Quality improvement project of low back pain management in general practice using 'audit and feedback' strategy

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Abbreviations

ABC= Achievable Benchmarks of Care

A&F= Audit and feedback

ALIF= Anterior lumbar interbody fusion

CC= Care Connect

CT= Computer tomography

CEBAM= Belgian Centre for Evidence-Based Medicine

EMG= electromyography

GMD= Global medical file ('Globaal medisch dossier')

GP= General practitioner

HAIO= Huisarts in Opleiding

ICPC= International classification of primary care

KCE= Federaal Kenniscentrum voor de gezondheidszorg

LBP= Low Back Pain

N= Number

NSAID= Non-Steroidal Anti-Inflammatory Drug

NSLBP= Non-Specified Low Back Pain

MRI= Magnetic resonance imaging

US= Ultrasound

X-ray= Röngtenscan

X^2-test= chi square test

Y= year

Abstract (Nederlands)

Achtergrond

Lage rugpijn is wereldwijd een van de meest voorkomende musculoskeletale gezondheidsproblemen en is een van de meest voorkomende redenen voor een consult bij de huisarts. Lage rugpijn can veroorzaakt worden door een specifieke ziekte, maar is meestal aspecifiek. Lage rugpijn is dus vaak zelflimiterend, maar doordat de richtlijnen in Vlaanderen onvoldoende nageleefd worden, wordt er vaak veel medicatie, afwezigheidsattesten en beeldvorming voorgeschreven door huisartsen. Hierdoor kan lage rugpijn veel kosten voor de maatschappij met zich meebrengen. Met behulp van enkele praktische tools, zoals de 'audit en feedback'-strategie, zou de zorg voor lage rugpijn kunnen geoptimaliseerd worden.

Methodologie

Deze studie betreft een kwaliteitsverbeterend project in de huisartsenpraktijk en bevat een retrospectieve en prosprectieve studiegroep van volwassen patiënten met lage rugpijn die volgens het ICPC-2 classificatie system gecodeerd werden met code L03, L84 of L86, respectievelijk gedurende 18 maanden van 01/10/2022 tot 31/03/2024 en 6 maanden van 01/07/2024 tot 31/12/2024. Gedurende deze studie werden verschillendende kwaliteitsindicatoren, zoals het voorschrijven van beeldvorming, opioïden, NSAIDs/Acetaminophen, benzodiazepines, werkverlet, kinesitherapie, verwijzing naar de specialist en noodzaak tot chirurgie, geanalyseerd om bij beide groepen de kwaliteit van zorg betreffende lage rugpijn te vergelijken. De kwaliteitsindicatoren werden statistisch geanalyseerd met behulp van X^2-testen om statistisch significante verschillen tussen de retrospectieve en prospectieve groep weer te geven.

Resultaten

In totaal werden 206 patiënten in de retrospectieve groep en 74 patiënten in de prospectieve groep geïncludeerd. Aan de ene kant is er een statistisch significante daling (p-waarde <0,05) van voorgeschreven medicatie zoals NSAIDs/Acetaminophen, Opioïden en Benzodiazepines tussen de twee studie groepen. Aan de andere kant is er een statistisch significante stijging (p-waarde <0,05) van verwijzing naar specialisten. Daarnaast toonden de resultaten een stijging van voorgeschreven beeldvorming van 5,96% en kinesitherapie van 7,45% en een daling van werkverlet van 8,09%.

Conclusie

De 'audit en feedback'-strategie kan in de huisartsenpraktijk een handige tool zijn om de kwaliteit van zorg voor lage rugpijn te verbeteren. Het kan rechtstreeks de medische kosten doen dalen door onnodige medicatievoorschriften te reduceren, alsook onrechtstreeks de kosten laten dalen vermindering in werkverlet. Meer kwaliteitsverbeterende projecten voor lage rugpijn in huisartsenpraktijken zijn noodzakelijk om dezelfde effecten/trends te bevestigen.

Abstract

Background

Low back pain is globally, one of the most common musculoskeletal problems and is one of the most frequent reasons for consultation in general practice. Low back pain can originate from a specific pathology, but is most often non-specific. So low back pain is often self-limiting, but unfortunately due to a lack of correct use of guidelines in Flanders, a lot of prescriptions for medication, medical leave and imaging are written by doctors. For this reason, low back pain can bring high costs for society. So practical tools, such as the 'audit and feedback' strategy, may help improving clinical care of low back pain.

Methodology

This study is a quality improvement project for general practice and involves a retrospective and prospective study group of adult patients with low back pain, coded as L03, L84 or L86 following the ICPC-2 classification system, during an 18-months period from 01/10/2022 until 31/03/2024 and 6-months period from 01/07/2024 until 31/12/2024, respectively. During this study several quality indicators such as the prescription of imaging, opioids, NSAIDs/Acetaminophen, benzodiazepines, medical leave, physical therapy, referral to specialist and surgery were analyzed in order to compare both study groups regarding the quality low back pain management. The quality indicators were statistically analyzed with X^2-tests to evaluate statistical differences of outcomes between the retrospective and prospective group.

Results

In total 206 patients in the retrospective group and 74 patients in the prospective group were included in this study. On one hand, there is a statistically significant reduction (p-value <0,05) of prescribed medication such as NSAIDs/Acetaminophen, Opioids and Benzodiazepines between the two groups. On the other hand, there is a statistically significant increase (p-value <0,05) of specialist referrals. Furthermore, results showed an increase of prescription of imaging and physical therapy of 5,96% and 7,45%, respectively and decrease of work absenteeism of 8,09%.

Conclusion

'Audit and feedback' strategy in general practice can be a useful tool to improve quality of care for patients with low back pain. It can directly reduce medical costs by reducing unnecessary prescription of certain medication and indirectly, due to work absenteeism reduction. More quality improving projects for low back pain management in general practice are needed to confirm the same trend/effects.

1. Introduction

Low back pain (LBP) is globally, one of the most common musculoskeletal problems and is one of the most frequent reasons for a consultation in general practice (1,2,3). Globally, the current estimates of incidence and prevalence of LBP are 245.9 million cases/year (3.2%; 15th worldwide cause) and 577.0 million cases (7.6%; 15th worldwide cause) respectively. (4) LBP is also the main cause of years lived with disability worldwide (2,5). In Western society LBP has a prevalence around 32% in adults. The highest prevalence of low back pain has been reported in high- income countries (32.9%), with lower rates in middle- income countries (25.4%) and low-income countries (16.7%) in some studies. (6) In Flanders the annual incidence of low back pain diagnosis for women and men is 43 per 1000 patients and 46 per 1000 patients, respectively. It is the 6th and 5th most frequent diagnosis respectively for women and men in general practice. (7) The risk of developing recurrent low back pain within a year after the resolution of an episode of acute low back pain is estimated to be approximately 25%. (6) It is consequently one of the major global public health problems.

LBP can originate from a specific pathology such as inflammatory disorders, infections, malignancies, osteoporosis, structural deformity, radicular syndrome or fractures; but very often LBP is described as Non-specific low back pain (NSLBP) (2, 6, 8). NSLBP is defined as low back pain not attributable to a known cause and represents 90–95% of the cases of LBP. NSLBP is a self-limiting disease which often improves without treatment. (2,9,10) However, around 25% of the patients receive imaging and approximately half of the patients receive analgesics. (2, 11, 12, 13, 14)

The overuse of imaging, opioids, and surgery remains a widespread problem in the management of low back pain. (2, 6, 15, 16) Low back pain (LBP) is also the leading cause of activity limitation and absenteeism from work, and results in a huge medical burden and economic cost. (1, 4) The pooled estimate of the proportion of people returning to work was 68.2%, 85.6% and 93.3% at 1 month, 1–6 months and 6 months or longer follow-up, respectively. (17) Moreover, medical costs may lower due to prescribing more physical therapy as a treatment for LBP. (2)

Despite the availability of guidelines, treatment of low back pain varies widely and is notoriously resistant to change. Health care providers often rely on shared beliefs and opinions rather than evidence to make treatment decisions. This ignorance of or unwillingness to follow evidence-based practice recommendations is responsible for what has become popularly known as the know-do gap – the gap between what is known and what is done in practice. The pervasive use of ineffective treatments for LBP is considered a likely contributor to its high prevalence. (18) Therefore, an evidence-based approach can be helpful to reduce the know-do gap as well as reduce unnecessary treatment. In Belgium, the KCE (Federaal Kenniscentrum voor de

gezondheidszorg) managed to set guidelines aiming for a more universal and evidence-based quality of care concerning low back pain. (19)

Therefore, professional health care performance can improve by using an ‘Audit and feedback strategy’ (A&F). (1, 20, 21) A&F interventions intend to improve quality of care in healthcare organizations by improving healthcare professionals’ performance. Their professional performance is analyzed during an audit. Subsequently, results are provided and discussed during the feedback process with the healthcare professionals hoping to encourage healthcare professionals to take action or make changes to follow evidence-based standards. So, in other words, this strategy intends to encourage health care professionals to change their clinical practice when there is an inconsistence with desired practice as described on explicit criteria or standards and evidence-based guidelines. (20, 22) The effects of A&F vary widely, but most of the time small-to-moderate improvements in quality of care are achieved using the A&F strategy. (22) The effects of A&F depend on several factors such as comparisons to their high-performing peers, substantial room for improvement, clinical priority, action plans, or combination of strategies (22).

2. Methodology

Context and population

After approval from the ethical committee (see appendix section 7.2 'OBC approval' - MP028003), aggregated data concerning LBP was acquired. Aggregated retrospective and prospective data were extracted from one Belgian general practitioner practice called 'De Zorgpoort' in Lommel. The aggregated retrospective data was collected for a period of 18 months from 01/10/2022 until 31/03/2024 and the prospective data was collected for a period of 6 months from 01/07/2024 until 31/12/2024. The aggregated data was extracted via a strict protocol from the electronic medical record software CareConnect (General Practitioner) using specific ICPC-2 codes (23,24).

Inclusion criteria for this study were defined as every adult patient (older than 18 years old) with low back pain with an active global medical file who present themselves in the participating general practice and which were coded with one of the three specific ICPC-2 codes (L03, L84 and L86) during the two study periods as stated above. Exclusion criteria were an age under 18 years old or no active global medical file.

Subsequently, the aggregated data of 206 patients and 74 patients were collected from the retrospective and prospective data, respectively. No active recruitment was used in this study. An information letter was provided to inform the patients about this study.

Audit and feedback

Only aggregated data was exported and used in this project and reported to the participating general practitioners, but no individual data (e.g., names, nationality, addresses …) were extracted out of the electronical medical files of the patients. The data was reviewed manually in order to collect all aggregated information properly and due to limitations of the statistic module in CareConnect.

The aggregated data included following categories: Demographic information (age and gender) and information about quality indicators (imaging, opioids/NSAIDs use, physiotherapy, employment status, referral to specialist and surgery) as stated below.

Several Quality indicators are defined by the Belgian Centre for Evidence-Based Medicine (CEBAM) and are listed below (2, 25):

<u>Quality indicators:</u>

- Percentage of adults with low back pain where imaging is requested.
- Percentage of adults with low back pain that got a prescription for opioids in comparison with adults with low back pain who got a prescription for non-steroidal anti-inflammatory drugs (NSAIDs)

- Percentage of adults with low back pain where physiotherapeutic rehabilitation was required.
- Employment status of people with low back pain

Other indicators towards quality of care in low back pain:

- Percentage of adults with low back pain with a referral to a specialist doctor (orthopedic surgeon, neurosurgeon, pain clinic)
- Percentage of adults with low back pain with surgery

The outcomes of the participating general practitioners were later compared to evidence-based goal-settings and analyzed to evaluate the quality of care of low back pain management. The results were compared with general benchmarks and Achievable Benchmarks of Care (ABC) from the Intego study from Paridaens et al. (2) The ABC approach is a benchmarking method that sets 'real world' goals based on the performance of the 10% best performing practices. ABC defines "top performance" using the "pared mean", defined as the average performance of the subset of those providers with the highest scores for the indicator under consideration. (2, 26)

Later, the first feedback based on retrospective data results were shared during a meeting with the doctors of the participating general practice. During this feedback the results concerning quality of care of low back pain were discussed based on the quality indicators (as stated above) using retrospective data. During this feedback the results, pitfalls and points of interest were discussed to improve the quality of care during the prospective period of this study. After the prospective period of the study a new feedback moment was provided to see the potential differences and improvement of low back pain management of the participating general practice.

Data analysis

So retrospective and prospective results of the participating general practice were discussed in this feedback moment. This implicates that the doctors of general practice were used as study object and every single doctor of the general practices is aware of this role as 'study object'. To be clear, individual doctors of the participating general practices were not analyzed individually. So, all data was used to analyze/evaluate the participating general practice in general regarding to their quality of care of low back pain management. The statistical analyses were executed with Microsoft Excel's statistic models using X^2-tests.

3. Results

In this section all the acquired results concerning the retrospective and prospective data of patients with LBP are listed to give an overview of all aggregated data. In total 206 patients over an 18-month period were included in the retrospective data group and 74 patients over a 6-month period were included in the prospective data group. There were 2269, 2653 and 2797 adult patients with an active GMD at the participating general practice in 2022, 2023 and 2024, respectively.

Demographic characteristics

Table 1 below shows the demographic information of the retrospective and prospective data. The demographic retrospective data is comparable to the prospective study group. The distribution of patients is normal because there is almost a similar distribution of percentages in each age group in both study groups. There were more male than female patients analyzed in both study groups.

Table 1: Demographic characteristics

	Retrospective		**Prospective**	
Gender	N (total 206)	(%)	N (total 74)	(%)
Male	111	53,88	44	59,46
Female	95	46,12	30	40,54
Age				
18-24 y	9	4,37	3	4,05
25-34 y	25	12,14	10	13,51
35-44 y	30	14,56	17	22,97
45-54 y	57	27,67	16	21,62
55-64 y	36	17,48	7	9,46
65-74 y	28	13,59	13	17,57
>75 y	19	9,22	8	10,81

Table 2 below represents the data distribution of ICPC coding from Care Connect in both study groups. There is similar/symmetrical distribution of ICPC coding between the retrospective and prospective study group. Table 2 also shows that approximatively one third of the patients has low back pain with radiating pain and two third of the study population has low back pain without radiating pain.

Table 2				
	Retrospective		**Prospective**	
ICPC Coding	N (total 206)	(%)	N (total 74)	(%)
L03 Symptomen/klachten lage rug	117	56,80	41	55,41
L84 Rugsyndroom zonder uitstralende pijn	16	7,77	5	6,76
L86 Rugsyndroom met uitstralende pijn	73	35,44	28	37,84

Quality indicators

Table 3 below demonstrates the retrospective and prospective data of low back pain quality indicators relating with their desired benchmark from the Intego study. (2) The benchmark and overall mean percentages are percentages from an electronic audit from general practices in Flanders relating to the Intego study. (2) These measurements (percentages) give a general impression of the desired (10% best-performing) percentages (benchmarks) that every general practice in Flanders should aim for, and it gives an impression of the general levels (overall mean percentages) of other general practices in Flanders which can be used to compare this participating general practice with the overall mean level in Flanders.

Table 3: Quality indicators with benchmarks							
	Retrospective		**Prospective**		**P-value**	**Overall Mean***	**ABC Benchmark***
Quality indicators	N (total 206)	(%)	N (total 74)	(%)		(%)	(%)
Imaging	52	25,12	23	31,08	0,33	15,97	4,20
NSAIDs/Acetaminophen	87	42,23	12	16,21	**0,000059**	45,93	27,16
Opioids	62	30,01	13	17,57	**0,03**	18,92	12,74
Benzodiazepines	38	15,48	5	6,8	**0,016**		
Physical therapy	96	46,60	40	54,05	0,27	19,47	37,67
Medical leave	64	31,07	17	22,98	0,19	23,16	11,87
Specialist referral	25	12,14	21	28,38	**0,0012**		
Surgery	2	0,97	2	2,7	0,28		

*Percentages from the Intego study – Paridaens et al. (2)

Table 3 also shows a relative increase from the retrospective group to the prospective group of prescription of imaging, referral to a specialist and surgery of approximately 6% (from 25,12% to 31,08%), 16% (from 12,14% to 28,38%) and 2% from (0,97% to 2,7%), respectively. There were four patients who underwent surgery, two patients in the retrospective study group and two patients in the prospective study group. Two patients in the retrospective study group underwent a microdiscectomy at the level L5/S1. One patient of the prospective group had an ALIF surgery at the level L5/S1, and the second patient had focal decompression surgery at the level of L4/L5.

Table 4 displays a brief overview of which types of imaging was requested as well as the amount of these different types of imaging. Table 4 underlines that MRI was by far the most requested imaging modality in both study groups.

Regarding table 3, there is also a relative increase of physical therapy around 8% from 46,60% in the retrospective group to 54,05% in the prospective group. However, this increase in physical therapy is not statistically significant (P-value 0,27).

Nevertheless, the relative increase in referrals to specialists around 16% is statistically significant (P-value = 0,0012 <0,05). An overview of the different specialist domains to which referrals were made, is shown in table 5. Table 5 shows that most referrals were made for further investigation of low back pain such as an EMG investigation, extra clarification by a neurosurgeon or referral to a pain clinic to adjust pain medication or getting an infiltration.

Furthermore table 3 shows a statistically significant reduction of the prescription of medication such as NSAIDs/Acetaminophen (P-value = 0,000059 <0,05), Opioids (P-value = 0,03 <0,05) and Benzodiazepines (P-value = 0,016 <0,05) of approximately 15%, 12,5% and 9% respectively. Table 6 below gives also a more detailed structural overview of all medication prescribed by all doctors during this study. The category ‘Other’ medication in table 4 points out that doctors are used to prescribe a various scala of medication to treat low back pain besides the usual opioids, NSAIDs and Acetaminophen. The use of benzodiazepines and other medication represents around 25% and 17,5% in the retrospective and prospective group, respectively.

Moreover table 3 demonstrates an 8% reduction of individual prescription of medical leave. Despite a clear reduction of individual prescribed medical leave, the total days of medical leave was 758 days and 266 days in the retrospective and prospective group, respectively. Consequently, the mean duration of medical leave was elevated from 11,84 days in the retrospective study group to 15,65 days in the prospective study group.

Table 4: Imaging				
	Retrospective		**Prospective**	
	N (total 206)	(%)	N (total 74)	(%)
Imaging	52	25,12	23	31,08
MRI	32	15,53	16	21,62
CT	11	5,34	4	5,41
X-ray	8	3,88	2	2,70
Bone scan	1	0,49		
Ultrasound			1	1,35

Table 5: Referral specialist				
	Retrospective		**Prospective**	
	N (total 206)	(%)	N (total 74)	(%)
Referral specialist	25	12,14	21	28,38
Pain clinic	11	5,34	8	10,81
Neurosurgery	6	2,91	4	5,41
Rheumatology			2	2,70
EMG	11	5,34	8	10,81
Gynecology			1	1,35

Table 6: Medication				
	Retrospective		**Prospective**	
Medication	N (total 206)	(%)	N (total 74)	(%)
Opioids	62	30,01	13	17,54
Tramadol	3	1,46	4	5,41
Tradonal	16	7,77	1	1,35
Zaldiar	9	4,37	1	1,35
Dafalgan Codeïne	3	1,46	2	2,70

Contramal	23	11,17	5	6,76
Durogesic	1	0,49		
Minitran	1	0,49		
Oxynorm	4	1,94		
Skudexa	2	0,97		
Nsaids	82	39,81	11	14,86
Aceclofenac	5	2,42		
Diclofenac	25	12,14	2	2,70
Ibuprofen	30	14,56	7	9,46
Cataflam	3	1,46		
Gambaram	1	0,49		
Celebrex	6	2,91	1	1,35
Meloxicam	1	0,49		
Motifene	1	0,49		
Vimovo	4	1,94	1	1,35
Acetaminophen	8	3,88	2	2,70
Other	52	25,24	13	17,57
Lyrica			1	1,35
Baclofen	11	5,34	4	5,41
Diazepam	35	16,99	4	5,41
Rivotril	1	0,49		
Zolpidem	2	0,97	1	1,35
Medrol injectie	2	0,97		
Flexiumgel	1	0,49	3	1,35

4. Discussion

Core messages

First of all, this manuscript serves as a quality improving project within a general practice. One of the subgoals was to increase a correct and sufficient ICPC coding of low back pain within CareConnect (CC) in the prospective study group in order to maximize the use of the statistic module in CC. There was significant difference seen between two study groups. The hypothesis for this non-significant change in correct coding is the fact that some doctors prefer to use 'evaluation (evaluatie)' instead of 'care element (zorgelement)' in CC while making medical notes. During feedback moments, participating doctors mentioned that they forgot to change this habit sometimes because of limited time during busy working days.

Furthermore, the primary goalsetting was to improve quality indicators of low back pain management in the participating general practice. Fortunately, there is made improvement for most of the quality indicators.

The biggest improvement was seen in prescription of medication because there was a statistically significant difference between both groups for prescription of NSAIDs/acetaminophen, opioids and benzodiazepines. The biggest difference was seen at prescribing NSAIDs/acetaminophen to patients with LBP. There was a reduction of 26,02% of the use of NSAIDs/Acetaminophen. This sudden decline was not expected because NSAIDs/Acetaminophen is classic medication for pain relief for patients with LBP and the large decline was never a specific demand during feedback moments (27).

A significant decline of 12,44% of the use of opioids and benzodiazepines was also observed. This is a great achievement in this study because misuse of opioids and benzodiazepines can easily cause (serious) adverse effects from dependence to intoxication and respiratory difficulties. (28, 29) This significant decline is in line with other studies like *Lacroix et al.* which states that audit and feedback can effectively reduce high-risk opioid prescriptions and reduce opioid prescribing among the highest volume prescribers, and like the study of *Xuan Xie et al.* which has three trials in an emergency department where opioid use decreased using audit and feedback. (30, 31) The reduction of the prescribed medication also directly brings a reduction in public medical costs for society. (32)

There was also an increase of prescribing physical therapy and specialist referrals which also suggest that the doctors had an augmented awareness of the benefits using exercise therapy in low back pain rather than prescribing medication and sedentarism, as well as using the support of other specialized centra to handle complex cases. As stated above, a small increase of physical therapy around 8% was seen between both study groups which already exceeded the ABC benchmark in the Intego study. (2) Exercise therapy is important to manage and prevent chronicity of low back pain by mobilizing patients. (33) So, exercise therapy also serves as a preventive measurement of LBP to avoid future events of LBP. (34)

Another quality indicator that slightly improved without statistically significance was work absenteeism. There was a reduction of 8,09% of prescribing medical leave from 31,07% in the retrospective study group to 22,98% in prospective study group. Unfortunately, there is no suitable study to compare the impact of audit and feedback in other studies, but the study from *Wynne-Jones et al* stated that the pooled estimate for occurrence of work absence in workers with LBP was 15,5%. (17) So, despite the decrease, there still seems to be an overprescription of medical leave in the participating general practice. Nevertheless, the reduction of prescribed medical leave is possibly due to higher awareness of the indirectly financial implication of the participating doctors because of the feedback moments during this study. (35)

Finally, there was one quality indicator which deteriorated during this study, namely the prescription of imaging. This deterioration was not statistically significant, but in the prospective study group was a small increase equal to 5,96% of prescribed imaging. The prescription of imaging is also far above the overall mean in table 3 which suggest an overuse of imaging. Nevertheless, there was a lot of focus on this subject during follow-up moments with the participating general practice because of the financial impact for society and continuous overuse of imaging for low back pain diagnosis. (11, 36) On the one hand, a systematic review and meta-analysis from *Badejo et al.* showed that audit and feedback interventions are associated with a modest reduction of diagnostic image ordering with moderate certainty. Individual study effects range from a non-significant trend toward worsening to a highly significant improvement. (37) On the other hand, the study from *Eccles et al.* stated that 6-monthly audit and feedback is ineffective to reduce the radiograph request in primary care. (38)

Practical implications

The practical implication of this paper is that audit and feedback in a general practice can lead to improvements in clinical care. In this case improvement in management of low back pain. So, clinical care can improve by teaching and raising awareness among doctors. So, Audit and feedback can be easily implemented in daily practice as long as there is enough goodwill among the participating general practice, and when the database is not too extensive, otherwise it costs more time to review everything. Ideally, there are also benchmarks available from the literature with which the results can be compared.

Using the analysis of the Intego study (2), benchmarks and overall mean levels could be set for patients with low back pain. The overall mean levels and benchmarks in table 3 are guiding principles for other general practices regarding the comparison of low back pain management in different general practices. The benchmarks are based on the top 10% of general practices.

Thanks to this study, the prospective results showed that the prescription of NSAIDs and Acetaminophen improved to beneath the benchmark level. The need for Opioids declined beneath the overall mean as well as prescribed medical leave. Finally, physical therapy increased even further above the benchmark. This increase of physical therapy was also due to a more optimal multidisciplinary cooperation with two physiotherapists connected to the participating general practice.

So, audit and feedback with motivated doctors can improve clinical care and consequently directly and indirectly lower medical costs for society.

Strengths and limitations

This manuscript contains several strengths and limitations. One of the strengths of this study is the fact that the study took place in a general practice with doctors who were truly motivated and committed to this study. They had an internal motivation to improve their clinical care of low back pain. The fact that this study took place in only one general practice is a strength as well as a limitation because the data is now gathered in a uniform way, but on the other hand only limited data from small sample sizes were available to make an evaluation. So, more comparable research/studies need to be done to confirm if the effects remain the same or even further improve. Another strength was the fact that the participating doctors were open for feedback.

Another limitation is the lack of consequent coding of low back pain in CareConnect. Therefore, a lot of information cannot be investigated, and this may potentially bias the study results. The fact that the Intego study (2) used other methods/measurements/coding, made it difficult to make one on one comparison with this study and their benchmarks and overall mean measurements. On the other hand, it was also a strength to practically use the Intego study as a guideline to improve the level of low back pain management.

5. Conclusion

The use of ‘audit and feedback’ strategy in general practice can be a useful tool to improve quality of care for patients with low back pain and simultaneously reducing public medical costs in general practice. This manuscript demonstrates a reduced amount of prescription for medication such as opioids, benzodiazepines, NSAIDs/acetaminophen and work absenteeism while having an increase of physical therapy prescription after using the ‘audit and feedback’ strategy. Due to certain limitations in this study, more studies in different general practices are needed to confirm the same trend/effects in other general practices and to evaluate if the prescription of imaging can decrease as well.

6. References

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7. Appendix

7.1 OBC protocol

GROEP BIOMEDISCHE WETENSCHAPPEN
HERESTRAAT 49, O&N II – BUS 700
BE-3000 LEUVEN

Template 2022.12

MASTERPAPER PROTOCOL: PROSPECTIVE STUDY USING OTHER NON-SPECIFIED RESEARCH DESIGN

1. APPLICANTS

Protocol - full title	Approach of low back pain in a multidisciplinary setting
Version 1: Date submission	Date:29/11/2023
Version 2: Date resubmission	(to add in case of resubmission) Date:4/05/2024
Version 3: Date third submission	(to add in case of third submission) Date:Click here to enter a date.
Principal Investigator – Promotor	**Name: Prof. Dr. Bert Vaes**
	Telephone: +32 (0)16 337 468
	E-mail: bert.vaes@kuleuven.be
Following both questions should be answered:	
The principal investigator is a health professional according to the Law of 10 May 2015. YES x NO □	
The supervisor has read and approved the submission for ethics approval. YES □	
Co-Investigator – Co-Promoter	**Name: Prof. dr. Johan Vliers**
	Telephone: +32 (0)16 23 00 23
	E-mail: johan.vliers@bleyenbergh.com
The co- investigator is a health professional according to the Law of 10 May 2015. YES x NO □	
Sub-investigator – Student(s)	**Name: Dr. Bert Rooyackers**
	Student number: R0800509
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	Name:
	Student number:
	Telephone:

	E-mail:
	Name:
	Student number:
	Telephone:
	E-mail:

2. BACKGROUND AND RATIONALE

Explain the background and scientific relevance of the planned research. This should be done in a sufficiently elaborated way so that readers can get a sufficient understanding of the performed research in the area and the research questions of this project. References can be added at the end of this template.

Low back pain (LBP) is globally a common musculoskeletal problem.(1) The current estimates of incidence, prevalence, and disability-adjusted life years (DALYs) of LBPs are 245.9 million cases/year (3.2%; 15th worldwide cause), 577.0 million cases (7.6%; 15th worldwide cause) and 64.9 million DALYs (2.6% of all DALYs; 6th worldwide cause), respectively.(2)

Low back pain (LBP) is the leading cause of activity limitation and absenteeism from work, and results in a huge medical burden and economic cost. It is consequently one of the major global public health problems. (1)(2) The pooled estimate of the proportion of people returning to work was 68.2%, 85.6% and 93.3% at 1 month, 1–6 months and 6 months or longer follow-up periods, respectively. (7) Low back pain (LBP) is the leading contributor to years lived with disability. Non-specific LBP is defined as low back pain not attributable to a known cause and represents 90–95% of the cases of LBP. (3)

In Western society a systematic review demonstrated a point prevalence of 32% in adults and 12% in adolescents. The highest point prevalence of low back pain has been reported in high- income countries (32.9%), with lower rates in middle- income countries (25.4%) and low-income countries (16.7%) in some studies. The risk of developing recurrent low back pain within a year after the resolution of an episode of acute low back pain is estimated to be approximately 25%. (8)

In Flanders the annual incidence of low back pain diagnosis for female and male is 43 per 1000 patients and 46 per 1000 patients, respectively. It is the 6th and 5th most diagnosis respectively for female and male in general practice. (6)

The overuse of imaging, opioids, and surgery remains a widespread problem in the management of low back pain. (8) Despite the availability of guidelines, treatment of low back pain varies widely and is notoriously resistant to change. Health care providers often rely on shared beliefs and opinions rather than evidence to make treatment decisions. This ignorance of or unwillingness to follow evidence-based practice recommendations is responsible for what has become popularly known as the know-do gap – the gap between what is known and what is done in practice. The pervasive use of ineffective treatments for LBP is considered a likely contributor to its high prevalence. (9) Therefore, an evidence-based approach can be helpful to reduce the know-do gap as well as reduce unnecessary treatment. In Belgium, the KCE (Federaal Kenniscentrum voor de gezondheidszorg) managed to set guidelines aiming for a more universal and evidence-based quality of care concerning low back pain. (4)

Furthermore, professional health care performance can improve by using an 'Audit and feedback strategy'. This strategy intends to encourage health care professionals to change their clinical practice when there is an inconsistence with desired practice as described on explicit criteria or standards and evidence-based guidelines. So, audit and feedback interventions can contribute to improve quality of care. (10)

3. STUDY OBJECTIVES

Explain the aims and objectives of your study. Describe the research questions and hypotheses of your study.

Performing an electronic clinical audit using aggregated retrospective data to evaluate low back pain management in two general practices in Flanders (Belgium) in order to improve their quality of care in low back pain management by giving feedback after the analysis of quality indicators (as listed below) in low back pain management. Aggregated prospective data will be used to check for differences in performance before and after the feedback in both general practices with respect to the quality indicators of low back pain management.

4. RESEARCH METHOD

Present the research design and explain potential ethical implications of the planned methodology.

Aggregated retrospective and prospective data will be extracted from two Belgian general practitioners' practices called 'De Zorgpoort' in Lommel and 'Huisartsenpraktijk Heideveld' in Genk. The aggregated data will be extracted via a strict protocol from the electronic medical record software CareConnect (General Practitioner) from Corilus using the statistic module. In order to collect all aggregated information properly and due to limitations of the statistic module in CareConnect, data will be reviewed manually, and the electronic data will be aggregated in a standardized way using specific codes from CareConnect. So only aggregated data will be exported and used in this project and reported to the participating general practitioners, but no individual data (e.g., names, date of birth, addresses …) will be extracted out of the electronical medical files of the patients. Several Quality indicators are defined by the Belgian Centre for Evidence-Based Medicine (CEBAM) and are listed below:

Quality indicators:

1. Percentage of adults with low back pain where imaging is requested.
2. Percentage of adults with low back pain that got a prescription for opoids in comparison with adults with low back pain who got a prescription for non-steriodal anti-inflammatory drugs (NSAIDs)
3. Percentage of adults with low back pain where physiotherapeutic rehabilitation was required.
4. Employment status of people with low back pain

Other indicators towards quality of care in low back pain:

5. Percentage of adults with low back pain with a referral to a specialist doctor (orthopedic surgeon, neurosurgeon, pain clinic)
6. Percentage of adults with low back pain with surgery

Those outcomes of the participating general practitioners will be compared to evidence-based goal-settings and analyzed to evaluate the quality of care regarding low back pain in both general practices. Later, the first feedback based on retrospective data results will be shared using a presentation/report regarding (the doctors of) the participating general practices. During this feedback the results concerning quality of care of low back pain will be discussed based on the quality indicators (as stated above) using retrospective data. During this feedback the results, pitfalls and points of interest will be discussed in order to improve the quality of care during the prospective period of this study. After the prospective period of the study a new feedback moment (using a presentation/report) will be provided to see the potential differences and improvement of low back pain management of the participating general practices. So retrospective and prospective results of one participating general practice will be discussed in those feedback moments with the relevant participating general practice. This implicates that the (doctors of the) two general practices are used as study object and every single doctor of the general practices is aware of this role as 'study object'. To be clear, individual doctors of the participating general practices will not be analyzed individually. So, all data will be used to generally analyze/evaluate the participating practices regarding to their quality of care of low back pain management. This may implicate that one of the two general practices can have a more favorable audit in this study report (regarding the retrospective or prospective data) than the other practice. The two participating general practices are aware of this implication and still agree to participate with this study. The e-mails in subsection 13.2 'Annexes' illustrates the awareness and approval of every single doctor of the participating general practices. Those mails are in other words a centralized approval of every single doctor after reading my protocol and after a group discussion in of the weekly meetings of the respective participating general practice. Ethical implications such as the need for informed consent to collect all data can be waived because all data is aggregated data while performing good clinical practice and the data will not contain any individual patient data as stated before. An information letter as listed below will be provided to inform the patients about this study. The information letter will be sent digitally to the patients using the Care Connect communication module/network. The information letter will also be printed and made visible in the participating general practices. The printed information letters can also be distributed during a consultation.

5. SELECTION AND WITHDRAWAL OF PARTICIPANTS

5.1 Inclusion and exclusion criteria

List details such as age, sex, disease, characteristics etc., under which a participant is deemed to be suitable (eligible) to participate in the study.

Inclusion criteria for this study includes every adult patient (older than 18 years old) with low back pain with an active global medical file who present themselves in one of the two general practitioners' practices called 'De Zorgpoort' in Lommel and 'Huisartsenpraktijk Heideveld' in Genk. Exclusion criteria are an age under 18 years old or no active global medical file. The aggregated data will include following categories: Demographic information (age, gender and nationality), medical background information (medical history of back pain, chronic pain medication …) and quality

indicators (imaging, opoids/nsaids use, psychiotherapy, employment status, referral to specialist and surgery).

5.2 Sample size and population

Give the number of participants to be enrolled, together with the rationale for the sample size and how it relates to the total population. Does the ratio between sample size and population size makes it easy to identify participants? In case of working with a small population describe which measures will be taken to prevent re-identification.

The incidence of low back pain in Flanders is around 45 per 1000 patients. The general practices have around 4500 patients. So, the expected sample size of available data for one year follow-up will be around 180 patients. This sample size will give us enough data to analyze the quality indicators as stated above and to evaluate improvement of quality of care of low back pain in the general practices.

5.3 Recruitment

Specify who will recruit the participants, how this will happen, and by whom the participants will be approached for inclusion and obtainment of the informed consent form.

No active recruitment will be used in this study. Retrospective data will be aggregated from the statistical database in Care Connect. Prospective data will also be extracted from the statistical database Care Connect using aggregated data from normal consultations of patients with good clinical practice in the participating general practices. The aggregated data of all adult patients with low back pain will be monitored during this process by using clear codes of the medical records system from the participating general practices.

Een voorbeeldtekst die je hier mag gebruiken vind je in ***het document met toelichtingen.***

Example texts that you may use here can be found in the ***explanatory document.***

Vergeet niet te vermelden hoe je eventuele telefoonnummers/mailadressen of andere contactinformatie verkrijgt.

Do not forget to mention how you receive phone numbers/e-mail addresses of other contact information.

5.4 Expected duration

Specify the expected duration of the whole study, and define the beginning and ending of the study for the study participant.

Voorbeeldtekst die je hier mag gebruiken: De studie zal starten na goedkeuring van de ethische commissie.

Example text that you may use here: The study will begin after the ethical approval of the committee.

Aggregated retrospective data will be extracted from Care Connect from 01/10/2022 until 30/04/2024. Aggregated prospective data will be collected from 14/06/2024 until 31/05/2025. The ultimate deadline for the analysis of data will be until 30/09/2025.

6. ANALYSIS

Describe methods for data analysis in detail. Describe the measures taken to avoid, or at least minimize, biases.

Aggregated data will be analyzed using a digital statistical program called 'R statistics version 4.3.2'. A significant level of 0.05 will be used. Variables are unpaired. Demographic information as gender, age and nationality as well as important data about medical history as chronic (pain) medication, previous episodes of low back pain and important co-morbidities will be aggregated and analyzed. Descriptive statistics as Chi^2-test, two proportion Z-test, Unpaired students t-test or Mann-Whitney U-tests can be used during the statistical analysis from the aggregated data to evaluate a significant statistical improvement in performance at the participating general practices.

7. DATA HANDLING AND MANAGEMENT

7.1 Data storage and management

Explain which type of data you are using, how the privacy of the participants is being protected (e.g. pseudonymisation or anonymization), how the data is safely stored, how the data is safely shared and what will happen to the data at the end of the project.

Een voorbeeldtekst die je hier mag gebruiken vind je in ***het document met toelichtingen.***

Data will be aggregated in two general practitioner practices in Flanders (Belgium), called "De Zorgpoort" and "Huisartsenpraktijk Heideveld". Retrospective data will be collected in "De Zorgpoort" from 01/10/2022 until 31/03/2024. Aggregated prospective data will be collected from 14/06/2024 until 31/08/2025 in "De Zorgpoort". The aggregated retrospective data in "Huisartsenpraktijk Heideveld" will be collected from 01/10/2022 until 31/03/2024. The aggregated prospective data in "Huisartsenpraktijk Heideveld" will be collected from 01/12/2024 until 31/08/2025. This data will be aggregated using consultation reports in two general practitioner practices as stated above. No individual patient data will leave the general practitioner practice during our analysis. Only aggregated data will be analyzed and reported at the participating practices. Contact information about the participating general practitioner practices:

- De Zorgpoort, Kerkplein 14, 3920 Lommel, Belgium, Dr. Jos Vanhoof, info@dezorgpoort.be, +3211 55 02 30.
- Huisartsenpraktijk Heideveld, Mosselerlaan 135/bus 1, 3600 Genk, Belgium, Dr. Stijn Indeherberge, dr.indeherberge@gmail.com, Dr. Karolien Lemmens, karolienlemmens@hotmail.com, +3289 35 27 89, https://doktersheideveld.be.

*A text example that you can use here can be found **in the document with explanations**.*

Voor de verzameling en opslag van mijn data maak ik gebruik van (**duid aan wat van toepassing is**):

- ☐ Project- of teamgebonden opslaglocatie op de beveiligde server van KU Leuven of UZ Leuven via mijn promotor of begeleider
- ☐ REDCap, aangeboden door KU Leuven en UZ Leuven
- ☐ OneDrive for Business, aangeboden door KU Leuven
- ☐ Persoonlijke computer, beveiligd met een sterk wachtwoord, tweestapsverificatie of gespecialiseerd programma (7-Zip, AEScrypt, …)
- ☐ Andere, mits beargumentering, namelijk: ……..

For the collection and storage of my data I use (indicate what is applicable):

- ☐ Project or team-related storage location on the secure server of KU Leuven or UZ Leuven via my supervisor or supervisor
- ☐ REDCap, offered by KU Leuven and UZ Leuven
- ☐ OneDrive for Business, offered by KU Leuven

X **Personal computer, protected with a strong password, two-step verification or specialized program (7-Zip, AEScrypt, …)**

- ☐ Other, if substantiated, namely: ……..

7.2 Declaration of Confidentiality and Careful Management of Information and Personal Data

Please read carefully following section. By participating in this project you commit to following declaration.

In the framework of his / her Master's thesis, the student(s) will have access to all kinds of data, information, results and documents. In order to ensure the confidentiality of this Information and the privacy of those involved, within the framework of his / her Master's thesis the student(s) should always deal with the Information with the greatest care and discretion. In particular research related to patients and including the collection and analysis of personal data requires the utmost of care and discretion. Therefore, at all times the student must observe complete confidentiality with respect to the Information he / she has collected during the course of his / her Master's thesis.

In performing this research, the student(s) commit(s) him/herself to the following confidentiality obligations:

- *He / she accepts, during and after the completion of the Master's thesis,* ***the obligation to strictly observe the confidentiality of the Information he / she has collected*** *and the activities to which he / she has participated, and regarding the patients, healthy volunteers and the staff members with whom he / she comes into contact;*

- *He / she will only process and collect data that is* ***relevant*** *and* ***necessary*** *for his / her Master's thesis;*

- *He / she will* ***not share information*** *with persons not directly involved within the framework of his / her research; only the* ***investigator, possible group members*** *and his/her* ***supervisor*** *will have access to the data*

- *He / she will take* ***all necessary steps*** *to protect the confidentiality of Information and the privacy of those involved;*

- *He / she will handle with* ***care and responsibility*** *the Information and the access granted to him/her to information systems and digital media.*

- *He/ she will discuss the* ***confidentiality***, ***storage*** *and* ***sharing*** *of files with his/her supervisor. He/she will use* ***anonymisation*** *or* ***pseudonymisation*** *in order to limit the risks of data leaks and data loss.*

- *If pseudonymisation is used, he/she will treat the pseudonymisation* ***key*** *or the* ***encryption table*** *containing the pseudonyms and the identifiable information fields with the* ***same confidentiality*** *as the original data. He/she will* ***never store the key or encryption table at the same device*** *(e.g. laptop or desktop) as the work file or database containing the pseudonymised data.*

- *Wherever possible, he/she will use a* ***project based or team based storage location*** *for storing and exchanging data. He/she will contact his/her supervisor to discuss the possibility of using an internal or external service of KU Leuven or UZ Leuven to save data. If not possible, he/she will use OneDrive for Business, provided by KU Leuven, REDCap,provided by KU Leuven and UZ Leuven, or a password protected device for storing collected data. Applications such as* ***Google Drive, a personal OneDrive (except OneDrive for Business, provided by KU Leuven) or WeTransfer will be avoided at all times****.*

- *He/she will always encrypt confidential information and files with a* ***password***, ***two-step verification*** *or* ***specialized program*** *such as 7-Zip or AEScrypt.*

- *When sharing a copy of strictly confidential data, he/she will always* ***encrypt*** *the data with a secure password or unique code. For sharing large files, a* ***secure application*** *such as Belnet Filesender will be used.*

- *In the event of a* ***data breach*** *he/she will immediately contact his/her supervisor*

As this research is conducted in the context of a Master's Thesis, the legal basis for the processing of personal data is the public interest. This research will generate knowledge and new insights that (directly or indirectly) will benefit society.

All investigators shall treat all information and data relating to the study as confidential and shall not disclose such information to third parties or use such information for any purpose other than the performance of the study. The collection, processing and disclosure of personal data, such as participants' contact information, health information and medical information, is subject to compliance with the General Data Protection Regulation (GDPR).

When approval is given by the Ethics Committee, it is confirmed that the proposed processing of personal data meets the requirements of the GDPR. Consequently, from a GDPR perspective, there is no objection to start the processing operations. When approval is given, this application will, In accordance with the GDPR, become

included in KU Leuven's register of processing activities in the context of research and public service. ***No separate privacy application should be submitted for this type of studies.***

8. ASSESSMENT OF RISKS AND SAFETY

In case of safety issues (adverse events / serious adverse events) the student will promptly contact the Principal Investigator / Promotor who will be responsible for follow up. Please describe possible adverse events following your research and confirm that the name of the Principal Investigator and other relevant point of contacts have been integrated in the ICF to the participants.

During this study there are no risks nor safety issues to be considered because all data will be aggregated using good clinical practice.

9. APPROVAL

Data can only be collected if the head of the institution or department where the data will be collected has been informed of the study and has approved the study. If applicable, please confirm this approval and give the essential contact information.

Hereby we confirm that data collection is performed with approval of the head of the respective unit(s) or department(s) where data collecting is taking place. Contact details of the head of the participating general practices are:

- *De Zorgpoort, Kerkplein 14, 3920 Lommel, Belgium, Dr. Jos Vanhoof, jos.vanhoof@dezorgpoort.be, +3211 55 02 30.*
- Huisartsenpraktijk Heideveld, Mosselerlaan 135/bus 1, 3600 Genk, Belgium, Dr. Stijn Indeherberge, dr.indeherberge@gmail.com, Dr. Karolien Lemmens, karolienlemmens@hotmail.com, +3289 35 27 89, https://doktersheideveld.be.

10. PUBLICATION POLICY

Please read carefully following section. By participating in this project you commit to following declaration.

Publications will be coordinated by the Principal Investigator. Authorship to publications will be determined in accordance with the KU Leuven policy on authorship.

11. DIRECT ACCESS TO SOURCE DATA AND DOCUMENTS

Please read carefully following section

The investigator(s) and the institution(s) will permit study-related monitoring, audits, ethical review and regulatory inspections (where appropriate) by providing direct access to source data.

12. REFERENCES

Please add references here

1. Wu A, March L, Zheng X, Huang J, Wang X, Zhao J, Blyth FM, Smith E, Buchbinder R, Hoy D. Global low back pain prevalence and years lived with disability from 1990 to 2017: estimates from the Global Burden of Disease Study 2017. Ann Transl Med. 2020 Mar;8(6):299. doi: 10.21037/atm.2020.02.175. PMID: 32355743; PMCID: PMC7186678.
2. Mattiuzzi C, Lippi G, Bovo C. Current epidemiology of low back pain. J Hosp Manag Health Policy 2020;4:15.Oliveira CB, Maher CG, Pinto RZ, Traeger AC, Lin CC, Chenot JF, van Tulder M, Koes BW.
3. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. Eur Spine J. 2018 Nov;27(11):2791-2803. doi: 10.1007/s00586-018-5673-2. Epub 2018 Jul 3. PMID: 29971708.
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5. NHG-werkgroep: Bons SCS, Borg MAJP, Van den Donk M, Koes BW, Kuijpers T, Ostelo RWJG, Schaafstra A, Spinnewijn WEM, Verburg-Oorthuizen AFE, Verweij HA. NHG-richtlijnen aspecifieke lage rugpijn. 2017.
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7. Wynne-Jones G, Cowen J, Jordan JL, et al. Absence from work and return to work in people with back pain: a systematic review and meta-analysis. Occupational and Environmental Medicine 2014;71:448-456.
8. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. Lancet. 2017 Feb 18;389(10070):736-747. doi: 10.1016/S0140-6736(16)30970-9. Epub 2016 Oct 11. PMID: 27745712.
9. Scott NA, Moga C, Harstall C. Managing low back pain in the primary care setting: the know-do gap. Pain Res Manag. 2010 Nov-Dec;15(6):392-400. doi: 10.1155/2010/252695. PMID: 21165374; PMCID: PMC3008665.
10. Jamtvedt G, Flottorp S, Ivers N. Audit and Feedback as a Quality Strategy. In: Busse R, Klazinga N, Panteli D, et al., editors. Improving healthcare quality in Europe: Characteristics, effectiveness and implementation of different strategies [Internet]. Copenhagen (Denmark): European Observatory on Health Systems and Policies; 2019. (Health Policy Series, No. 53.) 10.Available from: https://www.ncbi.nlm.nih.gov/books/NBK549284/

13. ANNEXES

1. *A template of the **ICF** has been developed and is available on https://med.kuleuven.be/nl/obc/Documenten or https://med.kuleuven.be/nl/obc/Documents_en. This must be used as a basis and adapted where necessary.*

   In case an alternative template is being used, a motivation should be provided here.
   Please copy your information letter here.

2. *All relevant information and documents regarding your research design*

3. *Every **advertisement, flyer, poster**, etc. that will be used in the study should be added.*
   *If recruitment will be done through **social media** or by **mail**, please also add the text or illustration that will be used.*
4. *Other (if applicable)*

1) Informatiebrief

GROEP BIOMEDISCHE WETENSCHAPPEN
HERESTRAAT 49, O&N II – BUS 700
BE-3000 LEUVEN

Template 2022.12

Titel van de studie: Benadering van lage rugpijn (in een multidisciplinaire setting)

Onderzoeksinstelling: KU Leuven

Ethisch comité: Ethische Commissie Onderzoek UZ/KU Leuven.

Onderzoekers: Bert Rooyackers, Huisarts in opleiding, bert.rooyackers@student.kuleuven.be
Prof. Dr. Bert Vaes, bert.vaes@kuleuven.be
Prof. Dr. Johan Vliers, johan.vliers@bleyenbergh.com

Met behulp van deze informatiebrief wordt U op de hoogte gebracht over een studie in kader van een kwaliteitsverbeterend project voor het verbeteren van de behandeling/benadering van lage rugpijn in de huisartsenpraktijk.

Doelstellingen en verloop van de studie

Deze studie betreft een kwaliteitsverbeterend project. Bij de deelnemende huisartsenpraktijken zal een audit uitgevoerd worden betreffende de zorgkwaliteit en benadering van lage rugpijn aan de hand van verschillende kwaliteitsindicatoren zoals gebruik van beeldvorming, NSAID-gebruik, uitoefenen van kinesitherapie, werkongeschiktheid, verwijzing naar een specialist en noodzaak tot chirurgisch ingrijpen. Na het uitvoeren van de audit zullen de resultaten gedeeld worden met de desbetreffende huisartsenpraktijken met als doel handvaten/aandachtspunten mee te geven om de zorgkwaliteit betreffende lage rugpijn te verbeteren. Na deze feedback zal via deze studie verder gekeken worden naar de potentiële verbeteringen/veranderingen in de behandeling van lage rugpijn bij de deelnemende huisartsenpraktijken.

Wij willen U informeren en benadrukken dat de studie een bijdrage kan leveren aan het verbeteren van de zorgkwaliteit betreffende de benadering van lage rugpijn in de deelnemende huisartsenpraktijken.

Voor deze studie zal er enkel geaggregeerde data (m.a.w. geen persoonlijke data/persoonsgegevens) van ongeveer 200 patiënten gebruikt worden voor de analyse van deze studie. Er wordt enkel data gebruikt van volwassen patiënten (18 jaar of ouder) die lage rugpijnklachten hebben of doorgemaakt hebben. Overigens moet er ook een actief globaal medisch dossier in de huisartsenpraktijk aanwezig zijn om de data te kunnen gebruiken. Tot slot is het belangrijk om te benadrukken dat de huisartsen(praktijken) het studieobject zijn in deze studie. Er worden dus geen persoonsgegevens van patiënten verzameld/gebruikt tijdens deze studie.

Beschrijving van de risico's en van de voordelen

De huisartsen(praktijken) zijn in deze studie het studieobject en er zal enkel data (geen persoonsgegevens) verzameld worden tijdens deze studie. Deze studie houdt voor U dus geen enkel (gezondheids)risico in.

Door gebruik te maken van de geaggregeerde data (geen persoonsgegevens) in de deelnemende praktijken en vervolgens analyse en feedback te voorzien bij de deelnemende huisartsenpraktijken, zou de kwaliteit van de behandeling/benadering van lage rugpijn in de huisartsenpraktijk kunnen verbeteren.

Deze studie kost U verder geen tijd aangezien de onderzoeker alle nodige data (geen persoonsgegevens) zal verzamelen en verwerken.

Over deze studie moet u weten dat:

- Deze studie MP028003 opgesteld is na evaluatie door EC Onderzoek UZ/KU Leuven.
- De gegevens die in het kader van uw deelname worden verzameld, zijn volledig anoniem. Er worden geen persoonsgegevens zoals naam, geboortedatum, adres, enz. verzameld. Bij de publicatie van de resultaten is uw anonimiteit verzekerd.

Als u bijkomende informatie wenst over hoe wij uw anonieme gegevens gebruiken, maar ook ingeval van problemen, bijkomende vragen of als u zich zorgen maakt, kan u contact opnemen met de onderzoeker Bert Rooyackers via bert.rooyackers@kuleuven.be of via het telefoonnummer +32 476 611 803 en de hoofdonderzoeker Prof Dr. Bert Vaes via het telefoonnummer +32 16 337 468 (werkuren) of via e-mail bert.vaes@kuleuven.be. Ook de functionaris voor gegevensbescherming van het onderzoekcentrum staat te uwer beschikking.
De contactgegevens van deze laatste zijn als volgt:
– KU Leuven, e-mail dpo@kuleuven.be

- Als u vragen hebt met betrekking tot uw rechten, kan u contact opnemen met de Ethische Commissie Onderzoek UZ/KU Leuven (ec@uzleuven.be; 016 34 86 00 (werkdagen tussen 10 en 11 uur))
- Tot slot, indien u een klacht heeft over de verwerking van uw gegevens, kunt u contact opnemen met de Belgische toezichthoudende instantie die toeziet op de naleving van de grondbeginselen van de bescherming van persoonsgegevens:

  De Belgische toezichthoudende instantie heet:
  Gegevensbeschermingsautoriteit (GBA)
  Drukpersstraat 35,
  1000 Brussel
  Tel. +32 2 274 48 00
  e-mail: contact(at)apd-gba.be
  Website: www.gegevensbeschermingsautoriteit.be

Alvast bedankt,

Met vriendelijke groet
Dr. Bert Rooyackers

7.2 OBC approval

GROEP BIOMEDISCHE WETENSCHAPPEN
HERESTRAAT 49, O&N II – BUS 700
BE-3000 LEUVEN

English version below.

Ons kenmerk: MP028003
Uw kenmerk: Masterproef studie: Benadering van lage rugpijn in een multidisciplinaire setting
Leuven, 29-11-2024

GEEN BEZWAAR BRIEF

Geachte Professor Professor Bert Vaes
Geachte Bert Rooyackers

De Ethische Commissie Onderzoek UZ/KU Leuven bevestigt hierbij dat er geen bezwaren zijn tegen het uitvoeren van de voorgestelde studie, zoals ze werd beschreven in het protocol. De Commissie is van oordeel dat er vanuit ethisch standpunt geen bezwaren zijn bij de voorgestelde studie. De studie werd goedgekeurd op 29-11-2024

De Onderwijs-Begeleidings-Commissie voor Medische Ethiek (OBC) heeft in delegatie van het EC Onderzoek UZ/KU Leuven het vermeld protocol onderzocht en besproken op haar vergadering.

Het betreft hier een klinische audit die met behulp van retrospectieve en prospectieve gegevens probeert na te gaan of de behandeling van rugklachten verbeterd kan worden. Er is geen enkele rechtstreekse interventie bij patiënten (ook geen survey afgenomen bij patiënten). Uiteraard moeten de dossiergegevens met aandacht voor beroepsgeheim en privacy geanalyseerd, geëxporteerd en verwerkt worden, dit is in orde. De interventie is een interventie in een huisartsenpraktijk: namelijk geven van feedback over hoe de aanpak van lagerugpijn al dan niet overeenstemt met klinische richtlijnen (om dan in een tweede fase te zien of dit tot een veranderde praktijkvoering aanleiding geeft). De (artsen van de) huisartspraktijken zijn derhalve het "studie-object". De studie is goed uitgewerkt. Overeenstemming met de artsen over de studie is in orde. Informatiebrief voor de patiënten betreffende het gebruik van hun gegevens is ok. Er zijn geen bezwaren tegen de studie.

EC Onderzoek heeft geen bezwaar tegen het project mits vertrouwelijke behandeling van de gegevens en naleving van de Belgische wetgeving omtrent privacy. EC wenst de hoofdonderzoeker/promotor van de studie te wijzen op zijn/haar verantwoordelijkheid betreft de privacy van de persoons-/patiëntgegevens bij contact met levende personen, patiënten en/of inzage in het elektronisch medisch dossier, inclusief de correcte implementatie hiervan door medewerkers en studenten.

Deze geen bezwaar brief betreft de indiening van 28-11-2024 en wordt gegeven voor de duur van de Masterproef van de betrokken student(en). Elke wijziging aan het protocol doet dit advies vervallen. U dient in dat geval tijdig een amendement voor advies voor te leggen aan de Onderwijs-Begeleidings-Commissie (OBC) die de initiële studie heeft geëvalueerd.

EC bevestigt dat ze werkt in overeenstemming met de ICH-GCP principes (International Conference on Harmonization Guidelines on Good Clinical Practice), met de meest recente versie van de Verklaring van Helsinki en met de van toepassing zijnde wetten en regelgeving.

EC bevestigt dat in geval van belangenconflict, de betrokken leden niet deelnemen aan de besluitvorming omtrent de studie.

Met vriendelijke groet,

Prof. dr. Minne Casteels
Voorzitter
Ethische Commissie Onderzoek UZ/KU Leuven

Prof. dr. Pascal Borry
Voorzitter
Onderwijs-BegeleidingsCommissie voor Medische Ethiek KU Leuvenv

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Aandachtspunten (indien van toepassing)

EC benadrukt dat een GCP-opleiding van elke hoofdonderzoeker verwacht wordt. EC benadrukt tevens dat de hoofdonderzoeker/promotor verantwoordelijk is voor de uitvoering van het projectvoorstel in overeenstemming met de van toepassing zijnde wetten en voorschriften, waaronder, maar niet beperkt tot, de EU-verordening 2016/679 (Algemene Verordening Gegevensbescherming), de Belgische wet betreffende de rechten van patiënten van 22/8/2002, en het beleid van de instelling waar het onderzoek zal worden uitgevoerd.

Bij gebruik van elektronisch medische gegevens is een formeel akkoord van de dienstraad vereist. De opdrachtgever is verantwoordelijk voor de conformiteit van de anderstalige documenten met de Nederlandstalige documenten.

Dit advies van EC houdt niet in dat zij de verantwoordelijkheid voor de geplande studie op zich neemt. U blijft hiervoor zelf verantwoordelijk.

Bovendien dient u als hoofdonderzoeker erover te waken dat de resultaten van dit onderzoek, correct worden weergegeven in publicaties, rapporten voor de overheid enz.

U wordt eraan herinnerd dat bij klinische studies iedere door u waargenomen ernstige verwikkeling onmiddellijk zaan EC moet worden gemeld, ook al is het oorzakelijke verband met de studie onduidelijk.

Our reference: MP028003
Your reference: Master's thesis study: Benadering van lage rugpijn in een multidisciplinaire setting
Leuven, 29-11-2024

DEFINITIVE FAVOURABLE ADVICE

Dear Professor Professor Bert Vaes
Dear Bert Rooyackers

The Research Ethics Committee UZ/KU Leuven hereby confirms that there are no objections to conducting the proposed study, as it was described in the protocol. After a thorough ethical review, the Commission found no concerns regarding the study. The study was approved on 29-11-2024

De Onderwijs-Begeleidings-Commissie voor Medische Ethiek (OBC) heeft in delegatie van het EC Onderzoek UZ/KU Leuven het vermeld protocol onderzocht en besproken op haar vergadering.

Het betreft hier een klinische audit die met behulp van retrospectieve en prospectieve gegevens probeert na te gaan of de behandeling van rugklachten verbeterd kan worden. Er is geen enkele rechtstreekse interventie bij patiënten (ook geen survey afgenomen bij patiënten). Uiteraard moeten de dossiergegevens met aandacht voor beroepsgeheim en privacy geanalyseerd, geëxporteerd en verwerkt worden, dit is in orde. De interventie is een interventie in een huisartsenpraktijk: namelijk geven van feedback over hoe de aanpak van lagerugpijn al dan niet overeenstemt met klinische richtlijnen (om dan in een tweede fase te zien of dit tot een veranderde praktijkvoering aanleiding geeft). De (artsen van de) huisartspraktijken zijn derhalve het "studie-object". De studie is goed uitgewerkt. Overeenstemming met de artsen over de studie is in orde. Informatiebrief voor de patiënten betreffende het gebruik van hun gegevens is ok. Er zijn geen bezwaren tegen de studie.

The Committee has no objection to the project provided that the data are handled confidentially and there is compliance with the Belgian legislation concerning privacy. The Research Ethics Committee UZ/KU Leuven reminds the principal investigator/promotor of the study of their responsibilities with regard to the privacy of personal / patient details, when in contact with living persons, patients, and / or contained within electronic medical records, including the correct implementation by employees and students.

This letter of no objection concerns the submission of 28-11-2024v and is given for the duration of the Master's thesis of the student(s) concerned. Any amendment to the protocol will invalidate this advice. In that case, you must submit an amendment for advice to the committee that previously approved your file must be submitted.

The Committee confirms that they work in accordance with the ICH-GCP principles (International Conference on Harmonisation Guidelines on Good Clinical Practice), with the most recent version of the Helsinki Declaration, and with applicable laws and regulations.

The Committee confirms that in case of a conflict of interest, the members concerned have not participated in decision regarding the study.

Yours sincerely,

Prof. dr. Minne Casteels
President / Chairperson
Research Ethics Committee UZ/KU Leuven

Prof. dr. Pascal Borry
President / Chairperson
Education-Support Committee for Medical Ethics KU Leuven

Points of Interests (if applicable)

EC Research emphasizes that GCP-training is expected from every principal investigator. EC Research refers also to the Belgian legislation (Law from 8/12/1992 for the protection of personal privacy and Law from 22/8/2002 regarding the rights of the patient), and the General Data Protection Regulation (which comes into effect on May 25th 2018).

For use of electronic medical data, a formal agreement from the clinical departmental board is

required. The study promotor is responsible for the conformity of foreign language documents with the Dutch language version.

This opinion from EC Research does not imply that it takes responsibility for the planned study. You remain responsible for this yourself. In addition, as the principal investigator, you must ensure that the results of this research are correctly displayed in publications, reports for the government, etc.

You are reminded that any serious complication you observe must be reported immediately to the Ethics Committee, even if the causal link with the study is unclear.