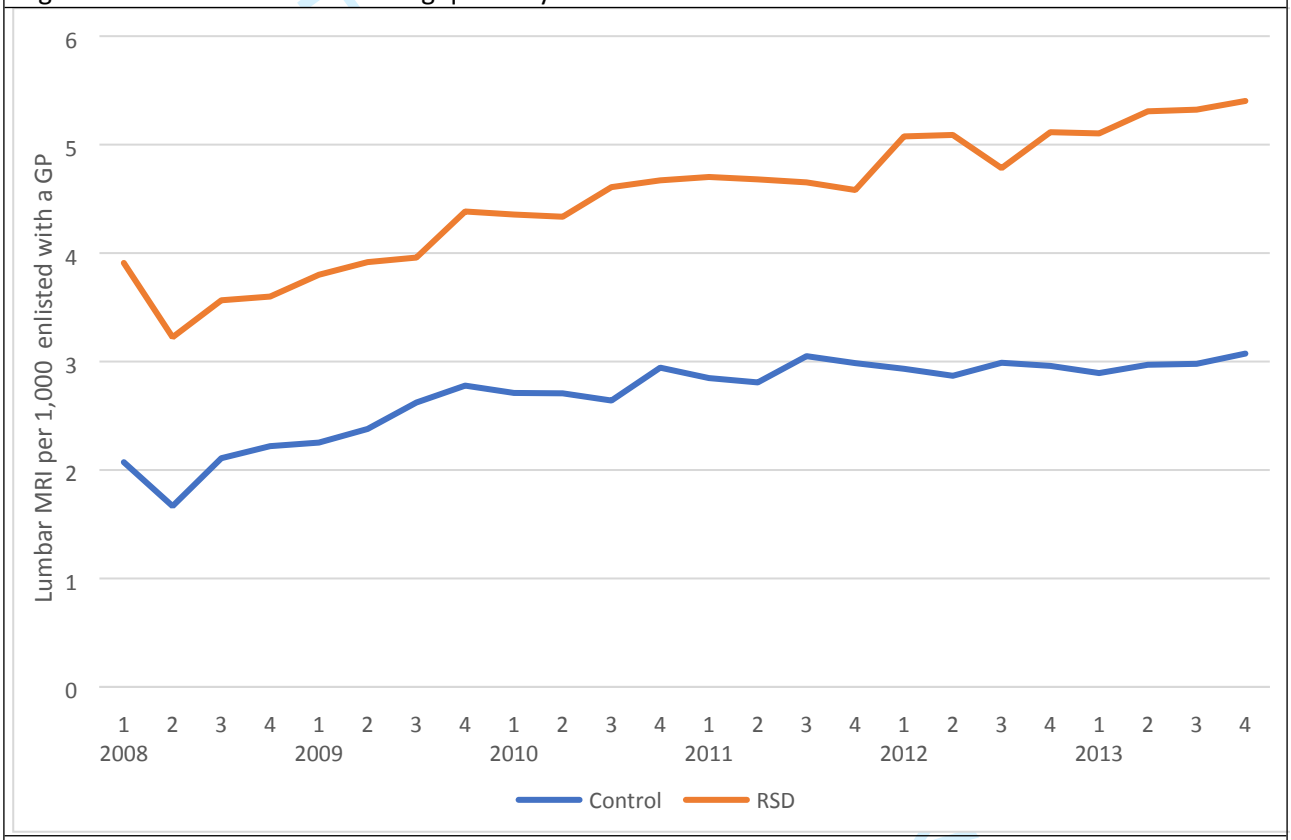
Supplementary material: Does changed referral options affect the use of magnetic resonance imaging for low back pain patients? Evidence from a natural experiment using nationwide data.

In this supplementary material we report the details of the robustness checks of the DD model in the paper. First we present results of reorganising data to quarterly levels and re-assessment of the DD model. Second we present the PSM model and assess the assumptions behind this model.

DD model using quarterly level

The results are presented below. Figure A.1 show the trends in lumbar MRI rates using quarterly data, and table A.1 show the DD results where we use quarter dummies (Q1, Q2 Q3 and Q4) to take away the obvious seasonality that shows up in figure A.1.

Figure A.1: Lumbar MRI rates using quarterly data



Notes: *Lumbar MRIs per 1,000 enlisted with a GPs in Region of Southern Denmark and the control regions from 2008 to 2013. Abbreviations: RSD Region of Southern Denmark, Control (Zealand Region, Central Denmark Region and North Denmark Region) GP general practitioner, MRI magnetic resonance imaging.*

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Table A.1: DD estimates using quarterly data

	Model (1) 2010-13 vs 2008-9	Model (2) 2010-13 vs 2008-9	Model (3) 2010-13 vs 2008-9	Placebo 2009 vs 2008
RSD	1.53***	1.53***	1.55***	1.56***
Post treatment	0.61***	0.61***	0.62***	0.49***
DD (RSD x Post treatment)	**0.46*** **	**0.46*** **	**0.43*** **	**-0.05**
Quarter 1	-	-0.20***	-0.20***	-0.27***
Quarter 2	-	-0.27***	-0.27***	-0.46***
Quarter 3	-	-0.13***	0.99***	-0.16***
Quarter 4	-	Omitted	Omitted	Omitted
Constant	2.26***	2.41***	2.42***	2.24***
Clustered error terms at GP level	Y	Y	N	Y
GP FE	N	N	Y	N
Quarterly time trend dummies (quarter 1-24)	N	N	Y	N

Notes: *Four DD models controlling for* seasonality shown in figure A.1. *Abbreviations: * p<0.05, ** p<0.01, *** p<0.001, DD Difference in Difference, RSD Region of Southern Denmark, Post treatment, years from 2010-2013, GP general practitioner, GP FE, Fixed Effects using general practitioners,*

Figure A.1 show that the trends in MRI rates seem to be parallel even in the unadjusted rates. The common trend assumption is conditional on the covariates and the placebo test in column 4 in table A.1 confirms that the change in MRI rates in RSD, conditional on the covariates, is not significantly different from the control before 2010 (i.e. 2009 vs 2008). However the post-2010 effects are still positive and significant with levels between 0.43 and 0.46, which is close to ¼ of the treatment effects in the results based on annual data. Hence the robustness check using quarterly data confirms the results in the paper.

PSM model

The PSM approach requires that the common support assumption is fulfilled. Hence, covariates that describes the bias between the treatment and control group, is needed to produce propensity scores to weigh the MRI rates. A disadvantage of the PSM as compared to DD is that it does not control for unobserved variables causing bias – hence it is relying on a rich set of covariates. However, by using the MRI rate in 2008 and 2009 as matching covariates we indirectly control for unobservable variables. The reason is that it can be argued that any unobserved selection bias between treatment- and control groups may also be present in the outcome variable before the reform. Hence, including the historic MRI rates for 2008 and 2009 as matching variables is a way to control for unobserved heterogeneity between treatment and control GPs and this approach is generally believed to be very strong – also compared to DD (G.W. ; J.M. Wooldridge Imbens, 2009) and (Martin Huber et al., 2013).

Table A.2 show the treatment effect of the reform using PSM with various sets of covariates. It is evident that the effect is positive and significant but also that the magnitude of the effect is much higher than the DD estimates. We use Stata psmatch2 command with conventional options; nearest neighbour with (caliper = ¼ of the standard deviation on the propensity scores) and bootstrapped error terms. As the DD clusters at GP level we also tried to estimate the PSM treatment effect by simply running an OLS regression on the matched

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sample using the propensity scores as weights and then cluster at GP level in the OLS (B. Arpino and M. Cannas, 2016). This did not change the results.

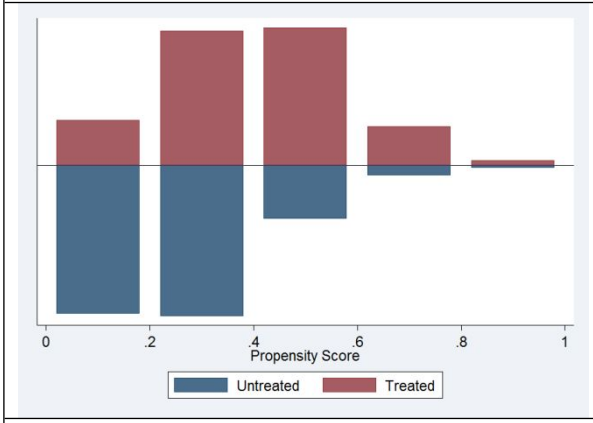
Figure A.2 assesses the common support assumption, which is key to PSM. As the histograms are overlapping it shows that for any GP in RSD there exists a control GP with the same propensity score – hence there exist a suitable match for all RSD GPs. Table A.3 show that the bias between treated and control GPs has been reduced substantially for most of the covariates. This indicates that comparison after matching is valid. Some covariates are not biased in the unmatched sample but turns biased in the matched sample and therefore we try to run the PSM model with the historic outcome variables only. Table A.2 show that this change the magnitude of the effect but not the significance.

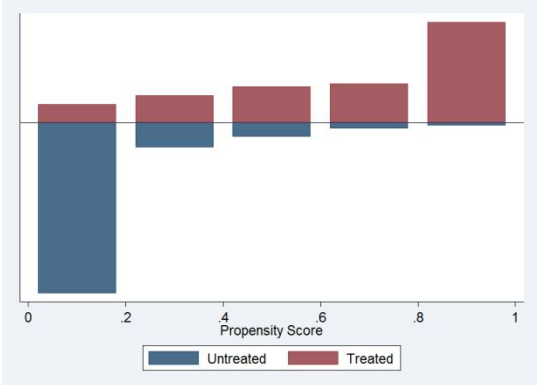
Table A.2: Average treatment effect of the treated using propensity score matching

	Model (1)	Model (2)	Model (3)
ATT	2.81***	8.01***	3.80***
CI	[1.87 ; 3.75]	[7.29 ; 8.84]	[2.67 ; 4.94]
Table 1 covariates	N	Y	Y
MRI rates in 2008 and 2009	Y	N	Y

*Notes: Three PSM models controlling for different covariates. Abbreviations: ATT Average treatment effect of the treated, CI 95% confidence interval, Table 1 covariates included, Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at physiotherapist, visits at chiropractor, visits at office-based spine specialist, use of pain medication, MRI magnetic resonance imagining, Y yes, N no, *** p<0.001*

Figure A.2: Common support for two models





Propensity scores using covariates from table 1, which include; *Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399.999, Male, 18-59 year of age, visit at physiotherapist, visits at chiropractor, visits at office-based spine specialist, use of pain medication*

Propensity scores using covariates using covariates from table 1 in the manuscript, which include; *Comorbidity score 2+, Full time job, Vocational education, Marital status single, Income DKK 0-399,999, Male, 18-59 year of age, visit at physiotherapist, visits at chiropractor,*

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	visits at office-based spine specialist, use of pain medication and MRI rates in 2008 and 2009.

Table A.3: Bias reduction for the Propensity Score Matching model

Covariate		RSD (mean)	Control (mean)	% bias	% bias reduction	t	p
Charlson index	U	0.032	0.029	38.2		6.550	0.000
	M	0.032	0.031	11.3	71	1.560	0.118
Income	U	0.897	0.885	36.5		5.780	0.000
	M	0.897	0.889	23.2	36	4.060	0.000
Vocational education	U	0.444	0.451	-20.8		-3.340	0.001
	M	0.444	0.453	-27.3	-31	-4.560	0.000
Pain medication	U	0.153	0.151	6.3		1.040	0.296
	M	0.153	0.152	3.6	43	0.590	0.555
Single	U	0.320	0.326	-9.4		-1.530	0.126
	M	0.321	0.300	29.3	-213	4.690	0.000
Gender (women)	U	0.508	0.508	-0.2		-0.040	0.971
	M	0.508	0.491	27.1	12281	4.440	0.000
Full time job	U	0.552	0.558	-9.0		-1.490	0.136
	M	0.552	0.569	-29.7	-230	-4.500	0.000
Visits to physiotherapist	U	0.086	0.096	-42.8		-7.050	0.000
	M	0.086	0.100	-57.3	-34	-7.250	0.000
Visits to Office based specialists	U	0.037	0.037	-3.3		-0.540	0.591
	M	0.037	0.027	38.7	-1074	6.100	0.000
Visits to chiropractor	U	0.079	0.072	29.7		5.040	0.000
	M	0.079	0.096	-73.9	-149	-6.880	0.000
MRI rate 2008	U	14.297	[a]8.068	136.7		25.540	0.000
	M	14.234	13.460	17.0	88	2.270	0.023
MRI rate 2009	U	16.059	10.032	130.1		23.770	0.000
	M	16.085	16.920	-18.0	86	-2.030	0.043

Abbreviations: *RSD Region of Southern Denmark, Control (the Zealand Region, the Central Denmark Region and the North Denmark Region) GP general practitioner, MRI magnetic resonance imaging, % percentage, t t-statistics, p p-value, U unmatched, M matched*

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6, 7, 9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	N/A
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7,8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	5
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	N/A

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		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	12
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11,12
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14, 15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14, 15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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