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Referrals for uncomplicated lower back pain: a cluster parallel randomized trial of patient centered communication to improve the management of acute back pain in primary care. A study protocol.

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ABSTRACT

Introduction

Back ache is one of the most frequent encounters in General Practice. Investigation and referral remain common despite the self-limiting character of episodes that are largely not attributable to specific underlying injuries. Communication is a powerful tool to identify patients` ideas, concerns and expectation (ICE) setting the base for transferring and adjusting adequate clinical information. This study aims to evaluate whether ICE can decrease unnecessary medicine in the management of acute backache in primary care.

Methods and analysis

Recruitment to this parallel cluster randomised trial will take place amongst general practitioners belonging to four independent practice networks in Northern Bavaria/Germany. At baseline, 24 out 48 doctors will be randomly assigned to take part in a one-day training session covering theoretical background and clinical implementation of ICE communication. They will also be given access to an interactive online tool for reflective practice on their communication preferences. Primary outcome measures are referrals to diagnostic imaging, physiotherapy and specialist obtained from routine practice data, compared between intervention and control group. Secondary outcomes are patients' and doctors' satisfaction via structured questionnaires and semi-structured interview. Blinding is attempted by hiding trial purpose and treatment allocation from the participating doctors.

Ethics and dissemination

Ethical approval for the study was obtained [296_17B]. Results will be disseminated by conference presentations and journal publications.

Trial registration

The trial is registered in clinicaltrials.gov [NCT03711071].

KEYWORDS

Primary Care, communication, doctor-patient relationship, consultation, information-exchange, shared-decision making, medical education, low back pain, diagnosis, over investigation;

ARTICLE SUMMARY

Strengths and limitations of this study

- A thorough randomised parallel design was chosen to compare the effect of patient centred communication training on doctors' clinical behaviour in the management of acute back pain.
- The practice networks included in the trial involve a broad spectrum of urban and rural practices being representative for German Primary Care.
- Blinding is more difficult to achieve in nonpharmacological trials and represents a clear limitation of this study. Masking participating doctors towards treatment allocation is attempted by allocating the behavioural intervention at two stages: The intervention group will undergo the ICE training session at baseline; the control group will be offered training once data collection is accomplished. An effort will be made to hide outcome measures from all participants.
- The difficulty of recording ICE communication genuinely administered during consultations without introducing a considerable threat of bias (performance and reporting bias) is a clear limitation of this study. The effect of one ICE training session on doctors' behaviour focused on in this study can only act as a proxy for using more ICE when communicating with patients.
- The innovative character of this research project bears its risks. In Bavaria/South Germany, this is the first project establishing a practice network for research purposes in Primary Care and the feasibility of a randomised controlled trial in this setting will need to be tested.

INTRODUCTION

Back pain is one of the most frequent reasons for encounter in General Practice.[1 2] It affects all ages with a peak in prevalence in the fifth decade and a decrease in the sixth and seventh decade of life. In a German Health Survey, as many as 39% of female and 31% of male participants aged 18 to 80 reported episodes of back pain within the last seven days.[3] A multiregional study conducted in Germany confirmed a social and educational impact revealing higher prevalence in patients with poor education (47% in patients with nine years of education or less compared to 27% with more than 12 years of education).[4] Patients suffering from back pain were also shown to have increased levels of comorbidity.[5-12]

Reasons for low back pain often remain unspecific with 80-90% of cases not being attributable to a specific injury or lesion[13]. The majority of episodes are self-limiting, of which 90% show spontaneous remissions within six weeks. Only less than 7% of episodes remain chronic [1]. Nevertheless, investigation and referral remain common and back pain clearly

represents a condition contributing to unnecessary health care and costs. These are responsible for expenditures in the dimension of 8.4 billion Euros per year in Germany, of which 15% are contributable to expenses for medical interventions and 85% to periods of unemployment and resulting loss of productivity.[3]

Dismissing information regarding diagnostic and therapeutic procedures can be the cause of false patient expectations leading to unnecessary medicine. Communication is a simple but powerful tool with a great potential of transferring relevant and adequate information, and patient-centered communication has been shown to influence patient contentedness and adherence to medical treatment.[14-16] However, patients' frequent complaint of poor communication and inadequate treatment is an indication for a clear mismatch between patients' and physicians' concerns.[17-23] Patient-centered communication can be promoted by ICE, an easily applicable and internationally approved tool to improve communication skills within a patient-centered consultation by encouraging patients to disclose their *ideas, concerns and expectations*.[24] Despite increasing evidence of a positive influence on health related outcomes such as improved communication skills and medication prescribing,[17] the implementation of ICE in daily routine is still lacking, may be because physicians view patient-centered communication as being time- and cost-intensive.[25]

Discrepancy between clinical facts and patients' expectations leading to unnecessary medicine can be responsible for irrelevant health care with a high amount of direct and indirect economic losses. In this research project, we will evaluate whether the implementation of the ICE technique can contribute to more sensible resource allocation and less unnecessary medicine in the management of acute backache in primary care.

METHODS AND ANALYSIS

Aims

The overall purpose of the proposed study is to carry out a patient centered communication training and to evaluate its influence on the prevention of unnecessary medicine. We would like to know whether ICE is applicable in daily routine, enhances patient satisfaction during consultations, and results in a reduction of diagnostic imaging and specialist referring with a positive impact on financial resources by reducing direct and indirect health care costs.

The primary aim to be achieved is to examine the effect of doctors' ICE training on patient referral rates for acute back pain. ICE communication training will be developed and administered within the network of research practices. Patient attitudes regarding their physical indisposition, and possible diagnostic and treatment options will be addressed by

exploring ideas, concerns and expectations. Subsequent consultations of patients presenting with uncomplicated backache will be monitored in terms of referrals to further imaging, physiotherapy or specialists.

The secondary aim is to assess how ICE communication can influence consultation quality based on doctors' and patient views.

Trial design and setting

The design of a randomized trial of nonpharmacological treatment applying parallel cluster randomization has been chosen to overcome the difficulty of allocating doctors working in the same practice to different interventions, without running the risk of contamination.[26] Trials of nonpharmacological treatment test complex behavioral interventions involving several components that are difficult to describe, standardize and administer consistently to all patients. To overcome these difficulties the rules of the Consort Statement of nonpharmacological treatments were applied in the design of the proposed study.[27] The observations of patients treated for acute back pain by the same doctor may be correlated or clustered. Each doctor taking part in this trial forms a cluster of clinical treatment decisions being similar and not independent from one another.

Participant Recruitment

The clusters will involve two levels: Doctors recruited to receive training in patient centered communication (intervention group) or no training (control group), and patients being treated by these doctors for acute back pain.

General Practitioners will be randomized to receive the intervention or not. They will be recruited from four independent practice networks forming "Forschungspraxen Franken", a research network located in rural and urban areas of Franconia/ Northern Bavaria comprising 119 General Practitioners from 77 practices, of which 30 are single handed and 47 are group practices.

Patients aged 18 and above with a new episode of unspecific back pain, defined as no prior visit for low back pain within the previous six weeks, will be included.

Allocation sequence generation and randomization

At baseline, 48 General Practitioners will be randomized to receive the intervention or not, with participating doctors acting as units of randomization and analysis. To minimize contamination in the control group, randomization to ICE communication training will take place at the practice level with units of randomizations being single handed or group practices belonging to the research network “Forschungspraxen Franken”. This ensures that doctors being allocated to the control group will not be surrounded by colleagues having received the communication training.

Stratification will be imposed on the randomization process to minimize numeral imbalance over treatment groups during the course of randomization. As all practices will be available at the time of generating the sequence, the random allocation rule can be applied. To ensure numeral balance of the number of individuals randomized to each group, practices will be stratified by numbers of GPs per practice. The sequence will be generated independently within each stratum. For example, in a stratum with a sample size of 6 practices with three GP partners each, three practices will be allocated to the control group and three will be allocated to the intervention group by drawing six concealed envelopes containing 3 group A and 3 group B allocations without replacing them, thus allocating all 3 of the 6 practices to the control group and 3 to intervention group.[28]

Blinding

Blinding of participating doctors towards the intervention will not be possible and represents a considerable threat of bias. However, the following attempts will be undertaken to hide from participating doctors who of them received true treatment allocation: Firstly, all participants will be blinded towards the explicit purpose and design of the study. Secondly, ICE communication training will be offered to all participants: to GPs in the intervention group as a true intervention at the beginning of the RCT, and to control GPs as a pretend intervention at the end of the trial. The treatment allocation for each site and each doctor will be kept at the Department of Primary Care in Erlangen. The invitation for the communication training will be sent to both intervention and control practices, but control practices will have their training at a later point in time. Practices and GPs forming the clusters, health care assistants involved with data collection, nor patients seeing their GPs for backache will be aware of the intentional delay. Even though it will not be possible to blind doctors towards having received ICE communication training, this approach attempts to blind those supposed to administer the ICE communication (the doctors) and those responsible for data entry and processing (the receptionists) towards the true treatment intentions and study outcomes. Due to the anonymized nature of patient data collected for referral outcomes, patients will not need to be made aware of the research project. However, patients invited to the qualitative part of the

study will be informed that the surgery is participating in a research project being concerned with communication issues.

Interventions

The intervention consists of a one-day training session for participating doctors covering the theoretical background of ICE in relation to the national guidelines for acute back pain,[29] followed by practical implementations of standardized patient scenarios with patient actors and group reflection on communication skills. Emphasis will be placed on the development of supporting structures to be tailored towards participating doctors' needs, such as telephone hotlines or web-based tools.

In addition to the training, doctors will be given access to a password-protected online platform that holds a summary of the training session content for personal reference, as well as an interactive practice game to help doctors reflect on their individual communication style. The platform will also feature a questionnaire about attitudes towards the ICE concept that doctors can fill online for self-reflection.

Outcomes

Primary outcomes

The primary outcome measure consists in GP referrals in the weeks and months following the ICE training, involving referrals to diagnostic imaging, physiotherapy, specialist neurologists, orthopedic surgeons, and hospital admissions. These will pertain both to the cluster level (doctors' decisions) and the individual level (patient referrals).

Inclusion criteria are consultations involving patients over 18 years of age seeing their doctor for uncomplicated acute backache based on the following ICD codes: M43.19, M54.05, M54.06, M54.07, M54.08, M54.15, M54.16, M54.17, M54.18, M54.3, M54.4, M54.5, M54.85, M54.86, M54.87, M54.88, M54.89, M54.95, M54.96, M54.97, M54.98, M54.99. In parallel with definitions of *acute* backache in the national guidelines,[29] inclusion will be restricted to patients not having consulted their GPs for back problems within the last six weeks. Patients with known diagnoses of specific back pain such as disk prolapse, vertebral body fracture or malignant disease will be excluded.

Secondary outcomes

Patient satisfaction will be explored via a structured questionnaire focusing on doctor-patient communication during the consultation.

Qualitative semi-structured interviews with doctors will investigate the relevance of ICE communication in daily practice routine, and which aspects need to be considered and developed further to ensure broad applicability.

Associating patient and doctors' factors for referrals will be considered including patient age, gender and co-morbidities (depression, chronic backache), as well as doctors' age, gender and practice characteristics (rural, urban).

Sample Size

Sample size calculations endorse the necessary inflation of the sample size due to the cluster design, allowing for each doctor forms a cluster of clinical decisions that contain similar treatment decisions not independent from one another. Sample sizes also take into consideration the intracluster correlation coefficient, the number of events, the expected effect and the power of the study. Assuming a referral rate for acute backache of 30 %, as reported in German routine data,[30] an absolute alteration in referring patients in the magnitude of 10 % was considered as clinically relevant. Presuming an intra-cluster correlation coefficient (ICC) of 0.05, a significance level of 0.05 and a power of 0.8, 24 GPs seeing 40 patients each will be needed in each study group to detect a decrease in referrals from 30 % in the control group to 20 % or less in the intervention group. Alternative sample size requirements will be considered based on actual referral rates.

Data analysis

Data analysis will estimate the effect of ICE training through logistic regression**,** examining the association between the ICE training intervention (the main explanatory variable) and further referrals (main outcome variable). Random effects logistic regression will be applied to evaluate the influence of other factors such as patient, doctor and practice characteristics.

Data collection and management

Data collection will focus on consultations for unspecific acute back pain and starts once doctors from the intervention group have completed the ICE training session. Patients consulting the participating doctors with acute backache will be identified via the practice electronic health records and their routine data will be collected. A trained receptionist will

extract the predefined outcome and exposure variables described above in a standardized data collection sheet. According to sample size requirements, data collection will involve 40 consecutive patients fulfilling the inclusion criteria. Data collection will continue until data of 40 consultations for acute backache will have been collected for each of the 48 GPs, resulting in a final number of 1920 consultations. A modified CONSORT flow diagram will be provided to describe and specify number of practices, doctors and patients throughout the different stages of the trial.

Data on patient satisfaction will be collected post intervention via validated questionnaires handed out to 40 consecutive patients having seen their GP for an acute health problem.

Patients' perspectives will be explored in interviews with patients having seen their GP for uncomplicated backache in the past year. These will focus on general aspects of communication during the consultation and will not necessarily be in relation to the study doctors.

Patient and public involvement

Patients were not involved in the development of the research question or in the design of the study. The intervention was considered to involve no burden to patients. However, patients' involvement and their perspectives will play an important role in the interviews and questionnaire based surveys described above. The outcomes of this research project will be disseminated to participating practices and their patients.

TRIAL MONITORING

Quality assurance is attempted through methodological rigor, keeping all possible biases to a minimum. The center for clinical studies monitoring the study's progress regularly will have to ensure that the methodology is applied adequately.

ETHICS AND DISSEMINATION

Patient data collection will take place by a dedicated member of staff within a health centre assuring patient anonymity of the collected data. The data sheets being transferred to the department of Primary Care at the University of Erlangen-Nürnberg will not allow detecting patient identity.

Ethic approval was received by the institutional review board of Erlangen University ethic commission (*Ethikkommission der Friedrich-Alexander-Universität Erlangen-Nürnberg,*

Erlangen, Germany; Ethics Committee of the University Erlangen-Nuremberg: Number 296_17 B).

Results from this study will be published in peer-reviewed scientific journals according to reporting guidelines and presented at conferences.

Word count: 2.749

AUTHOR CONTRIBUTIONS

AS: Study design, methods, writing original draft

LB: Project management, theoretical development, methodological adjustment

SH: Study design, methods, review and editing

IT: Project partner, concept and development of interactive online tool for reflective practice

MR: Study design, methods, supervision, review and editing

TK: Study design, supervision, review and editing

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COMPETING INTERESTS

None declared.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	d/a
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	d/a
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	d/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8-9
	13b	For each group, losses and exclusions after randomisation, together with reasons	d/a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	d/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	d/a
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	d/a
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	d/a
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	d/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	d/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	d/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	3
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	d/a
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	d/a

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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ABSTRACT

Introduction

Low back pain (LBP) is one of the most frequent encounters in General Practice. Investigation and referral remain common despite the self-limiting character of episodes that are largely not attributable to specific underlying injuries. Identifying patients` ideas, concerns and expectations (ICE) is a well established element within consultation skills training and has been shown to improve prescribing. It can be a powerful communication tool setting the base for transferring and adjusting adequate clinical information. This study aims to evaluate whether ICE can decrease unnecessary medicine in the management of acute low back pain in primary care.

Methods and analysis

Research Question: Does ICE training intervention have an effect on doctors' referrals of patients suffering from acute LBP?
Population: Recruitment to this parallel cluster randomized trial will take place amongst general practitioners belonging to four independent practice networks in Northern Bavaria/Germany.
Intervention: At baseline, 24 out of 48 doctors will be randomly assigned to take part in a one-day training session covering theoretical background and clinical implementation of patient-centred communication by stimulating ICE. They will also be given access to a web-based supporting tool for reflective practice on their communication skills.
Comparison: GPs in the control group will continue consultations as usual.
Outcome: Outcome measures are referrals to diagnostic imaging, physiotherapy and specialists obtained from routine practice data, compared between intervention and control group.
Time: Referrals of patients consulting their doctors for documented LBP will be monitored up to three months after the ICE training intervention.

Ethics and dissemination

Ethical approval for the study was obtained by the Ethics Committee of the University Erlangen-Nuremberg [296_17B]. Results will be disseminated by conference presentations and journal publications.

Trial registration

The trial is registered in clinicaltrials.gov [NCT03711071].

KEYWORDS

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Strengths and limitations of this study

- A thorough randomised parallel design was chosen to compare the effect of patient centred communication training on doctors' clinical behaviour in the management of acute low back pain.
- The practice networks included in the trial involve a broad spectrum of urban and rural practices being representative for German primary care.
- Blinding is more difficult to achieve in nonpharmacological trials and represents a clear limitation of this study. Masking participating doctors towards treatment allocation is attempted by allocating the behavioural intervention at two stages: The intervention group will undergo the ICE training session at baseline; the control group will be offered training once data collection is accomplished. An effort will be made to hide outcome measures from all participants.
- The difficulty of monitoring ICE communication technique during consultations without introducing a considerable threat of bias (performance and reporting bias) is a clear limitation of this study. The effect of one ICE training session on doctors' behaviour focused on in this study can only act as a proxy for using more ICE when communicating with patients.
- The innovative character of this research project bears its risks. In Bavaria/South Germany, this is the first project establishing a practice network for research purposes in primary care and the feasibility of a randomized controlled trial in this setting will need to be tested.

INTRODUCTION

Back pain is one of the most frequent reasons for encounter in General Practice.[1,2] It affects all ages with a peak in prevalence in the fifth decade and a decrease in the sixth and seventh decade of life. In a German Health Survey, as many as 39% of female and 31% of male participants aged 18 to 80 reported episodes of back pain within the last seven days.[3] A multiregional study conducted in Germany confirmed a social and educational impact revealing higher prevalence in patients with poor education (47% in patients with nine years of education or less compared to 27% with more than 12 years of education).[4] Patients suffering from back pain were also shown to have increased levels of comorbidity.[5-12]

Reasons for low back pain (LBP) often remain unspecific with 80-90% of cases not being attributable to a specific injury or lesion[13]. The majority of episodes are self-limiting, of which 90% show spontaneous remissions within six weeks. Only less than 7% of episodes remain chronic [1]. Nevertheless, investigation and referral remain common and back pain clearly represents a condition contributing to unnecessary health care and costs. These are responsible for expenditures in the dimension of 8.4 billion Euros per year in Germany, of which 15% are contributable to expenses for medical interventions and 85% to periods of unemployment and resulting loss of productivity.[3]

Insufficient information regarding diagnostic and therapeutic procedures can be the cause of false patient expectations. Communication is a simple but powerful tool with a great potential of transferring relevant and adequate information, and patient- centred communication has been shown to influence patient contentedness and adherence to medical treatment.[14-16] However, patients' frequent complaint of poor communication and inadequate treatment is an indication for a clear mismatch between patients' and physicians' concerns.[17-23] Patient-centred communication can be promoted by ICE, an easily applicable and internationally approved communication technique, that encourages patients to disclose their *ideas, concerns and expectations* within a consultation.[24] Despite increasing evidence of a positive influence on health related outcomes such as improved communication skills and medication prescribing,[17] the implementation of ICE in clinical routine is still lacking, may be because physicians view patient-centred communication as being time- and cost-intensive.[25]

Unnecessary medicine often emerges from discrepancy between clinical facts and patients' expectations, resulting in irrelevant health care with a high amount of direct and indirect economic losses. A recent cluster randomized trial confirmed clinical benefit of a cognitive education programme for patients with LBP.[26] In this research project, we will evaluate whether the implementation of the ICE technique can contribute to more sensible resource allocation and less unnecessary medicine in the management of acute LBP in primary care.

METHODS AND ANALYSIS

Aims

The overall purpose of the proposed study is to carry out a patient centred communication training based on ICE technique and to evaluate its ability of preventing unnecessary medicine. We would like to know whether ICE is applicable in daily routine, enhances patient satisfaction during consultations, and results in a reduction of diagnostic imaging and specialist referring with a positive impact on financial resources by reducing direct and indirect health care costs.

The primary aim to be achieved is to examine the effect of doctors' ICE training on patient referrals for acute LBP. ICE communication training will be developed and administered within the network of research practices. Patient attitudes regarding their physical indisposition, and possible diagnostic and treatment options will be addressed by exploring ideas, concerns and expectations. Subsequent consultations of patients presenting with uncomplicated LBP will be monitored in terms of referrals to further imaging, physiotherapy or specialists.

The secondary aim of this project is to assess how ICE communication can influence consultation quality based on doctors' and patient views, and will be reported elsewhere.

Trial design and setting

The design of a randomized trial of nonpharmacological treatment applying parallel cluster randomization has been chosen to overcome the difficulty of allocating doctors working in the same practice to different interventions without running the risk of contamination.[27] Trials of nonpharmacological treatment test complex behavioural interventions involving several components that are difficult to describe, standardize and administer consistently to all patients. To overcome these difficulties the rules of the Consort Statement of nonpharmacological treatments were applied in the design of the proposed study.[28] The observations of patients treated for acute LBP by the same doctor may be correlated or clustered. Each doctor taking part in this trial forms a cluster of clinical treatment decisions being similar and not independent from one another.

Participant Recruitment

The clusters will involve two levels: Doctors recruited to receive training in patient centred ICE communication (intervention group) or no training (control group), and patients being treated by these doctors for acute LBP.

General Practitioners will be randomized to receive the intervention or not. They will be recruited from four independent practice networks forming “Forschungspraxen Franken”, a newly set up research network located in rural and urban areas of Franconia/ Northern Bavaria comprising 119 General Practitioners from 77 practices, of which 30 are single handed and 47 are group practices.

Patients aged 18 and above with a new episode of unspecific LBP, defined as no prior visit for LBP within the previous six weeks, will be included. Patients consulting their doctors for LBP will be identified via the practice electronic health records. Inclusion criteria are consultations involving patients over 18 years of age consulting their doctor for uncomplicated acute LBP based on the following ICD codes: M43.19, M54.05, M54.06, M54.07, M54.08, M54.15, M54.16, M54.17, M54.18, M54.3, M54.4, M54.5, M54.85, M54.86, M54.87, M54.88, M54.89, M54.95, M54.96, M54.97, M54.98, M54.99. According to the definitions of acute LBP in the national German guidelines,[29] inclusion will be restricted to patients not having consulted their GPs for back problems within the last six weeks. Patients with diagnoses of specific back pain such as disk prolapse, vertebral body fracture or malignant disease, either already known or added during the observation period, will be excluded. Please see a more detailed description under data collection and management.

Allocation sequence generation and randomization

At baseline, 48 General Practitioners will be randomized to receive the intervention or not, with participating doctors acting as units of randomization and analysis. To minimize contamination in the control group, randomization to ICE training intervention will take place at the practice level with units of randomizations being single handed or group practices belonging to the research network “Forschungspraxen Franken”. This ensures that doctors being allocated to the control group will not be surrounded by colleagues having received the ICE training intervention.

Stratification will be imposed on the randomization process to minimize numeral imbalance over treatment groups during the course of randomization. As all practices will be available at the time of generating the sequence, the random allocation rule can be applied. Retrospectively, the possible occurrence of selection bias will be assessed by identifying the

number of participants initially recruited as well as those actually included, and by comparing characteristics of individuals between intervention and control group at baseline.

To ensure numeral balance of the number of individuals randomized to each group, practices will be stratified by numbers of GPs per practice. The sequence will be generated independently within each stratum. For example, in a stratum with a sample size of six practices comprising four GP partners each, three practices will be allocated to the control group and three will be allocated to the intervention group by drawing six concealed envelopes containing three group A and three group B allocations without replacing them, thus allocating three of the six practices to the control group and three to the intervention group.[30]

Blinding

The fact that blinding of participating doctors towards the intervention will not be possible represents a considerable threat of bias. However, the following attempts will be undertaken to hide from participating doctors who of them received true treatment allocation: Firstly, all participants will be blinded towards the explicit purpose and design of the study. Secondly, ICE communication training will be offered to all participants: to GPs in the intervention group as a true intervention at the beginning of the RCT, and to control GPs as a pretend intervention at the end of the trial. The treatment allocation for each site and each doctor will be kept at the Department of Primary Care in Erlangen. The invitation for the communication training will be sent to both intervention and control practices, but control practices will have their training at a later point in time. Practices and GPs forming the clusters, health care assistants involved with data collection, nor patients seeing their GPs for backache will be aware of the intentional delay. Even though it will not be possible to blind doctors towards having received ICE communication training, this approach attempts to blind those supposed to administer the ICE communication (the doctors) and those responsible for data entry and processing (the receptionists) towards the true treatment intentions and study outcomes. Due to the anonymized nature of patient data collected for referral outcomes, patients will not need to be made aware of the research project.

Interventions

Then ICE training intervention consists of a one-day educational session for doctors encouraging reflection on actual doctor-patient communication and introducing the theoretical background of ICE. In close association with recommendations of the national guidelines for acute LBP,[29] the training provides clues on how to encourage patients to report their ideas, concerns and expectations, and offers communication skills training through standardized patient scenarios.

Furthermore, a web-based supporting tool tailored towards participating doctors' needs will be implemented. Doctors will be given access to a password-protected online platform that holds a summary of the training session content for personal reference, as well as an interactive practice game to help doctors reflect on their individual communication style. The platform will also feature a questionnaire about attitudes towards the ICE concept that doctors can fill online for self-reflection.

Outcomes

The primary outcome measure consists in GP referrals in the weeks and months following the ICE training intervention, involving referrals to diagnostic imaging, physiotherapy, specialist neurologists, orthopaedic surgeons, and hospital admissions. These will pertain both to the cluster level (doctors' decisions) and the individual level (patient referrals).

Associating factors for referrals will be considered including patient age, gender and co-morbidities (depression, chronic back pain), as well as doctors' age, gender and practice characteristics (rural, urban).

The patient and doctor perspective will be evaluated via questionnaires and interviews based on a qualitative study design which is not part of this study protocol, but which will be reported separately.

Sample Size

Sample size calculations endorse the necessary inflation of the sample size due to the cluster design, allowing for each doctor forming a cluster of clinical decisions that contain similar treatment decisions not independent from one another. Sample sizes also take into consideration the intracluster correlation coefficient, the number of events, the expected effect and the power of the study. Assuming a referral rate for acute LBP of 30 %, as

reported in German routine data,[31] an absolute alteration in referring patients in the magnitude of 10 % was considered as clinically relevant. Presuming an intra-cluster correlation coefficient (ICC) of 0.05, a significance level of 0.05 and a power of 0.8, 24 GPs seeing 40 patients each will be needed in each study group to detect a decrease in referrals from 30 % in the control group to 20 % or less in the intervention group. Alternative sample size requirements will be considered based on actual referral rates.

Data analysis

Data analysis will compare referral in the intervention and treatment group in terms of the proportion of patients referred for further diagnostics or treatment out of all patients consulting for LBP. The effect of ICE training will be estimated through logistic regression, examining the association between the ICE training intervention (the main explanatory variable) and further referrals (main outcome variable). Random effects logistic regression will be applied to evaluate the influence of other factors such as patient, doctor and practice characteristics.

A per-protocol (PP) analysis will be applied, including only participants attending the ICE training intervention in order to focus on the effect of the ICE training. This approach is justified by intervention assignment taking place in a blinded manner prior to the analysis.

Data collection and management

Data collection will focus on consultations for unspecific acute LBP and starts once doctors from the intervention group have completed the ICE training session. Patients consulting the participating doctors for acute LBP will be identified via the practice electronic health records and routinely generated clinical data will be collected retrospectively. A trained practice health care assistant will extract the predefined outcome and exposure variables described above in a standardized data collection sheet. According to sample size requirements, data collection will involve 40 consecutive patients fulfilling the inclusion criteria. Anticipating about four consultations for uncomplicated LBP per GP per week, data collection will continue up to 12 weeks post intervention until data of 40 consultations will have been collected for each of the 48 GPs, resulting in a final number of 1920 of consultations.

A modified CONSORT flow diagram will be provided to describe and specify number of practices, doctors and patients throughout the different stages of the trial.

Patient and public involvement

Patients were not involved in the development of the research question nor in the design of the study. The intervention was considered to involve no burden to patients. However, patients' involvement and their perspectives will play an important role in interview and questionnaire based surveys that will be described elsewhere. The outcomes of this research project will be disseminated to participating practices and their patients.

TRIAL MONITORING

Quality assurance is attempted through methodological rigor, keeping all possible biases to a minimum. The centre for clinical studies monitoring the study's progress regularly will have to ensure that the methodology is applied adequately.

ETHICS AND DISSEMINATION

Patient data collection will take place by a dedicated member of staff within a health centre assuring patient anonymity of the collected data. Informed Consent will therefore not be required. The data sheets being transferred to the department of primary care at the University of Erlangen-Nürnberg will not allow detecting patient identity.

Ethic approval was received by the institutional review board of Erlangen University ethic commission (*Ethikkommission der Friedrich-Alexander-Universität Erlangen-Nürnberg,* Erlangen, Germany; Ethics Committee of the University Erlangen-Nuremberg, Erlangen/Germany: Number 296_17 B).

Results from this study will be published in peer-reviewed scientific journals according to reporting guidelines and presented at conferences.

Word count: 2.960

AUTHOR CONTRIBUTIONS

AS: Study design, methods, writing original draft

LB: Project management, theoretical development, methodological adjustment

SH: Study design, methods, review and editing

IT: Project partner, concept and development of interactive online tool for reflective practice

MR: Study design, methods, supervision, review and editing

TK: Study design, supervision, review and editing

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COMPETING INTERESTS

None declared.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym (p1, 3-6)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry (p3, 5)
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support(p11,16-17)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (p10;11)
	5b	Name and contact information for the trial sponsor (p11)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities (p10,54)
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitor. comm.) (p10,19-23)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpub.) examining benefits and harms for each intervention (p4)
	6b	Explanation for choice of comparators (p2,42)
Objectives	7	Specific objectives or hypotheses (p5, 5-31)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) (p5, 36ff)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained (p5, 36ff)
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) (p6,20ff)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (p8, 5 ff)
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) (N/A)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (N/A)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (N/A)
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended (p8,32ff)
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) (p9,52)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations (p8,55ff)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (p6,11ff)

Methods: Assignment of interventions (for controlled trials)

Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions (p6,44ff)

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned (p6, 55ff)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions (6,55ff)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how (p7,25ff)
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial (p7,42ff)
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol (p9,40ff)
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols (p9,40ff)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol (p9,40ff)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol (p9,18ff)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) (p9,24ff)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) (p9,30ff)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed (p10,20ff)

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial (D/A)
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct (p10,6ff)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor (p10,19ff)

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval (p10,19ff)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) (p10,19ff)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) (p10,31)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable (N/A)
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial (p7,47ff)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site (p11,25)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators (p10, 30ff)
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation (-)
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions (p10,43)
	31b	Authorship eligibility guidelines and any intended use of professional writers (N/A)
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code (N/A)

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Referrals for uncomplicated lower back pain: a cluster parallel randomized trial of patient centred communication to improve the management of acute back pain in primary care. A study protocol.

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Referrals for uncomplicated lower back pain: a cluster parallel randomized trial of patient centred communication to improve the management of acute back pain in primary care. A study protocol.

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ABSTRACT

Introduction

Low back pain (LBP) is one of the most frequent encounters in General Practice. Investigation and referral remain common despite the self-limiting character of episodes that are largely not attributable to specific underlying injuries. Identifying patients` ideas, concerns and expectations (ICE) is a well established element within consultation skills training and has been shown to improve prescribing. It can be a powerful communication tool setting the base for transferring and adjusting adequate clinical information. This study aims to evaluate whether ICE can decrease unnecessary medicine in the management of acute low back pain in primary care.

Methods and analysis

Research Question: Does ICE training intervention have an effect on doctors' referrals of patients suffering from acute LBP?
Population: Recruitment to this parallel cluster randomized trial will take place amongst general practitioners belonging to four independent practice networks in Northern Bavaria/Germany.
Intervention: At baseline, 24 out of 48 doctors will be randomly assigned to take part in a one-day training session covering theoretical background and clinical implementation of patient-centred communication by stimulating ICE. They will also be given access to a web-based supporting tool for reflective practice on their communication skills.
Comparison: GPs in the control group will continue consultations as usual.
Outcome: Outcome measures are referrals to diagnostic imaging, physiotherapy and specialists obtained from routine practice data, compared between intervention and control group.
Time: Referrals of patients consulting their doctors for documented LBP will be monitored up to three months after the ICE training intervention.

Ethics and dissemination

Ethical approval for the study was obtained by the Ethics Committee of the University Erlangen-Nuremberg [296_17B]. Results will be disseminated by conference presentations and journal publications.

Trial registration

The trial is registered in clinicaltrials.gov [NCT03711071].

KEYWORDS

Primary care, communication, doctor-patient relationship, consultation, information-exchange, shared-decision making, medical education, low back pain, diagnosis, over investigation;

ARTICLE SUMMARY

Strengths and limitations of this study

- A thorough randomised parallel design was chosen to compare the effect of patient centred communication training on doctors' clinical behaviour in the management of acute low back pain.
- The practice networks included in the trial involve a broad spectrum of urban and rural practices being representative for German primary care.
- Blinding is more difficult to achieve in nonpharmacological trials and represents a clear limitation of this study. Masking participating doctors towards treatment allocation is attempted by allocating the behavioural intervention at two stages: The intervention group will undergo the ICE training session at baseline; the control group will be offered training once data collection is accomplished. An effort will be made to hide outcome measures from all participants.
- The difficulty of monitoring ICE communication technique during consultations without introducing a considerable threat of bias (performance and reporting bias) is a clear limitation of this study. The effect of one ICE training session on doctors' behaviour focused on in this study can only act as a proxy for using more ICE when communicating with patients.
- The innovative character of this research project bears its risks. In Bavaria/South Germany, this is the first project establishing a practice network for research purposes in primary care and the feasibility of a randomized controlled trial in this setting will need to be tested.

INTRODUCTION

Back pain is one of the most frequent reasons for encounter in General Practice.[1,2] It affects all ages with a peak in prevalence in the fifth decade and a decrease in the sixth and seventh decade of life. In a German Health Survey, as many as 39% of female and 31% of male participants aged 18 to 80 reported episodes of back pain within the last seven days.[3] A multiregional study conducted in Germany confirmed a social and educational impact revealing higher prevalence in patients with poor education (47% in patients with nine years of education or less compared to 27% with more than 12 years of education).[4] Patients suffering from back pain were also shown to have increased levels of comorbidity.[5-12]

Reasons for low back pain (LBP) often remain unspecific with 80-90% of cases not being attributable to a specific injury or lesion[13]. The majority of episodes are self-limiting, of which 90% show spontaneous remissions within six weeks. Only less than 7% of episodes remain chronic [1]. Nevertheless, investigation and referral remain common and back pain clearly represents a condition contributing to unnecessary health care and costs. These are responsible for expenditures in the dimension of 8.4 billion Euros per year in Germany, of which 15% are contributable to expenses for medical interventions and 85% to periods of unemployment and resulting loss of productivity.[3]

Insufficient information regarding diagnostic and therapeutic procedures can be the cause of false patient expectations. Communication is a simple but powerful tool with a great potential of transferring relevant and adequate information, and patient- centred communication has been shown to influence patient contentedness and adherence to medical treatment.[14-16] However, patients' frequent complaint of poor communication and inadequate treatment is an indication for a clear mismatch between patients' and physicians' concerns.[17-23] Patient-centred communication can be promoted by ICE, an easily applicable and internationally approved communication technique, that encourages patients to disclose their *ideas, concerns and expectations* within a consultation.[24] Despite increasing evidence of a positive influence on health related outcomes such as improved communication skills and medication prescribing,[17] the implementation of ICE in clinical routine is still lacking, may be because physicians view patient-centred communication as being time- and cost-intensive.[25]

Unnecessary medicine often emerges from discrepancy between clinical facts and patients' expectations, resulting in irrelevant health care with a high amount of direct and indirect economic losses. A recent cluster randomized trial confirmed clinical benefit of a cognitive education programme for patients with LBP.[26] In this research project, we will evaluate whether the implementation of the ICE technique can contribute to more sensible resource allocation and less unnecessary medicine in the management of acute LBP in primary care.

METHODS AND ANALYSIS

Aims

The overall purpose of the proposed study is to carry out a patient centred communication training based on ICE technique and to evaluate its ability of preventing unnecessary medicine. We would like to know whether ICE is applicable in daily routine, enhances patient satisfaction during consultations, and results in a reduction of diagnostic imaging and specialist referring with a positive impact on financial resources by reducing direct and indirect health care costs.

The primary aim to be achieved is to examine the effect of doctors' ICE training on patient referrals for acute LBP. ICE communication training will be developed and administered within the network of research practices. Patient attitudes regarding their physical indisposition, and possible diagnostic and treatment options will be addressed by exploring ideas, concerns and expectations. Subsequent consultations of patients presenting with uncomplicated LBP will be monitored in terms of referrals to further imaging, physiotherapy or specialists.

The secondary aim of this project is to assess how ICE communication can influence consultation quality based on doctors' and patient views, and will be reported elsewhere.

Trial design and setting

The design of a randomized trial of nonpharmacological treatment applying parallel cluster randomization has been chosen to overcome the difficulty of allocating doctors working in the same practice to different interventions without running the risk of contamination.[27] Trials of nonpharmacological treatment test complex behavioural interventions involving several components that are difficult to describe, standardize and administer consistently to all patients. To overcome these difficulties the rules of the Consort Statement of nonpharmacological treatments were applied in the design of the proposed study.[28] The observations of patients treated for acute LBP by the same doctor may be correlated or clustered. Each doctor taking part in this trial forms a cluster of clinical treatment decisions being similar and not independent from one another.

Participant Recruitment

The clusters will involve two levels: Doctors recruited to receive training in patient centred ICE communication (intervention group) or no training (control group), and patients being treated by these doctors for acute LBP.

General Practitioners will be randomized to receive the intervention or not. They will be recruited from four independent practice networks forming “Forschungspraxen Franken”, a newly set up research network located in rural and urban areas of Franconia/ Northern Bavaria comprising 119 General Practitioners from 77 practices, of which 30 are single handed and 47 are group practices.

Patients aged 18 and above with a new episode of unspecific LBP, defined as no prior visit for LBP within the previous six weeks, will be included. Patients consulting their doctors for LBP will be identified via the practice electronic health records. Inclusion criteria are consultations involving patients over 18 years of age consulting their doctor for uncomplicated acute LBP based on the following ICD codes: M43.19, M54.05, M54.06, M54.07, M54.08, M54.15, M54.16, M54.17, M54.18, M54.3, M54.4, M54.5, M54.85, M54.86, M54.87, M54.88, M54.89, M54.95, M54.96, M54.97, M54.98, M54.99. According to the definitions of acute LBP in the national German guidelines,[29] inclusion will be restricted to patients not having consulted their GPs for back problems within the last six weeks. Patients with diagnoses of specific back pain such as disk prolapse, vertebral body fracture or malignant disease, either already known or added during the observation period, will be excluded. Please see a more detailed description under data collection and management.

Allocation sequence generation and randomization

At baseline, 48 General Practitioners will be randomized to receive the intervention or not, with participating doctors acting as units of randomization and analysis. To minimize contamination in the control group, randomization to ICE training intervention will take place at the practice level with units of randomizations being single handed or group practices belonging to the research network “Forschungspraxen Franken”. This ensures that doctors being allocated to the control group will not be surrounded by colleagues having received the ICE training intervention.

Stratification will be imposed on the randomization process to minimize numeral imbalance over treatment groups during the course of randomization. As all practices will be available at the time of generating the sequence, the random allocation rule can be applied. Retrospectively, the possible occurrence of selection bias will be assessed by identifying the

number of participants initially recruited as well as those actually included, and by comparing characteristics of individuals between intervention and control group at baseline.

To ensure numeral balance of the number of individuals randomized to each group, practices will be stratified by numbers of GPs per practice. The sequence will be generated independently within each stratum. For example, in a stratum with a sample size of six practices comprising four GP partners each, three practices will be allocated to the control group and three will be allocated to the intervention group by drawing six concealed envelopes containing three group A and three group B allocations without replacing them, thus allocating three of the six practices to the control group and three to the intervention group.[30]

Blinding

The fact that blinding of participating doctors towards the intervention will not be possible represents a considerable threat of bias. However, the following attempts will be undertaken to hide from participating doctors who of them received true treatment allocation: Firstly, all participants will be blinded towards the explicit purpose and design of the study. Secondly, ICE communication training will be offered to all participants: to GPs in the intervention group as a true intervention at the beginning of the RCT, and to control GPs as a pretend intervention at the end of the trial. The treatment allocation for each site and each doctor will be kept at the Department of Primary Care in Erlangen. The invitation for the communication training will be sent to both intervention and control practices, but control practices will have their training at a later point in time. Practices and GPs forming the clusters, health care assistants involved with data collection, nor patients seeing their GPs for backache will be aware of the intentional delay. Even though it will not be possible to blind doctors towards having received ICE communication training, this approach attempts to blind those supposed to administer the ICE communication (the doctors) and those responsible for data entry and processing (the receptionists) towards the true treatment intentions and study outcomes. Due to the anonymized nature of patient data collected for referral outcomes, patients will not need to be made aware of the research project.

Interventions

Then ICE training intervention consists of a one-day educational session for doctors encouraging reflection on actual doctor-patient communication and introducing the theoretical background of ICE. In close association with recommendations of the national guidelines for acute LBP,[29] the training provides clues on how to encourage patients to report their ideas, concerns and expectations, and offers communication skills training through standardized patient scenarios.

Furthermore, a web-based supporting tool tailored towards participating doctors' needs will be implemented. Doctors will be given access to a password-protected online platform that holds a summary of the training session content for personal reference, as well as an interactive practice game to help doctors reflect on their individual communication style. The platform will also feature a questionnaire about attitudes towards the ICE concept that doctors can fill online for self-reflection.

Outcomes

The primary outcome measure consists in GP referrals in the weeks and months following the ICE training intervention, involving referrals to diagnostic imaging, physiotherapy, specialist neurologists, orthopaedic surgeons, and hospital admissions. These will pertain both to the cluster level (doctors' decisions) and the individual level (patient referrals). Sickness absence from work will be the secondary outcome measure.

Associating factors for referrals will be considered including patient age, gender and co-morbidities (depression, chronic back pain), as well as doctors' age, gender and practice characteristics (rural, urban).

The patient and doctor perspective will be evaluated via questionnaires and interviews based on a qualitative study design which is not part of this study protocol, but which will be reported separately.

Sample Size

Sample size calculations endorse the necessary inflation of the sample size due to the cluster design, allowing for each doctor forming a cluster of clinical decisions that contain similar treatment decisions not independent from one another. Sample sizes also take into consideration the intracluster correlation coefficient, the number of events, the expected effect and the power of the study. Assuming a referral rate for acute LBP of 30 %, as

reported in German routine data,[31] an absolute alteration in referring patients in the magnitude of 10 % was considered as clinically relevant. Presuming an intra-cluster correlation coefficient (ICC) of 0.05, a significance level of 0.05 and a power of 0.8, 24 GPs seeing 40 patients each will be needed in each study group to detect a decrease in referrals from 30 % in the control group to 20 % or less in the intervention group. Alternative sample size requirements will be considered based on actual referral rates.

Data analysis

Data analysis will compare referral in the intervention and treatment group in terms of the proportion of patients referred for further diagnostics or treatment out of all patients consulting for LBP. The effect of ICE training will be estimated through logistic regression, examining the association between the ICE training intervention (the main explanatory variable) and further referrals (main outcome variable). Random effects logistic regression will be applied to evaluate the influence of other factors such as patient, doctor and practice characteristics.

A per-protocol (PP) analysis will be applied, including only participants attending the ICE training intervention in order to focus on the effect of the ICE training. This approach is justified by intervention assignment taking place in a blinded manner prior to the analysis.

Data collection and management

Data collection will focus on consultations for unspecific acute LBP and starts once doctors from the intervention group have completed the ICE training session. Patients consulting the participating doctors for acute LBP will be identified via the practice electronic health records and routinely generated clinical data will be collected retrospectively. A trained practice health care assistant will extract the predefined outcome and exposure variables described above in a standardized data collection sheet. According to sample size requirements, data collection will involve 40 consecutive patients fulfilling the inclusion criteria. Anticipating about four consultations for uncomplicated LBP per GP per week, data collection will continue up to 12 weeks post intervention until data of 40 consultations will have been collected for each of the 48 GPs, resulting in a final number of 1920 of consultations.

A modified CONSORT flow diagram will be provided to describe and specify number of practices, doctors and patients throughout the different stages of the trial.

Patient and public involvement

Patients were not involved in the development of the research question nor in the design of the study. The intervention was considered to involve no burden to patients. However, patients' involvement and their perspectives will play an important role in interview and questionnaire based surveys that will be described elsewhere. The outcomes of this research project will be disseminated to participating practices and their patients.

TRIAL MONITORING

Quality assurance is attempted through methodological rigor, keeping all possible biases to a minimum. The centre for clinical studies monitoring the study's progress regularly will have to ensure that the methodology is applied adequately.

ETHICS AND DISSEMINATION

Patient data collection will take place by a dedicated member of staff within a health centre assuring patient anonymity of the collected data. Informed Consent will therefore not be required. The data sheets being transferred to the department of primary care at the University of Erlangen-Nürnberg will not allow detecting patient identity.

Ethic approval was received by the institutional review board of Erlangen University ethic commission (*Ethikkommission der Friedrich-Alexander-Universität Erlangen-Nürnberg,* Erlangen, Germany; Ethics Committee of the University Erlangen-Nuremberg, Erlangen/Germany: Number 296_17 B).

Results from this study will be published in peer-reviewed scientific journals according to reporting guidelines and presented at conferences.

Word count: 2.960

AUTHOR CONTRIBUTIONS

AS: Study design, methods, writing original draft

LB: Project management, theoretical development, methodological adjustment

SH: Study design, methods, review and editing

IT: Project partner, concept and development of interactive online tool for reflective practice

MR: Study design, methods, supervision, review and editing

TK: Study design, supervision, review and editing

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COMPETING INTERESTS

None declared.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym (page 1, lines 3-6)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry (p3, 5)
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support(p11,16-17)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (p10,11)
	5b	Name and contact information for the trial sponsor (p11)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities (p10,54)
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitor. comm.) (p10,19-23)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpub.) examining benefits and harms for each intervention (p4)
	6b	Explanation for choice of comparators (p2,42)
Objectives	7	Specific objectives or hypotheses (p5, 5-31)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) (p5, 36ff)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained (p5, 36ff)
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) (p6,20ff)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (p8, 5 ff)
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) (N/A)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (N/A)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (N/A)
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended (p8,32ff)
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) (p9,52)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations (p8,55ff)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (p6,11ff)

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions (p6,44ff)

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned (p6, 55ff)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions (6,55ff)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how (p7,25ff)
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial (p7,42ff)
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol (p9,40ff)
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols (p9,40ff)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol (p9,40ff)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol (p9,18ff)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) (p9,24ff)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) (p9,30ff)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed (p10,20ff)

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial (D/A)
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct (p10,6ff)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor (p10,19ff)

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval (p10,19ff)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) (p10,19ff)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) (p10,31)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable (N/A)
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial (p7,47ff)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site (p11,25)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators (p10, 30ff)
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation (-)
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions (p10,43)
	31b	Authorship eligibility guidelines and any intended use of professional writers (N/A)
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code (N/A)

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.