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Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol

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ARTICLE SUMMARY

Abstract

Introduction: Patients undergoing rehabilitation care for chronic musculoskeletal pain (CMP) face challenges as mismatches often exist between the patient's actual biopsychosocial profile and the treatment offered. There is still a lack of knowledge regarding recognition, adequate referral, and treatment, and varying points of view about the biopsychosocial profile for patients with CMP, which can result in medical shopping. In order to improve health care for patients with CMP, a transmural network in which different healthcare professionals collaborate in providing effective integrated healthcare will be composed striving to fulfill the Quadruple Aim of healthcare, whereby the improvement of population health, patient's experience of care, and work life for healthcare professionals, as well as a reduction in costs will be taken into account.

Methods and analysis: This feasibility study will examine the barriers and facilitators, perceived added value, and acceptability of the development, implementation, and transferability of the Network Pain Rehabilitation Limburg (NPRL) with a three-phase iterative and incremental design, based on key principles of a user-centred design. Focus groups, interviews, field notes, and questionnaires will be used in which healthcare professionals, as well as patients involved in the NPRL, will participate. The results of each phase will be analysed following the Consolidated Framework for Implementation Research (CFIR) and will be used to refine NPRL in daily practise.

Ethics and dissemination: Informed consent will be obtained from all participants. The results of this feasibility study will form the basis for refinement of NPRL and planning of a large-scale process and effect evaluation of the Quadruple Aim outcomes. Dissemination will include publications and presentations at national and international conferences.

Trial registration number: Medical Ethics Committee Z, the Netherlands, METC 17-N-133

Keywords

Feasibility, transmural network, integrated care, pain rehabilitation, musculoskeletal pain, Quadruple Aim

Strengths and limitations of the study

- This study will be the first to evaluate feasibility and acceptability of a transmural network for pain rehabilitation aiming to improve the continuity of care and reduce the number of inadequate referrals and treatments for patients with chronic musculoskeletal pain.
- Focus groups, interviews, field notes, and questionnaires will be used to evaluate the barriers and facilitators, perceived value, and acceptability of Network Pain Rehabilitation Limburg (NPRL).
- The evidence generated from this feasibility study will not only help to adjust the design and content of NPRL, but will also help inform future studies with developing and implementing transmural networks in healthcare.
- Data will be analysed using the Consolidated Framework for Implementation Research by Damschroder et al.
- In the future, a large-scale process and effective evaluation on the Quadruple Aim outcomes will be planned.

INTRODUCTION

Nineteen percent of adults in Europe suffer from moderate to severe chronic pain with a duration of at least 6 months according to a large-scale epidemiological study.[1] Also, about 18% of adults in the Netherlands have moderate to severe general chronic pain.[2] Almost 90% of individuals with chronic pain had experienced it for over 2 years.[3] The most reported chronic pain complaint was chronic musculoskeletal pain (CMP). CMP is a complex biopsychosocial experience that varies widely between people depending on the context and meaning of the pain and the impact of psychosocial factors on patient's functioning.[4 5]

Breivik *et al*[1] found that people with CMP were less able or even unable to do a range of daily activities and to maintain an independent lifestyle. In addition to pain itself, patients with CMP are often confronted with an elevated level of disability, depression, and anxiety resulting in an increased disease burden.[6-8] In addition, work absenteeism among these patients is very high.[1 9 10] In recent years, the direct and indirect costs for CMP patients are estimated at 20 billion Euro's in the Netherlands.[11] These costs are even higher than the annual costs of heart disease, cancer, and diabetes.[12] Although costs for CMP are high, only up to 60-74% of patients with CMP get treated, and only 2-5% get treated by a pain management specialist.[1 2 13] Currently, regardless treatment as received, 34-79% of Dutch CMP patients still indicate a feeling of inadequate treatment.[2 14] These patients seek a diagnosis or solution to their pain problem, which explains medical shopping. Even 61% of patients that started a multidisciplinary rehabilitation program visited 6 to > 20 different healthcare professionals one year before starting with multidisciplinary rehabilitation program.[15] A potential reason for these inefficiencies might be that the complexity of the patient's pain problem does not match with treatment as delivered, resulting in over or under treatment[16], which highlights the need for adequate (cost) effective treatment strategies.

This mismatch may be explained by the fact that the knowledge and perspective of healthcare professionals, decision makers, and the public varies regarding CMP, referral, and treatment.[13] Healthcare professionals receive inadequate training on the diagnosis and treatment of CMP, causing different points of view. Some healthcare professionals are more biomedical oriented and focus on explaining and solving the pain, whereas others are more biopsychosocial oriented and focus on optimising functioning despite CMP.[17] Therefore, referral and treatment

selections vary among healthcare professionals, which may result in less efficient care for patients with CMP.

Besides the different perspectives regarding CMP, general practitioners (GPs) in primary care and rehabilitation physicians (RPs) in secondary and tertiary care refer patients mostly based on their anamnesis and clinical experience. However, it appears to be difficult for GPs to identify the impact of all psychosocial factors on chronic low back pain patients, one of the most frequently encountered CMP problems.[18] Recently, different tools became available to support GPs in the decision-making process concerning (initial) treatment options for patients with chronic low back pain and fibromyalgia, especially focusing on the impact of psychosocial components.[19-22] However, these decision-making tools are not implemented in daily care yet in the Netherlands. In the Dutch health care system, patients with moderate to severe levels of disability and associated influencing psychosocial factors are seen by a RP. To support decision making by RPs, an evidence-based objective tool to classify patients objectively and transparently for a specific treatment is needed. Earlier studies have shown that the interrater reliability of the method currently used by RPs to classify the level of disability (WPN classification) is at least questionable.[23 24] In addition, healthcare professionals indicate a lack of overview regarding the complete supply of treatment methods, resulting in inadequate referrals.[25]

Ideally, after assessing the level of disability, the patient receives a treatment matching the complexity of the pain problem in line with the biopsychosocial profile. As in most situations, no cure for CMP is possible and evidence-based treatments are multicomponent pain rehabilitation with a biopsychosocial focus on being active and living a valuable life despite pain.[5 26-28] In primary care physiotherapy, cognitive-behavioural interventions and interventions focusing on biopsychosocial factors have shown long-term effects on patient outcomes.[29 30] Moreover, even positive effects were found when advice combined with pain education alone is given by GPs or therapists to patients with CMP.[31-33] In secondary and tertiary care, multidisciplinary pain rehabilitation programs with physical, psychological, and/or social/work related components, like Acceptance Commitment Therapy (ACT), Graded Activity (GA), and Exposure in vivo (EXP), are more effective than treatments focusing on one aspect of the biopsychosocial model for decreasing pain and disability in patients with disabling chronic low back pain.[34-39]

Despite this knowledge of the effective components of multidisciplinary rehabilitation programs, a wide variety of treatment approaches in various dosages are currently applied in regular rehabilitation programs in different private and public rehabilitation centres.[40] To overcome the different points of view as well as the lack of overview about treatment options, objective decision-making tools, and variety of treatments in the Netherlands, a national care standard for chronic pain was presented in 2017.[11] In this standard, a stepped and person-centred care approach for patients with CMP was proposed.

To implement care as part of the national care standard, a transmural network could be designed in which different healthcare professionals collaborate in providing person-centred rehabilitation care. Recently, different transmural integrated care health networks, for example for Parkinson's disease and palliative care, have been successfully developed and implemented in the Netherlands.[41 42] In line with these findings, a transmural pain rehabilitation network can provide a shared vision regarding CMP, including early recognition of subacute pain patients followed by suitable person-centred treatment and referral, is supposed to improve patients' levels of functioning despite pain and to prevent medical shopping of patients with CMP.[11] It should have an unambiguous view, stepped care, and a person-centred approach with guidelines for referral and treatment, coordination, and a continuous focus on improvement of care to increase the effectiveness, quality, and efficiency of healthcare for patients with CMP.[43] This approach fits with the advice of the World Health Organisation to focus on stimulating functioning when designing rehabilitation care.[44 45]

The Network Pain Rehabilitation Limburg (NPRL), in the province of Limburg, the Netherlands, will be designed striving to fulfil the Quadruple Aim, in which the improvement of population health, experience of care by patients, and work life satisfaction for physicians and staff, as well as a reduction in costs are important aspects to be taken into account.[46 47] Before evaluation the Quadruple Aim outcomes, as a first step a feasibility study will be performed aiming to explore the barriers and facilitators of the development, implementation, and transferability of NPRL. Following the UK Medical Research Council framework[48] for developing complex interventions will be useful as NPRL is a complex intervention because of the number of practices and integrated healthcare settings targeted in the NPRL and the number and variability of outcomes. This paper describes the study protocol of the feasibility study of NPRL for adults with CMP.

METHODS

Study design

A feasibility study with an iterative and incremental design, based on key principles of user-centred design[49 50] will be conducted in the South-East region of the Netherlands from October 2017 till October 2018. In this iterative process, the development of NPRL will take place in three phases, namely development, implementation, and transferability. The results of each phase will be used to refine the elements of the intervention and to shape the next phase, in which the barriers and facilitators of the different phases will be evaluated. During meetings, all healthcare professionals involved will be informed about the results and the adjustments to NPRL. In the subsequent phase, new adjustments will be integrated in daily practise. The development and implementation process will be 'practise-focused', indicating that the development will be based on the healthcare professionals' experiences with the current healthcare situation.

In phase 1, exploration of context will take place in order to develop the design of the NPRL and to educate the healthcare professionals involved. The focus will be on the barriers and facilitators in the development process of NPRL. Next, in phase 2 (implementation), the project focus will be on the specification of the content to adjust the design of the NPRL to daily practise. More insight into the barriers and facilitators of the implementation process will be collected. In phase 3 (transferability), the project will focus on the organisation of care in daily practise and the research focus will be on the barriers and facilitators for further implementation in other practices and organisations. In addition, preliminary data on efficiency will be collected. NPRL will be feasible in daily practise if the studied barriers and facilitators from the perspectives of healthcare professionals and patients are translatable to policies or guidelines that can be adjusted and integrated in daily practise.

Participants

In this transmural NPRL, healthcare professionals from different disciplines (GPs, physiotherapists, exercise therapists, mental health practice nurses, RPs, and rehabilitation teams) and different healthcare settings (primary, secondary, and tertiary care) will be asked for participation (Figure 1). The setting in primary care concerns general and therapy practices, in secondary care a private outpatient rehabilitation clinic and the outpatient rehabilitation department of a regional hospital, and in tertiary care a specialised rehabilitation clinic. The

quality criteria established for practices and organisations for enrolling in NPRL are described in Table 1.

Table 1: Inclusion criteria for healthcare professionals for enrolling in NPRL

Inclusion	Exclusion
Having a practice in the pilot area of NPRL. Willingness to attend the meetings and to implement the different elements of NPRL. GPs and mental health practice nurses must be linked to a participating therapist in order to make effective referrals to treat patients in (interdisciplinary) primary care regarding the protocol and vision of NPRL. Physiotherapists having a participating GP or RP. As they cannot refer a patient when the patient is too complex for them, they will not have an inclusion option for study participants if there is no participating GP or RP. Secondary and tertiary organisations have to meet the criteria of the Position Paper 'Medical Specialist Rehabilitation for chronic musculoskeletal pain' [2017][57].	A GP who has visited less than 2 out of 3 education days or a therapist who has participated in less than 3 out of 4 education days. Are not able to implement the protocols or assessment tool of NPRL in their own practice.

NPRL = Network Pain Rehabilitation Limburg; GP = general practitioner; RP = rehabilitation physician

In primary care, the recruitment will start with a primary care therapist or a GP interested in pain, and after consent to participate in NPRL. This person will be asked to recruit a GP or therapist with whom they already have intensive collaboration. For secondary and tertiary care, main organisations in the region providing rehabilitation care for patients with CMP will be asked to participate, so all healthcare settings in this region will be covered. Because of the nature and aim of this feasibility study, we decided to keep the number of healthcare professionals restricted. Based on earlier research, it has to be expected that in this situation the implementation process in daily practise can be easily adjusted when barriers arise.[42]

In addition to the involvement of healthcare professionals in this study, all patients treated by the participating healthcare professionals will be asked to evaluate NPRL and the perceived quality of care. The inclusion criteria for patients to participate in this study are described in Table 2.

Table 2: Inclusion criteria for patients in this feasibility study

Inclusion	Exclusion
Age ≥ 18 years old at the start of the study.	Any suspicion of a medical (orthopaedic, rheumatic, or neurological) disease that can explain the current pain (e.g. rheumatism or hernia) complaints or that can be treated by sufficient therapy.
Patient living in the pilot area (physiotherapist, GP, or RP) of NPRL.	Any suspicion of a (underlying) psychiatric disease, for which psychiatric treatment is better suited, according to the expert opinion of the GP and RP.
Having musculoskeletal pain that is (suspected to be) chronic.	Pregnancy.
Treatment aim of the patient is to improve functioning despite the pain.	
Adequate Dutch literacy to complete the assessments.	

NPRL = Network Pain Rehabilitation Limburg; GP = general practitioner; RP = rehabilitation physician

It is expected that approximately 100 patients from all participating healthcare settings will give informed consent during the course of this study. They will receive questionnaires regarding satisfaction with care and their health status and pain related disability. Moreover, a sample of approximately 10 patients, who finished a treatment according to the protocol of NPRL, will be recruited for a focus group in which more information about barriers and facilitators from a patient perspective will be collected.

Intervention: Network Pain Rehabilitation Limburg

The main aim of NPRL is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. This should accomplish the Quadruple Aim: improvement of CMP patient functioning, experiences of care, and work life satisfaction of physicians and staff, as well as a reduction of healthcare costs of patients with CMP.

Each patient will receive the treatment needed to reach his/her optimal level of functioning. In order to reach this, a stepped care approach will be used for every individual patient. Depending on the level of disability and biopsychosocial factors involved, this will either include education only and no further treatment, monodisciplinary treatment in primary care, interdisciplinary treatment in primary care (collaboration between GPs, primary care therapists, and mental health practice nurses in assessing and treating patients with CMP who need mental support

besides physical exercise) or multidisciplinary treatment in secondary or tertiary care. Collaboration will be supported by facilitating communication between patients and all healthcare professionals involved in the trajectory of an individual patient by E-health.[51] In addition, the collaboration between healthcare professionals in different practices and organisations will be further supported by informative meetings and education days.

In order to facilitate the joint focus on improving the level of functioning despite pain, the following elements are integrated in NPRL:

Integral focus on assessment and referral: assessment tools

To support the healthcare professionals in their decision making for problem mapping and treatment selection, two evidence-based objective assessment tools will support the assessment of complexity of the pain problem; one tool for GPs and primary care therapists and one tool for RPs. The assessment tool for primary care is based on the Start Back Tool[20] and will help to advise patient treatment matched to the patient's biopsychosocial profile. The options are: advice only, treatments in primary care, or for decision making by a RP (Figure 2). The GP can also decide to advise patients for a treatment outside NPRL (psychiatrist, specific healthcare specialist, etc.). Since 2006, patients in the Netherlands can visit a primary care therapist without a referral of a GP,[52] so these therapists will also use this assessment tool. In this situation, a primary care therapist of NPRL will advise the patient to visit the GP for additional assessment and referral if needed as the GP is the gatekeeper to secondary and tertiary care.

When a patient visits a RP, the assessment tool for specialised rehabilitation care is used for decision making. This tool will assess the patient's view as well as the RP's view of the biopsychosocial problem and consists of two parts. The first part will guide the anamnesis of the RP and is based on two different ways to score disability related complexity, namely the Case Complexity Index and INTERMED method.[24 53 54] First, a standardised scoring method for assessing the biopsychosocial profile and care for the past and current situations will be used by the RP. Second, a set of CMP related questionnaires assessing anxiety, depression, catastrophising, fatigue, pain level, participation level, and general health will be completed by the patient. After completion of these questionnaires, scores will be interpreted by the RP. Based on scoring in both parts of the RP-assessment tool, patients will be categorised by profile, representing the patient's level of disability. In addition to primary and interdisciplinary

primary care, the second tool will assist the RP to further differentiate between available secondary or tertiary multidisciplinary rehabilitation programs (Figure 2).

Integral focus on treatment content and duration: treatment protocols

When the patient receives treatment, an individualised treatment plan based on their current needs will be made. Protocols will be based on the most recent evidence-based treatment methods such as GA, EXP, and ACT[34-37 39] and these will be used in all healthcare settings. As these evidence-based methods are developed for secondary and tertiary care, they will be adjusted for primary care. During evaluations in phase 1 and 2, healthcare professionals will be invited to provide feedback on the treatment protocols. As a result, adjustments to the content and duration of treatment protocols will be made if these adjustments are in line with the evidence-based treatment methods.

Integral focus on self-management: E-health application

All professionals and patients participating in the NPRL will make use of an E-health application: SanaCoach Pain Rehabilitation.[51] Also, primary care patients who receive 'advice only' can make use of this SanaCoach Pain Rehabilitation. The coach has different functions and goals in the treatment process. The primary goal is to support self-management. The main function of the coach is to provide pain education based on the education modules. Different eLearning modules are developed for the patients in order to teach them about the biopsychosocial aspects of pain. Furthermore, diaries are integrated into the coach in which patients can give feedback on changes in pain intensity, level of activity over time, and the interrelation between these variables. Moreover, healthcare professionals can use scores from these diaries to adjust treatment to individual patients. The coach also consists of a chat function between the patient and healthcare professionals to ensure short communication lines. All healthcare professionals involved in the care process of a patient have access to this chat function with that patient. Additionally, the assessment tool for primary care is integrated, which makes these results available for all involved healthcare professionals. For this study, the questionnaires for patients are also available via the coach. Based on the level of complexity of disability, the functions in the SanaCoach Pain Rehabilitation will be adjusted to the patient, such as the number of diaries and level of education.

Data collection

In this study, the feasibility of the development, implementation, and transferability of NPRL for adults with CMP will be investigated. Therefore, different data collection techniques such as observations, interviews, focus groups, and questionnaires will be combined to get more insight into the barriers and facilitators of NPRL (Table 3).

Table 3: Overview of data collection methods and respondents per phase

Phase	1	2	3
Time period	October 2017–February 2018	February 2018–June 2018	June 2018–October 2018
Goal project	Exploration of context will take place in order to develop the design of the NPRL and to educate the involved healthcare professionals.	Specification of the content to adjust the design of the transmural network to daily practise.	Organisation of care in daily practise and barriers and facilitators for implementation in other practices and organisations.
Goal evaluation	Insight into the barriers and facilitators of the development of NPRL.	Insight into the barriers and facilitators of the implementation of NPRL.	Insight into the barriers and facilitators of the transferability of NPRL.
Data collection method, respondents, and outcomes	<u>Focus groups and interviews</u> *Healthcare professionals* • Experiences with the informative meetings • Experiences with the education days • Expectations and views on working in NPRL • Current experiences (satisfaction) with working in NPRL • Barriers and facilitators <u>Questionnaire</u> *Healthcare professionals* • Current views and thoughts regarding patients with CMP • Referral pattern • Patient characteristics	<u>Focus groups and interviews</u> *Healthcare professionals* • Views on working in NPRL • Current experiences (satisfaction) with working in NPRL • Implications and recommendations of the implementation strategy for practise • Barriers and facilitators	<u>Focus groups and interviews</u> *Healthcare professionals* • Current experiences (satisfaction) with working in NPRL • Implications and recommendations of the implementation strategy for practise • Implications and recommendations for future research and project • Satisfaction with NPRL and with work life • Barriers and facilitators <u>Focus group</u> *+/- 10 patients* • Perceived quality of care • Experiences with NPRL • Barriers and facilitators <u>Questionnaire</u> *Healthcare professionals* • Referral pattern • Patient characteristics
	<u>Questionnaire start and end of treatment (T0 and T2)</u> *Patients* • Health status		

	• Quality of care • Usability of the SanaCoach Pain Rehabilitation <u>Questionnaire after referral (T1)</u> *Patients* • Quality and satisfaction with referral and care <u>Questionnaire or logbook of treatment</u> *Healthcare specialists* • Barriers and facilitators of the treatment protocol per patient <u>Notes</u> • Current views regarding NPRL • Barriers and facilitators

NPRL = Network Pain Rehabilitation Limburg; CMP= chronic musculoskeletal pain

During the informative meetings and education days, field notes will be made in order to collect information about the views on NPRL and its elements out of the perspectives of the healthcare professionals involved. At the end of each phase, focus groups and/or interviews will take place with (a selection of) the healthcare professionals involved. During the evaluation of phase 1, healthcare professionals will be asked about the barriers and facilitators they perceived while working in NPRL. Therefore, more information will be collected about expectations, views, experiences, and satisfaction. Also, experiences and opinions about the informative meetings and education days will be collected. Healthcare professionals will fill in an electronic questionnaire in phase 1 concerning decision making, treatments, and characteristics of the patients involved in the study. This information will give more insight into potential changes in referral policy between the situation in usual care and the situation within NPRL. Moreover, the questionnaire also asks for knowledge and perspectives regarding patients with CMP.

In phases 2 and 3, more emphasis will be put on the added value of NPRL including barriers and facilitators for implementation. This information will be used for recommendations for practise and future research. Also in these phases, information will be gained about the experiences and satisfaction with NPRL during a focus group with healthcare professionals. Moreover, in phase 3 (transferability), they will fill in an electronic questionnaire concerning decision making, treatments, and characteristics of the patients involved in the study. As part of the evaluation of phase 3, a focus group with a sample of 6 to 10 patients with CMP who are being treated by participating healthcare professionals will take place. During this focus group,

the emphasis will be on the satisfaction of care and experiences, leading to barriers and facilitators with NPRL.

Besides this information, the research team will keep up a logbook to get insight into the barriers and facilitators of NPRL. The field notes in this logbook will be the results of discussions with different healthcare professionals, patients, and stakeholders, as well as researchers. Additionally, patients will be asked to complete study-related questionnaires about the quality and their satisfaction with the decision making, treatment and education, and usability of the SanaCoach Pain Rehabilitation in order to further improve different elements of NPRL. Besides this feasibility data, also some questions about their work status, general health, and participation level will be asked as preliminary data on efficiency to objectify the progress of the treatment. They will receive this questionnaire at the start of the treatment (T0) and at the end of the treatment (T2). Patients referred to another healthcare professional will receive an extra questionnaire after the referral (T1) regarding the quality of and satisfaction with the decision making. Additionally, after completion of the treatment, a small questionnaire or logbook about the treatment of each patient separately must be handed in by the healthcare professionals. This information will be used to discover barriers and facilitators and desired adjustments of the treatment protocols.

Data Analysis

The Consolidated Framework for Implementation Research (CFIR) protocol according to Damschroder *et al*[55] will be used to develop this feasibility evaluation and analysis plan. This explanatory framework with theory-based constructs and mechanisms will be used to help explain whether an implementation may or may not succeed and to identify barriers and facilitators. In this iterative design, the results of each phase will be used to adapt the intervention for the next phase.

All field notes and logbooks will be collected. Additionally, the focus groups and interviews will be audio recorded and transcribed verbatim. Qualitative data will be analysed using the NVivo software (NVivo.version 11.1.0.411) following a directed content analysis method.[56] The analysis will be deductive (e.g. the identified themes will derive from existing theory). After familiarisation with the data, definitions for the CFIR constructs will be made based on the intervention in collaboration with the project team. Next, the different constructs will be assigned to the fewest codes possible. After developing analytic summaries and matrices, the data will be

compared to derive barriers and facilitators. A researcher with expertise in qualitative research without any involvement in the project will peer review the analysis by verification of the analysis of 20% of the interviews and focus groups. Also, a cross-check for interim findings with respondents will be performed.

Quantitative data will be analysed concurrently with the qualitative data. Descriptive statistics will be denoted as mean (standard deviation) or median (range) and number (%) for continuous and categorical data, respectively, with the use of IBM SPSS Statistics 24.

ETHICS AND DISSIMINATION

Informed consent will be obtained from all participants. Ethical approval for this study was granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133. The results of this feasibility study will form the base for refinement of NPRL and planning of a large-scale process and effect evaluation on the Quadruple Aim outcomes. Dissemination will include publications and presentations at national and international conferences.

DISCUSSION

This study will provide insight into the feasibility of NPRL, a transmural integrated healthcare network for CMP rehabilitation. The aim is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. It is expected that the study will provide information on barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability for further develop and refinement of the NPRL. If the study results suggest that NPRL is feasible and preliminary outcomes are positive, a large-scale process and effective evaluation of the Quadruple Aim outcomes will be performed.

The process of developing NPRL is in accordance with the Medical Research Council guidance on how to develop and evaluate complex interventions.[48] In the development process, existing evidence together with collected evidence based on the expertise of healthcare professionals was combined to develop the first version of NPRL. This first version of NPRL will be implemented on a restricted scale to test the feasibility. The evidence generated from this feasibility study will not only help to adjust the design and content of NPRL but will also inform future methodological studies on developing and implementing a transmural network in

healthcare. It is expected that this bottom-up development in combination with the limited number of participating healthcare professionals will lead to a successful implementation of the network. Nijkrake *et al*[42] did indicate this approach as one of the success factors of ParkinsonNet, a successful and cost-effective network in the Netherlands for patients with Parkinson's disease.

In conclusion, there is need for a transmural network in which different healthcare professionals collaborate in providing integrated healthcare for patients with CMP. The aim of NPRL is to improve the level of functioning of individual patients despite pain, experience of care by patients, and work life satisfaction for physicians and staff, as well as a reduction in costs. Therefore, this feasibility study will be conducted to explore the barriers and facilitators of the development, implementation, and transferability of NPRL. The results will be applied to refine a large-scale process and effective evaluation of the Quadruple Aim outcomes.

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AUTHORS CONTRIBUTIONS

JAMCFV, IPJH, and AJK conceived the original idea and outline of the study, and CL, MEK, IPJH, JAMCFV, and DR contributed to designing the study. JAMCFV, IPJH, and AJK were responsible for developing the intervention. CL was the primary writer of the study protocol in collaboration with MEK and IPJH. All authors discussed and commented on draft versions and approved the final version.

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ETHICS APPROVAL

Approval from the Medical Ethics Committee Z, the Netherlands, METC 17-N-133.

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Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

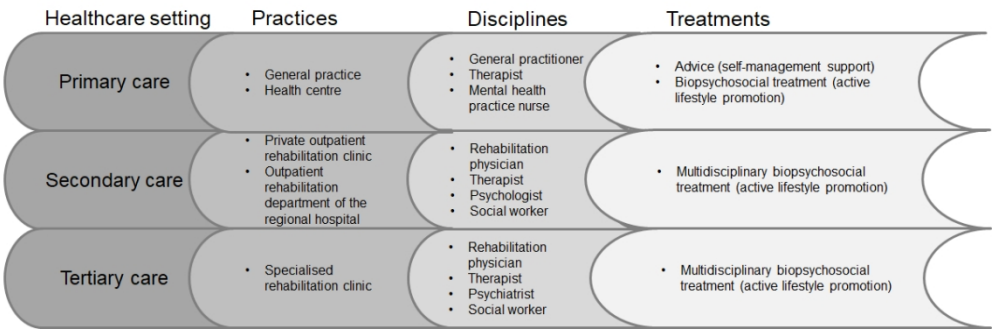

Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

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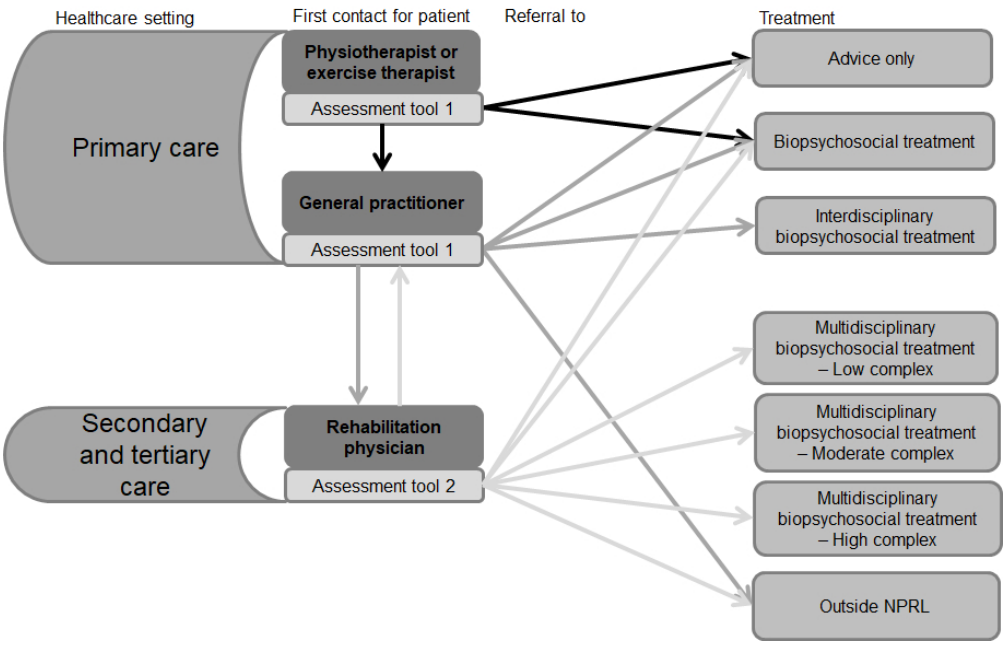

Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

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Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol

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Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol

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ARTICLE SUMMARY

Abstract

Introduction: Patients receiving a rehabilitation treatment for chronic musculoskeletal pain (CMP) face challenges as mismatches often exist between the complexity of patient's pain problem and the treatment offered. This can result in less efficient care for the patient and increased medical shopping. The Network Pain Rehabilitation Limburg (NPRL), a transmural integrated healthcare network, will be designed to improve daily care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach given by all involved healthcare professionals. A feasibility study will be performed which will give insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability of the NPRL.

Methods and analysis: This is a feasibility study with a three-phase iterative and incremental design, based on key principles of an user-centred design. It will examine the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability for further development and refinement of the NPRL. Mixed methods will be used in which healthcare professionals, as well as patients involved in the NPRL, will participate. The results of each phase will be analysed following the Consolidated Framework for Implementation Research (CFIR) and will be used to refine NPRL in daily practise.

Ethics and dissemination: Informed consent will be obtained from all participants. The results of this feasibility study will form the basis for refinement of NPRL and planning of a large-scale process and effect evaluation of the Quadruple Aim outcomes. Dissemination will include publications and presentations at national and international conferences. Ethical approval for this study was granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133.

Keywords

Feasibility, transmural network, integrated care, pain rehabilitation, musculoskeletal pain, Quadruple Aim

Strengths and limitations of the study

- This study will be the first to evaluate feasibility of a transmural network for pain patient's rehabilitation, which provides integrated care aiming to improve their level of functioning despite pain by stimulating a biopsychosocial approach given by all involved healthcare professionals.
- In an iterative, user-centered design, mixed methods will be used to evaluate the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability.
- Data will be analysed using the Consolidated Framework for Implementation Research by Damschroder et al.
- The evidence generated from this feasibility study will not only help to adjust the design and content of Network Pain Rehabilitation Limburg, but will also help future studies with developing and implementing transmural networks in healthcare.
- Depending on the results of this feasibility study, a large-scale process and effect evaluation on the Quadruple Aim outcomes will be planned.

INTRODUCTION

Nineteen percent of adults in Europe suffer from moderate to severe chronic pain with a duration of at least 6 months according to a large-scale epidemiological study.[1] Also, about 18% of adults in the Netherlands have moderate to severe general chronic pain.[2] Almost 90% of individuals with chronic pain had experienced it for over 2 years.[3] The most reported chronic pain complaint was chronic musculoskeletal pain (CMP). CMP is a complex biopsychosocial experience that varies widely between people depending on the context and meaning of the pain and the impact of psychosocial factors on patient's functioning.[4 5]

Breivik *et al*[1] found that people with CMP were less able or even unable to do a range of daily activities and to maintain an independent lifestyle. In addition to pain itself, patients with CMP are often confronted with an elevated level of disability, depression, and anxiety resulting in an increased disease burden.[6-8] In addition, work absenteeism among these patients is very high.[1 9 10] In recent years, the direct and indirect costs for CMP patients are estimated at 20 billion Euro's in the Netherlands.[11] These costs are even higher than the annual costs of heart disease, cancer, and diabetes.[12] Although costs for CMP are high, only up to 60-74% of patients with CMP get treated, and only 2-5% get treated by a pain management specialist.[1 2 13] Currently, regardless treatment as received, 34-79% of Dutch CMP patients still indicate a feeling of inadequate treatment.[2 14] These patients seek a diagnosis or solution to their pain problem, which explains medical shopping. Even 61% of patients that started a multidisciplinary rehabilitation program visited 6 to > 20 different healthcare professionals one year before starting with multidisciplinary rehabilitation program.[15] A potential reason for these inefficiencies might be that the complexity of the patient's pain problem does not match with treatment as delivered, resulting in over or under treatment[16], which highlights the need for adequate (cost) effective treatment strategies.

This mismatch may be explained by the fact that the knowledge and perspective of healthcare professionals, decision makers, and the public varies regarding CMP, referral, and treatment.[13] Healthcare professionals receive inadequate training on the diagnosis and treatment of CMP, causing different points of view.[17] Some healthcare professionals are more biomedical oriented and focus on explaining and solving the pain, whereas others are more biopsychosocial oriented and focus on optimising functioning despite CMP.[18] Therefore, referral and treatment

selections vary among healthcare professionals, which may result in less efficient care for patients with CMP.

Besides the different perspectives regarding CMP, general practitioners (GPs) in primary care and rehabilitation physicians (RPs) in secondary and tertiary care refer patients mostly based on their anamnesis and clinical experience. However, it appears to be difficult for GPs to identify the impact of all psychosocial factors on chronic low back pain patients, one of the most frequently encountered CMP problems.[19] Recently, different tools became available to support GPs in the decision-making process concerning (initial) treatment options for patients with chronic low back pain and fibromyalgia, especially focusing on the impact of psychosocial components.[20-23] However, these decision-making tools are not implemented in daily care yet in the Netherlands. In the Dutch health care system, patients with moderate to severe levels of disability and associated influencing psychosocial factors are seen by a RP. To support decision making by RPs, an evidence-based objective tool to classify patients objectively and transparently for a specific treatment is needed. Earlier studies have shown that the interrater reliability of the method currently used by RPs to classify the level of disability (WPN classification) is at least questionable.[24 25] In addition, healthcare professionals indicate a lack of overview regarding the complete supply of treatment methods, resulting in inadequate referrals.[26]

Ideally, after assessing the level of disability, the patient receives a treatment matching the complexity of the pain problem in line with the biopsychosocial profile. As in most situations, no cure for CMP is possible and evidence-based treatments are multicomponent pain rehabilitation with a biopsychosocial focus on being active and living a valuable life despite pain.[5 27-29] In primary care physiotherapy, cognitive-behavioural interventions and interventions focusing on biopsychosocial factors have shown long-term effects on patient outcomes.[30 31] Moreover, even positive effects were found when advice combined with pain education alone is given by GPs or therapists to patients with CMP.[32-34] In secondary and tertiary care, multidisciplinary pain rehabilitation programs with physical, psychological, and/or social/work related components, like Acceptance Commitment Therapy (ACT), Graded Activity (GA), and Exposure in vivo (EXP), are more effective than treatments focusing on one aspect of the biopsychosocial model for decreasing pain and disability in patients with disabling chronic low back pain.[35-40]

Despite this knowledge of the effective components of multidisciplinary rehabilitation programs, a wide variety of treatment approaches in various dosages are currently applied in regular rehabilitation programs in different private and public rehabilitation centres.[41] To overcome the different points of view as well as the lack of overview about treatment options, objective decision-making tools, and variety of treatments in the Netherlands, a national care standard for chronic pain was presented in 2017.[11] In this standard, a stepped and person-centred care approach for patients with CMP was proposed.

To implement care as part of the national care standard, a transmural network could be designed in which different healthcare professionals collaborate in providing person-centred rehabilitation care. Recently, different transmural integrated care health networks, for example for Parkinson's disease and palliative care, have been successfully developed and implemented in the Netherlands.[42 43] In line with these findings, a transmural pain rehabilitation network can provide a shared vision regarding CMP, including early recognition of subacute pain patients followed by suitable person-centred treatment and referral, is supposed to improve patients' levels of functioning despite pain and to prevent medical shopping of patients with CMP.[11] It should have an unambiguous view, stepped care, and a person-centred approach with guidelines for referral and treatment, coordination, and a continuous focus on improvement of care to increase the effectiveness, quality, and efficiency of healthcare for patients with CMP.[44] This approach fits with the advice of the World Health Organisation to focus on stimulating functioning when designing rehabilitation care.[45 46]

The Network Pain Rehabilitation Limburg (NPRL), a transmural integrated healthcare network for CMP rehabilitation, will be designed to ultimately fulfil the Quadruple Aim in the province of Limburg, the Netherlands.[47 48] The aim is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. As a first step a feasibility study will be performed. This study provides insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability of the NPRL. This paper describes the study protocol of the feasibility study of NPRL for adults with CMP.

METHODS

Study design

A feasibility study with an iterative and incremental design, based on key principles of user-centred design[49 50] will be conducted in the South-East region of the Netherlands from October 2017 till October 2018. This will follow the UK Medical Research Council framework[51] for developing complex interventions. It will be useful as NPRL is a complex intervention because of the number of practices and integrated healthcare settings targeted in the NPRL and the number and variability of outcomes. In this iterative process, the development of NPRL will take place in three phases, namely development, implementation, and transferability. The results of each phase will be used to refine the elements of the intervention and to shape the next phase, in which the barriers and facilitators of the different phases will be evaluated. During meetings, all healthcare professionals involved will be informed about the results and the adjustments to NPRL. In the subsequent phase, new adjustments will be integrated in daily practise. The development and implementation process will be 'practise-focused', indicating that the development will be based on the healthcare professionals' experiences with the current healthcare situation.

In phase 1, exploration of context will take place in order to develop the design of the NPRL and to educate the healthcare professionals involved. The focus will be on the barriers and facilitators in the development process of NPRL. Next, in phase 2 (implementation), the project focus will be on the specification of the content to adjust the design of the NPRL to daily practise. More insight into the barriers and facilitators of the implementation process will be collected. In phase 3 (transferability), the project will focus on the organisation of care in daily practise and the research focus will be on the barriers and facilitators for further implementation in other practices and organisations. In addition, preliminary data on efficiency will be collected. The qualitative data collected during the study will be analysed using The Consolidated Framework for Implementation Research (CFIR).[52] NPRL will be feasible in daily practise if the studied barriers and facilitators from the perspectives of healthcare professionals and patients are translatable to policies or guidelines that can be adjusted and integrated in daily practise.

Participants

In this transmural NPRL, healthcare professionals from different disciplines (GPs, physiotherapists, exercise therapists, mental health practice nurses, RPs, and rehabilitation

teams) and different healthcare settings (primary, secondary, and tertiary care) will be asked for participation (Figure 1). The setting in primary care concerns general and therapy practices, in secondary care a private outpatient rehabilitation clinic and the outpatient rehabilitation department of a regional hospital, and in tertiary care a specialised rehabilitation clinic. The quality criteria established for practices and organisations for enrolling in NPRL are described in Table 1.

Table 1: Inclusion criteria for healthcare professionals for enrolling in NPRL

Inclusion	Exclusion
Having a practice in the pilot area of NPRL. Willingness to attend the meetings and to implement the different elements of NPRL. GPs and mental health practice nurses must be linked to a participating therapist in order to make effective referrals to treat patients in (interdisciplinary) primary care regarding the protocol and vision of NPRL. Physiotherapists having a participating GP or RP. As they cannot refer a patient when the patient is too complex for them, they will not have an inclusion option for study participants if there is no participating GP or RP. Secondary and tertiary organisations have to meet the criteria of the Position Paper 'Medical Specialist Rehabilitation for chronic musculoskeletal pain' [2017].[53]	A GP who has visited less than 2 out of 3 education days or a therapist who has participated in less than 3 out of 4 education days. Are not able to implement the protocols or assessment tool of NPRL in their own practice.

NPRL = Network Pain Rehabilitation Limburg; GP = general practitioner; RP = rehabilitation physician

In primary care, the recruitment will start with a primary care therapist or a GP interested in pain, and after consent to participate in NPRL. This person will be asked to recruit a GP or therapist with whom they already have intensive collaboration. For secondary and tertiary care, main organisations in the region providing rehabilitation care for patients with CMP will be asked to participate, so all healthcare settings in this region will be covered. Because of the nature and aim of this feasibility study, we decided to keep the number of healthcare professionals restricted. Based on earlier research, it has to be expected that in this situation the implementation process in daily practise can be easily adjusted when barriers arise.[43]

In addition to the involvement of healthcare professionals in this study, all patients treated by the participating healthcare professionals will be asked to evaluate NPRL and the perceived quality of care. The inclusion criteria for patients to participate in this study are described in Table 2.

Table 2: Inclusion criteria for patients in this feasibility study

Inclusion	Exclusion
Age ≥ 18 years old at the start of the study. Patient living in the pilot area (physiotherapist, GP, or RP) of NPRL. Having musculoskeletal pain that is (suspected to be) chronic. Treatment aim of the patient is to improve functioning despite the pain. Adequate Dutch literacy to complete the assessments.	Any suspicion of a medical (orthopaedic, rheumatic, or neurological) disease that can explain the current pain (e.g. rheumatism or hernia) complaints or that can be treated by sufficient therapy. Any suspicion of a (underlying) psychiatric disease, for which psychiatric treatment is better suited, according to the expert opinion of the GP and RP. Pregnancy.

NPRL = Network Pain Rehabilitation Limburg; GP = general practitioner; RP = rehabilitation physician

It is expected that approximately 100 patients from all participating healthcare settings will give informed consent during the course of this study. They will receive questionnaires regarding satisfaction with care and their health status and pain related disability. Moreover, a sample of approximately 10 patients, who finished a treatment according to the protocol of NPRL, will be recruited for a focus group. In this focus group more information about barriers and facilitators from a patient perspective will be collected. In this way patients are able to react to each other which will illuminate various perspectives which leads to a faster data saturation about each topic, which is an advantage above interviews.[54]

Intervention: Network Pain Rehabilitation Limburg

The main aim of NPRL is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. This should accomplish the Quadruple Aim: improvement of CMP patient functioning, experiences of care, and work life satisfaction of physicians and staff, as well as a reduction of healthcare costs of patients with CMP.

Each patient will receive the treatment needed to reach his/her optimal level of functioning. In order to reach this, a stepped care approach will be used for every individual patient. Depending on the level of disability and biopsychosocial factors involved, this will either include; 1) education only and no further treatment, 2) monodisciplinary treatment in primary care, 3) multidisciplinary treatment in primary care (collaboration between GPs, primary care therapists, and mental health practice nurses in assessing and treating patients with CMP who need mental support besides physical exercise), 4) interdisciplinary treatment in secondary or 5) interdisciplinary treatment in tertiary care. Collaboration will be supported by facilitating communication between patients and all healthcare professionals involved in the trajectory of an individual patient by E-health.[55] In addition, the collaboration between healthcare professionals in different practices and organisations will be further supported by informative meetings and education days.

In order to facilitate the joint focus on improving the level of functioning despite pain, the following elements are integrated in NPRL:

Integral focus on assessment and referral: assessment tools

To support the healthcare professionals in their decision making for problem mapping and treatment selection, two evidence-based objective assessment tools will be used. These tools will support the assessment of the complexity of the pain problem; one tool for GPs and primary care therapists and one tool for RPs. The assessment tool for primary care is based on the Start Back Tool[20] and will help to advise patient treatment matched to the patient's biopsychosocial profile. The options are: advice only, treatments in primary care, or for decision making by a RP (Figure 2). The GP can also decide to advise patients for a treatment outside NPRL (psychiatrist, specific healthcare specialist, etc.). Since 2006, patients in the Netherlands can visit a primary care therapist without a referral of a GP,[56] so these therapists will also use this assessment tool. In this situation, a primary care therapist of NPRL will advise the patient to visit the GP for additional assessment and referral if needed as the GP is the gatekeeper to secondary and tertiary care.

When a patient visits a RP, the assessment tool for specialised rehabilitation care is used for decision making. This tool will assess the patient's view as well as the RP's view of the biopsychosocial problem and consists of two parts. The first part will guide the anamnesis of the

RP and is based on two different ways to score disability related complexity, namely the Case Complexity Index and INTERMED method.[25 57 58] First, a standardised scoring method for assessing the biopsychosocial profile and care for the past and current situations will be used by the RP. Second, a set of CMP related questionnaires assessing anxiety, depression, catastrophising, fatigue, pain level, participation level, and general health will be completed by the patient. After completion of these questionnaires, scores will be interpreted by the RP. Based on scoring in both parts of the RP-assessment tool, patients will be categorised by profile, representing the patient's level of disability. In addition to primary and interdisciplinary primary care, the second tool will assist the RP to further differentiate between available secondary or tertiary multidisciplinary rehabilitation programs (Figure 2).

Integral focus on treatment content and duration: treatment protocols

When the patient receives treatment, an individualised treatment plan based on their current needs will be made. The patient decides the treatment aim when he visits a healthcare professional. In case this is necessary, the practitioner will support the patient in setting functional goals. Protocols will be based on the most recent evidence-based treatment methods such as GA, EXP, and ACT[35-38 40] and these will be used in all healthcare settings. As these evidence-based methods are developed for secondary and tertiary care, they will be adjusted for primary care. During evaluations in phase 1 and 2, healthcare professionals will be invited to provide feedback on the treatment protocols. As a result, adjustments to the content and duration of treatment protocols will be made if these adjustments are in line with the evidence-based treatment methods.

Integral focus on self-management: E-health application

All professionals and patients participating in the NPRL will make use of an E-health application: SanaCoach Pain Rehabilitation.[55] Also, primary care patients who receive 'advice only' can make use of this SanaCoach Pain Rehabilitation. The coach has different functions and goals in the treatment process. The primary goal is to support self-management. The main function of the coach is to provide pain education based on the education modules. Different eLearning modules are developed for the patients in order to teach them about the biopsychosocial aspects of pain. Furthermore, diaries are integrated into the coach in which patients can give feedback on changes in pain intensity, level of activity over time, and the interrelation between these variables. Moreover, healthcare professionals can use scores from these diaries to adjust treatment to individual patients. The coach also consists of a chat function between the patient

and healthcare professionals to ensure short communication lines. All healthcare professionals involved in the care process of a patient have access to this chat function with that patient. Additionally, the assessment tool for primary care is integrated, which makes these results available for all involved healthcare professionals. For this study, the questionnaires for patients are also available via the coach. Based on the level of complexity of disability, the functions in the SanaCoach Pain Rehabilitation will be adjusted to the patient, such as the number of diaries and level of education.

Patient and Public Involvement

During the development of the research question, design, recruitment, and conduct of the study no patients were involved in the process. However, during the development of NPRL itself, a patient was involved in the development of the SanaCoach Pain Rehabilitation and treatment protocols. Moreover, the focus of this feasibility study is mainly on healthcare professionals. They were involved in the development of the treatment protocols, SanaCoach Pain Rehabilitation and in the development of the different communication strategies between the healthcare professionals themselves. The results of the study will be disseminated to the study participants via the webpage (www.netwerkpijnrevalidatie.nl) and social media accounts.

Data collection

In this study, the feasibility of the development, implementation, and transferability of NPRL for adults with CMP will be investigated. Therefore, different data collection techniques such as observations, interviews, focus groups, and questionnaires will be combined to get more insight into the barriers and facilitators of NPRL (Table 3).

Table 3: Overview of data collection methods and respondents per phase

Phase	1	2	3
Time period	October 2017–February 2018	February 2018–June 2018	June 2018–October 2018
Goal project	Exploration of context will take place in order to develop the design of the NPRL and to educate the involved healthcare professionals.	Specification of the content to adjust the design of the transmural network to daily practise.	Organisation of care in daily practise and barriers and facilitators for implementation in other practices and organisations.
Goal evaluation	Insight into the barriers and facilitators of the development of NPRL.	Insight into the barriers and facilitators of the implementation of NPRL.	Insight into the barriers and facilitators of the transferability of NPRL.
Data collection method,	Focus groups and interviews *Healthcare professionals*	Focus groups and interviews *Healthcare professionals*	Focus groups and interviews *Healthcare professionals*

respondents, and outcomes	• Experiences with the informative meetings • Experiences with the education days • Expectations and views on working in NPRL • Current experiences (satisfaction) with working in NPRL • Barriers and facilitators <u>Questionnaire</u> *Healthcare professionals* • Current views and thoughts regarding patients with CMP • Referral pattern • Patient characteristics	• Views on working in NPRL • Current experiences (satisfaction) with working in NPRL • Implications and recommendations of the implementation strategy for practise • Barriers and facilitators	• Current experiences (satisfaction) with working in NPRL • Implications and recommendations of the implementation strategy for practise • Implications and recommendations for future research and project • Satisfaction with NPRL and with work life • Barriers and facilitators <u>Focus group</u> *+/- 10 patients* • Perceived quality of care • Experiences with NPRL • Barriers and facilitators <u>Questionnaire</u> *Healthcare professionals* • Referral pattern • Patient characteristics
	<u>Questionnaire start and end of treatment (T0 and T2)</u> *Patients* •Health status •Quality of care •Usability of the SanaCoach Pain Rehabilitation <u>Questionnaire after referral (T1)</u> *Patients* • Quality and satisfaction with referral and care <u>Questionnaire or logbook of treatment</u> *Healthcare specialists* • Barriers and facilitators of the treatment protocol per patient <u>Notes</u> • Current views regarding NPRL • Barriers and facilitators		

NPRL = Network Pain Rehabilitation Limburg; CMP= chronic musculoskeletal pain

During the informative meetings and education days, field notes will be made in order to collect information about the views on NPRL and its elements out of the perspectives of the healthcare professionals involved. At the end of each phase, focus groups and/or interviews will take place with (a selection of) the healthcare professionals involved. During the evaluation of phase 1, healthcare professionals will be asked about the barriers and facilitators they perceived while working in NPRL. Therefore, more information will be collected about expectations, views, experiences, and satisfaction. Also, experiences and opinions about the informative meetings and education days will be collected. Healthcare professionals will fill in an electronic questionnaire in phase 1 concerning decision making, treatments, and characteristics of the patients involved in the study. This information will give more insight into potential changes in referral policy between the situation in usual care and the situation within NPRL. Moreover, the questionnaire also asks for knowledge and perspectives regarding patients with CMP.

In phases 2 and 3, more emphasis will be put on the added value of NPRL including barriers and facilitators for implementation. This information will be used for recommendations for practise and future research. Also in these phases, information will be gained about the experiences and satisfaction with NPRL during a focus group with healthcare professionals. Moreover, in phase 3 (transferability), they will fill in an electronic questionnaire concerning decision making, treatments, and characteristics of the patients involved in the study. As part of the evaluation of phase 3, a focus group with a sample of 6 to 10 patients with CMP who are being treated by participating healthcare professionals will take place. During this focus group, the emphasis will be on the satisfaction of care and experiences, leading to barriers and facilitators with NPRL.

Besides this information, the research team will keep up a logbook to get insight into the barriers and facilitators of NPRL. The field notes in this logbook will be the results of discussions with different healthcare professionals, patients, and stakeholders, as well as researchers. Additionally, patients will be asked to complete study-related questionnaires about the quality and their satisfaction with the decision making, treatment and education, and usability of the SanaCoach Pain Rehabilitation in order to further improve different elements of NPRL. Besides this feasibility data, also some questions about their work status, general health, and participation level will be asked as preliminary data on efficiency to objectify the progress of the treatment. They will receive this questionnaire at the start of the treatment (T0) and at the end of the treatment (T2). Patients referred to another healthcare professional will receive an extra

questionnaire after the referral (T1) regarding the quality of and satisfaction with the decision making. Additionally, after completion of the treatment, a small questionnaire or logbook about the treatment of each patient separately must be handed in by the healthcare professionals. This information will be used to discover barriers and facilitators and desired adjustments of the treatment protocols.

Data Analysis

In this iterative design with key principles of user-centered design, the results will be gathered in daily practice from the healthcare professional and patient perspective. The results of each phase will be used to adapt the intervention for the next phase. The Consolidated Framework for Implementation Research (CFIR) protocol according to Damschroder *et al*[52] will be used to develop this feasibility evaluation and analysis plan of the results. This explanatory framework with theory-based constructs and mechanisms will be used to explain whether an implementation may or may not succeed and to identify barriers and facilitators.

All field notes and logbooks will be collected. Additionally, the focus groups and interviews will be audio recorded and transcribed verbatim. Qualitative data will be analysed using the NVivo software (NVivo.version 11.1.0.411) following a directed content analysis method.[59] The analysis will be deductive (e.g. the identified themes will derive from existing theory). After familiarisation with the data, definitions for the CFIR constructs will be made based on the intervention in collaboration with the project team. Next, the different constructs will be assigned to the fewest codes possible. After developing analytic summaries and matrices, the data will be compared to derive barriers and facilitators. A researcher with expertise in qualitative research without any involvement in the project will peer review the analysis by verification of the analysis of 20% of the interviews and focus groups. Also, a cross-check for interim findings with respondents will be performed.

Quantitative data will be analysed concurrently with the qualitative data. Descriptive statistics will be denoted as mean (standard deviation) or median (range) and number (%) for continuous and categorical data, respectively, with the use of IBM SPSS Statistics 24.

ETHICS AND DISSEMINATION

Informed consent will be obtained from all participants. Ethical approval for this study was granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133. The results of

this feasibility study will form the base for refinement of NPRL and planning of a large-scale process and effect evaluation on the Quadruple Aim outcomes. Dissemination will include publications and presentations at national and international conferences.

DISCUSSION

This study will provide insight into the feasibility of NPRL, a transmural integrated healthcare network for CMP rehabilitation. The aim is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. It is expected that the study will provide information on barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability for further develop and refinement of the NPRL. If the study results suggest that NPRL is feasible and preliminary outcomes are positive, a large-scale process and effective evaluation of the Quadruple Aim outcomes will be performed.

The process of developing NPRL is in accordance with the Medical Research Council guidance on how to develop and evaluate complex interventions.[51] In the development process, existing evidence together with collected evidence based on the expertise of healthcare professionals was combined to develop the first version of NPRL. This first version of NPRL will be implemented on a restricted scale to test the feasibility. The evidence generated from this feasibility study will not only help to adjust the design and content of NPRL but will also inform future methodological studies on developing and implementing a transmural network in healthcare. It is expected that this bottom-up development in combination with the limited number of participating healthcare professionals will lead to a successful implementation of the network. Nijkrake *et al*[43] did indicate this approach as one of the success factors of ParkinsonNet, a successful and cost-effective network in the Netherlands for patients with Parkinson's disease.

In conclusion, there is need for a transmural network in which different healthcare professionals collaborate in providing integrated healthcare for patients with CMP. The aim of NPRL is to improve the level of functioning of individual patients despite pain, experience of care by patients, and work-life satisfaction for physicians and staff, as well as a reduction in costs. Therefore, this feasibility study will be conducted to explore the barriers and facilitators of the

development, implementation, and transferability of NPRL. The results will be applied to refine a large-scale process and effective evaluation of the Quadruple Aim outcomes.

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Reference Table 1

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AUTHORS CONTRIBUTIONS

JAMCFV, IPJH, and AJK conceived the original idea and outline of the study, and CL, MEK, IPJH, JAMCFV, and DR contributed to designing the study. JAMCFV, IPJH, and AJK were responsible for developing the intervention. CL was the primary writer of the study protocol in collaboration with MEK and IPJH. All authors discussed and commented on draft versions and approved the final version.

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COMPETING INTERESTS

CL, MEK and DR have nothing to disclose. AJK, JAMCFV, and IPJH report grants from Health Insurance Companies CZ, VGZ and Achmea, during the conduct of the study;

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ETHICS APPROVAL

Approval from the Medical Ethics Committee Z, the Netherlands, METC 17-N-133.

OPEN ACCESS

Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

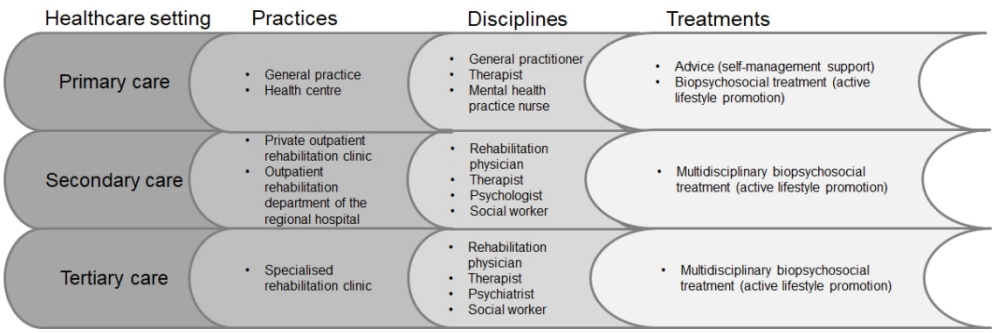

Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

102x34mm (300 x 300 DPI)

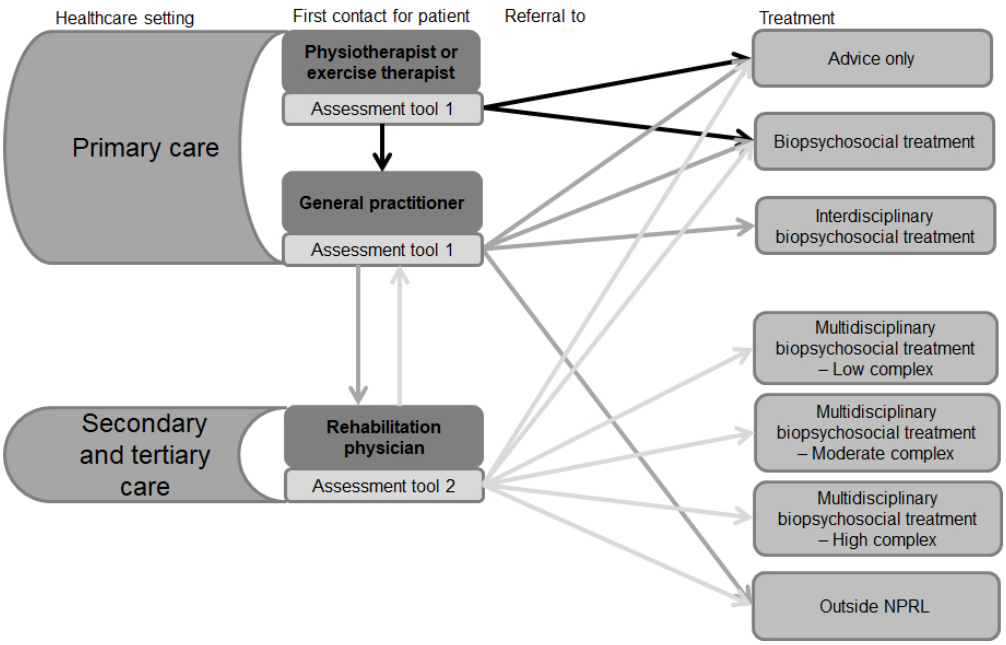

Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

77x49mm (300 x 300 DPI)

BMJ Open

Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol

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Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol

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ARTICLE SUMMARY

Abstract

Introduction: Patients having chronic musculoskeletal pain (CMP) face challenges as mismatches often exist between the complexity of patient's pain problem and the rehabilitation treatment offered. This can result in less efficient care for the patient and increased medical shopping. The Network Pain Rehabilitation Limburg (NPRL), a transmural integrated healthcare network, will be designed to improve daily care for patients with CMP. NPRL focusses on improving patient's level of functioning despite pain by stimulating a biopsychosocial approach given by all involved healthcare professionals. A feasibility study will be performed which will give insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for NPRL.

Methods and analysis: This study has a three-phase iterative and incremental design, based on key principles of an user-centred design. Mixed methods will be used in which healthcare professionals and patients involved in NPRL, will participate. In phase 1, NPRL will be developed and healthcare professionals educated. Phase 2 focusses on the implementation and phase 3 on the transferability of NPRL. In addition, preliminary data on patient's work status, general health, and participation level will be collected. The qualitative results of each phase will be analysed following the Consolidated Framework for Implementation Research (CFIR) and will be used to refine NPRL in daily practise.

Ethics and dissemination: Informed consent will be obtained from all participants. The results of this feasibility study will form the basis for refinement of NPRL and planning of a large-scale process and effect evaluation of the Quadruple Aim outcomes. Dissemination will include publications and presentations at national and international conferences. Ethical approval for this study was granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133.

Keywords

Feasibility, transmural network, integrated care, pain rehabilitation, musculoskeletal pain, Quadruple Aim

Strengths and limitations of the study

- This study will be the first to evaluate feasibility of a transmural network for pain patient's rehabilitation, which provides integrated care aiming to improve their level of functioning despite pain by stimulating a biopsychosocial approach given by all involved healthcare professionals.
- In an iterative, user-centered design, mixed methods will be used to evaluate the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability.
- Data will be analysed using the Consolidated Framework for Implementation Research by Damschroder et al.
- The evidence generated from this feasibility study will not only help to adjust the design and content of Network Pain Rehabilitation Limburg, but will also help future studies with developing and implementing transmural networks in healthcare.
- Depending on the results of this feasibility study, a large-scale process and effect evaluation on the Quadruple Aim outcomes will be planned.

INTRODUCTION

Nineteen percent of adults in Europe suffer from moderate to severe chronic pain with a duration of at least 6 months according to a large-scale epidemiological study.[1] Also, about 18% of adults in the Netherlands have moderate to severe general chronic pain.[2] Almost 90% of individuals with chronic pain had experienced it for over 2 years.[3] The most reported chronic pain complaint was chronic musculoskeletal pain (CMP). CMP is a complex biopsychosocial experience that varies widely between people depending on the context and meaning of the pain and the impact of psychosocial factors on patient's functioning.[4 5]

Breivik *et al*[1] found that people with CMP were less able or even unable to do a range of daily activities and to maintain an independent lifestyle. In addition to pain itself, patients with CMP are often confronted with an elevated level of disability, depression, and anxiety resulting in an increased disease burden.[6-8] In addition, work absenteeism among these patients is very high.[1 9 10] In recent years, the direct and indirect costs for CMP patients are estimated at 20 billion Euro's in the Netherlands.[11] These costs are even higher than the annual costs of heart disease, cancer, and diabetes.[12] Although costs for CMP are high, only up to 60-74% of patients with CMP get treated, and only 2-5% get treated by a pain management specialist.[1 2 13] Currently, regardless treatment as received, 34-79% of Dutch CMP patients still indicate a feeling of inadequate treatment.[2 14] These patients seek a diagnosis or solution to their pain problem, which explains medical shopping. Even 61% of patients that started a multidisciplinary rehabilitation program visited 6 to > 20 different healthcare professionals one year before starting with multidisciplinary rehabilitation program.[15] A potential reason for these inefficiencies might be that the complexity of the patient's pain problem does not match with treatment as delivered, resulting in over or under treatment[16], which highlights the need for adequate (cost) effective treatment strategies.

This mismatch may be explained by the fact that the knowledge and perspective of healthcare professionals, decision makers, and the public varies regarding CMP, referral, and treatment.[13] Healthcare professionals receive inadequate training on the diagnosis and treatment of CMP, causing different points of view.[17] Some healthcare professionals are more biomedical oriented and focus on explaining and solving the pain, whereas others are more biopsychosocial oriented and focus on optimising functioning despite CMP.[18] Therefore, referral and treatment

selections vary among healthcare professionals, which may result in less efficient care for patients with CMP.

Besides the different perspectives regarding CMP, general practitioners (GPs) in primary care and rehabilitation physicians (RPs) in secondary and tertiary care refer patients mostly based on their anamnesis and clinical experience. However, it appears to be difficult for GPs to identify the impact of all psychosocial factors on chronic low back pain patients, one of the most frequently encountered CMP problems.[19] Recently, different tools became available to support GPs in the decision-making process concerning (initial) treatment options for patients with chronic low back pain and fibromyalgia, especially focusing on the impact of psychosocial components.[20-23] However, these decision-making tools are not implemented in daily care yet in the Netherlands. In the Dutch health care system, patients with moderate to severe levels of disability and associated influencing psychosocial factors are seen by a RP. To support decision making by RPs, an evidence-based objective tool to classify patients objectively and transparently for a specific treatment is needed. Earlier studies have shown that the interrater reliability of the method currently used by RPs to classify the level of disability (WPN classification) is at least questionable.[24 25] In addition, healthcare professionals indicate a lack of overview regarding the complete supply of treatment methods, resulting in inadequate referrals.[26]

Ideally, after assessing the level of disability, the patient receives a treatment matching the complexity of the pain problem in line with the biopsychosocial profile. As in most situations, no cure for CMP is possible and evidence-based treatments are multicomponent pain rehabilitation with a biopsychosocial focus on being active and living a valuable life despite pain.[5 27-29] In primary care physiotherapy, cognitive-behavioural interventions and interventions focusing on biopsychosocial factors have shown long-term effects on patient outcomes.[30 31] Moreover, even positive effects were found when advice combined with pain education alone is given by GPs or therapists to patients with CMP.[32-34] In secondary and tertiary care, multidisciplinary pain rehabilitation programs with physical, psychological, and/or social/work related components, like Acceptance Commitment Therapy (ACT), Graded Activity (GA), and Exposure in vivo (EXP), are more effective than treatments focusing on one aspect of the biopsychosocial model for decreasing pain and disability in patients with disabling chronic low back pain.[35-40]

Despite this knowledge of the effective components of multidisciplinary rehabilitation programs, a wide variety of treatment approaches in various dosages are currently applied in regular rehabilitation programs in different private and public rehabilitation centres.[41] To overcome the different points of view as well as the lack of overview about treatment options, objective decision-making tools, and variety of treatments in the Netherlands, a national care standard for chronic pain was presented in 2017.[11] In this standard, a matched and person-centred care approach for patients with CMP was proposed.[42]

To implement care as part of the national care standard, a transmural network could be designed in which different healthcare professionals collaborate in providing person-centred rehabilitation care. Recently, different transmural integrated care health networks, for example for Parkinson's disease and palliative care, have been successfully developed and implemented in the Netherlands.[43 44] In line with these findings, a transmural pain rehabilitation network can provide a shared vision regarding CMP, including early recognition of subacute pain patients followed by suitable person-centred treatment and referral, is supposed to improve patients' levels of functioning despite pain and to prevent medical shopping of patients with CMP.[11] It should have an unambiguous view, matched care, and a person-centred approach with guidelines for referral and treatment, coordination, and a continuous focus on improvement of care to increase the effectiveness, quality, and efficiency of healthcare for patients with CMP.[45] This approach fits with the advice of the World Health Organisation to focus on stimulating functioning when designing rehabilitation care.[46 47]

The Network Pain Rehabilitation Limburg (NPRL), a transmural healthcare network for CMP rehabilitation, will be designed to ultimately fulfil the Quadruple Aim in the province of Limburg, the Netherlands.[48 49] NPRL provides integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. As a first step a feasibility study will be performed. This study aims to provide insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability of the NPRL. This paper describes the study protocol of the feasibility study of NPRL for adults with CMP.

METHODS

Study design

A feasibility study with an iterative and incremental design, based on key principles of user-centred design[50 51] will be conducted in the South-East region of the Netherlands from October 2017 till October 2018. This will follow the UK Medical Research Council framework[52] for developing complex interventions. It will be useful as NPRL is a complex intervention because of the number of practices and integrated healthcare settings targeted in the NPRL and the number and variability of outcomes. In this iterative process, the development of NPRL will take place in three phases, namely development, implementation, and transferability. The results of each phase will be used to refine the elements of the intervention and to shape the next phase, in which the barriers and facilitators of the different phases will be evaluated. During meetings, all healthcare professionals involved will be informed about the results and the adjustments to NPRL. In the subsequent phase, new adjustments will be integrated in daily practise. The development and implementation process will be 'practise-focused', indicating that the development will be based on the healthcare professionals' experiences with the current healthcare situation.

In phase 1, exploration of context will take place in order to develop the design of the NPRL and to educate the healthcare professionals involved. The focus will be on the barriers and facilitators in the development process of NPRL. Next, in phase 2 (implementation), the project focus will be on the specification of the content to adjust the design of the NPRL to daily practise. More insight into the barriers and facilitators of the implementation process will be collected. In phase 3 (transferability), the project will focus on the organisation of care in daily practise and the research focus will be on the barriers and facilitators for further implementation in other practices and organisations. In addition, preliminary data on efficiency will be collected. The qualitative data collected during the study will be analysed using The Consolidated Framework for Implementation Research (CFIR).[53] NPRL will be feasible in daily practise if the studied barriers and facilitators from the perspectives of healthcare professionals and patients are translatable to policies or guidelines that can be adjusted and integrated in daily practise.

Participants

In this transmural NPRL, healthcare professionals from different disciplines (GPs, physiotherapists, exercise therapists, mental health practice nurses, RPs, and rehabilitation teams) and different healthcare settings (primary, secondary, and tertiary care) will be asked for participation (Figure 1). The setting in primary care concerns general and therapy practices, in secondary care a private outpatient rehabilitation clinic and the outpatient rehabilitation department of a regional hospital, and in tertiary care a specialised rehabilitation clinic. The quality criteria established for practices and organisations for enrolling in NPRL are described in Table 1.

Table 1: Inclusion criteria for healthcare professionals for enrolling in NPRL

Inclusion	Exclusion
Having a practice in the pilot area of NPRL. Willingness to attend the meetings and to implement the different elements of NPRL. GPs and mental health practice nurses must be linked to a participating therapist in order to make effective referrals to treat patients in (interdisciplinary) primary care regarding the protocol and vision of NPRL. Physiotherapists having a participating GP or RP. As they cannot refer a patient when the patient is too complex for them, they will not have an inclusion option for study participants if there is no participating GP or RP. Secondary and tertiary organisations have to meet the criteria of the Position Paper 'Medical Specialist Rehabilitation for chronic musculoskeletal pain' [2017].[54]	A GP who has visited less than 2 out of 3 education days or a therapist who has participated in less than 3 out of 4 education days. Are not able to implement the protocols or assessment tool of NPRL in their own practice.

NPRL = Network Pain Rehabilitation Limburg; GP = general practitioner; RP = rehabilitation physician

In primary care, the recruitment will start with a primary care therapist or a GP interested in pain, and after consent to participate in NPRL. This person will be asked to recruit a GP or therapist with whom they already have intensive collaboration. For secondary and tertiary care, main organisations in the region providing rehabilitation care for patients with CMP will be asked to participate, so all healthcare settings in this region will be covered. Because of the nature and

aim of this feasibility study, we decided to keep the number of healthcare professionals restricted. Based on earlier research, it has to be expected that in this situation the implementation process in daily practise can be easily adjusted when barriers arise.[44]

In addition to the involvement of healthcare professionals in this study, all patients treated by the participating healthcare professionals will be asked to evaluate NPRL and the perceived quality of care. The inclusion criteria for patients to participate in this study are described in Table 2.

Table 2: Inclusion criteria for patients in this feasibility study

Inclusion	Exclusion
Age ≥ 18 years old at the start of the study.	Any suspicion of a medical (orthopaedic, rheumatic, or neurological) disease that can explain the current pain (e.g. rheumatism or hernia) complaints or that can be treated by sufficient therapy.
Patient living in the pilot area (physiotherapist, GP, or RP) of NPRL.	Any suspicion of a (underlying) psychiatric disease, for which psychiatric treatment is better suited, according to the expert opinion of the GP and RP.
Having musculoskeletal pain that is (suspected to be) chronic.	Pregnancy.
Treatment aim of the patient is to improve functioning despite the pain.	
Adequate Dutch literacy to complete the assessments.	

NPRL = Network Pain Rehabilitation Limburg; GP = general practitioner; RP = rehabilitation physician

It is expected that approximately 100 patients from all participating healthcare settings will give informed consent during the course of this study. They will receive questionnaires regarding satisfaction with care and their health status and pain related disability. Moreover, a sample of approximately 10 patients, who finished a treatment according to the protocol of NPRL, will be recruited for a focus group. In this focus group more information about barriers and facilitators from a patient perspective will be collected. In this way patients are able to react to each other which will illuminate various perspectives which leads to a faster data saturation about each topic, which is an advantage above interviews.[55]

Intervention: Network Pain Rehabilitation Limburg

The main aim of NPRL is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved

healthcare professionals. This should accomplish the Quadruple Aim: improvement of CMP patient functioning, experiences of care, and work life satisfaction of physicians and staff, as well as a reduction of healthcare costs of patients with CMP.

Each patient will receive the treatment needed to reach his/her optimal level of functioning. In order to reach this, a matched care approach will be used for every individual patient. Depending on the level of disability and biopsychosocial factors involved, this will either include; 1) education only and no further treatment, 2) monodisciplinary treatment in primary care, 3) multidisciplinary treatment in primary care (collaboration between GPs, primary care therapists, and mental health practice nurses in assessing and treating patients with CMP who need mental support besides physical exercise), 4) interdisciplinary treatment in secondary or 5) interdisciplinary treatment in tertiary care. Collaboration will be supported by facilitating communication between patients and all healthcare professionals involved in the trajectory of an individual patient by E-health.[56] In addition, the collaboration between healthcare professionals in different practices and organisations will be further supported by informative meetings and education days. All healthcare professionals with different specialisms will participate together in the meetings and education days. This ensures a common understanding of the biopsychosocial approach and rehabilitation treatment options. In order to facilitate this in daily practice, the following elements are integrated in NPRL:

Integral focus on assessment and referral: assessment tools

To support the healthcare professionals in their decision making for problem mapping and treatment selection, two evidence-based objective assessment tools will be used. These tools will support the assessment of the complexity of the pain problem; one tool for GPs and primary care therapists and one tool for RPs. The assessment tool for primary care is based on the Start Back Tool[20] and will help to advise patient treatment matched to the patient's biopsychosocial profile. The options are: advice only, treatments in primary care, or for decision making by a RP (Figure 2). The GP can also decide to advise patients for a treatment outside NPRL (psychiatrist, specific healthcare specialist, etc.). Since 2006, patients in the Netherlands can visit a primary care therapist without a referral of a GP,[57] so these therapists will also use this assessment tool. In this situation, a primary care therapist of NPRL will advise the patient to visit the GP for additional assessment and referral if needed as the GP is the gatekeeper to secondary and tertiary care.

When a patient visits a RP, the assessment tool for specialised rehabilitation care is used for decision making. This tool will assess the patient's view as well as the RP's view of the biopsychosocial problem and consists of two parts. The first part will guide the anamnesis of the RP and is based on two different ways to score disability related complexity, namely the Case Complexity Index and INTERMED method.[25 58 59] First, a standardised scoring method for assessing the biopsychosocial profile and care for the past and current situations will be used by the RP. Second, a set of CMP related questionnaires assessing anxiety, depression, catastrophising, fatigue, pain level, participation level, and general health will be completed by the patient. After completion of these questionnaires, scores will be interpreted by the RP. Based on scoring in both parts of the RP-assessment tool, patients will be categorised by profile, representing the patient's level of disability. In addition to primary and interdisciplinary primary care, the second tool will assist the RP to further differentiate between available secondary or tertiary multidisciplinary rehabilitation programs (Figure 2).

Integral focus on treatment content and duration: treatment protocols

When the patient receives treatment, an individualised treatment plan based on their current needs will be made. The patient decides the treatment aim when he visits a healthcare professional. In case this is necessary, the practitioner will support the patient in setting functional goals. Protocols will be based on the most recent evidence-based treatment methods such as GA, EXP, and ACT[35-38 40] and these will be used in all healthcare settings. As these evidence-based methods are developed for secondary and tertiary care, they will be adjusted for primary care. During evaluations in phase 1 and 2, healthcare professionals will be invited to provide feedback on the treatment protocols. As a result, adjustments to the content and duration of treatment protocols will be made if these adjustments are in line with the evidence-based treatment methods.

Integral focus on self-management: E-health application

All professionals and patients participating in the NPRL will make use of an E-health application: SanaCoach Pain Rehabilitation.[56] Also, primary care patients who receive 'advice only' can make use of this SanaCoach Pain Rehabilitation. The coach has different functions and goals in the treatment process. The primary goal is to support self-management. The main function of the coach is to provide pain education based on the education modules. Different eLearning modules are developed for the patients in order to teach them about the biopsychosocial aspects of pain. Furthermore, diaries are integrated into the coach in which patients can give

feedback on changes in pain intensity, level of activity over time, and the interrelation between these variables. Moreover, healthcare professionals can use scores from these diaries to adjust treatment to individual patients. The coach also consists of a chat function between the patient and healthcare professionals to ensure short communication lines. All healthcare professionals involved in the care process of a patient have access to this chat function with that patient. Additionally, the assessment tool for primary care is integrated, which makes these results available for all involved healthcare professionals. For this study, the questionnaires for patients are also available via the coach. Based on the level of complexity of disability, the functions in the SanaCoach Pain Rehabilitation will be adjusted to the patient, such as the number of diaries and level of education.

Patient and Public Involvement

During the development of the research question, design, recruitment, and conduct of the study no patients were involved in the process. However, during the development of NPRL itself, a patient was involved in the development of the SanaCoach Pain Rehabilitation and treatment protocols. Moreover, the focus of this feasibility study is mainly on healthcare professionals. They were involved in the development of the treatment protocols, SanaCoach Pain Rehabilitation and in the development of the different communication strategies between the healthcare professionals themselves. The results of the study will be disseminated to the study participants via the webpage (www.netwerkpijnrevalidatie.nl) and social media accounts.

Data collection

In this study, the feasibility of the development, implementation, and transferability of NPRL for adults with CMP will be investigated. Therefore, different data collection techniques such as observations, interviews, focus groups, and questionnaires will be combined to get more insight into the barriers and facilitators of NPRL (Table 3).

Table 3: Overview of data collection methods and respondents per phase

Phase	1	2	3
Time period	October 2017–February 2018	February 2018–June 2018	June 2018–October 2018
Goal project	Exploration of context will take place in order to develop the design of the NPRL and to educate the involved healthcare professionals.	Specification of the content to adjust the design of the transmural network to daily practise.	Organisation of care in daily practise and barriers and facilitators for implementation in other practices and organisations.

Goal evaluation	Insight into the barriers and facilitators of the development of NPRL.	Insight into the barriers and facilitators of the implementation of NPRL.	Insight into the barriers and facilitators of the transferability of NPRL.
Data collection method, respondents, and outcomes	<u>Focus groups and interviews</u> *Healthcare professionals* • Experiences with the informative meetings • Experiences with the education days • Expectations and views on working in NPRL • Current experiences (satisfaction) with working in NPRL • Barriers and facilitators <u>Questionnaire</u> *Healthcare professionals* • Current views and thoughts regarding patients with CMP • Referral pattern • Patient characteristics	<u>Focus groups and interviews</u> *Healthcare professionals* • Views on working in NPRL • Current experiences (satisfaction) with working in NPRL • Implications and recommendations of the implementation strategy for practise • Barriers and facilitators	<u>Focus groups and interviews</u> *Healthcare professionals* • Current experiences (satisfaction) with working in NPRL • Implications and recommendations of the implementation strategy for practise • Implications and recommendations for future research and project • Satisfaction with NPRL and with work life • Barriers and facilitators <u>Focus group</u> *+/- 10 patients* • Perceived quality of care • Experiences with NPRL • Barriers and facilitators <u>Questionnaire</u> *Healthcare professionals* • Referral pattern • Patient characteristics
	<u>Questionnaire start and end of treatment (T0 and T2)</u> *Patients* •Health status •Quality of care •Usability of the SanaCoach Pain Rehabilitation <u>Questionnaire after referral (T1)</u> *Patients* • Quality and satisfaction with referral and care <u>Questionnaire or logbook of treatment</u> *Healthcare specialists* • Barriers and facilitators of the treatment protocol per patient <u>Notes</u> • Current views regarding NPRL • Barriers and facilitators		

NPRL = Network Pain Rehabilitation Limburg; CMP= chronic musculoskeletal pain

During the informative meetings and education days, field notes will be made in order to collect information about the views on NPRL and its elements out of the perspectives of the healthcare professionals involved. At the end of each phase, focus groups and/or interviews will take place with (a selection of) the healthcare professionals involved. During the evaluation of phase 1, healthcare professionals will be asked about the barriers and facilitators they perceived while working in NPRL. Therefore, more information will be collected about expectations, views, experiences, and satisfaction. Also, experiences and opinions about the informative meetings and education days will be collected. Healthcare professionals will fill in an electronic questionnaire in phase 1 concerning decision making, treatments, and characteristics of the patients involved in the study. This information will give more insight into potential changes in referral policy between the situation in usual care and the situation within NPRL. Moreover, the questionnaire also asks for knowledge and perspectives regarding patients with CMP.

In phases 2 and 3, more emphasis will be put on the added value of NPRL including barriers and facilitators for implementation. This information will be used for recommendations for practise and future research. Also in these phases, information will be gained about the experiences and satisfaction with NPRL during a focus group with healthcare professionals. Moreover, in phase 3 (transferability), they will fill in an electronic questionnaire concerning decision making, treatments, and characteristics of the patients involved in the study. As part of the evaluation of phase 3, a focus group with a sample of 6 to 10 patients with CMP who are being treated by participating healthcare professionals will take place. During this focus group, the emphasis will be on the satisfaction of care and experiences, leading to barriers and facilitators with NPRL.

Besides this information, the research team will keep up a logbook to get insight into the barriers and facilitators of NPRL. The field notes in this logbook will be the results of discussions with different healthcare professionals, patients, and stakeholders, as well as researchers. Additionally, patients will be asked to complete study-related questionnaires about the quality and their satisfaction with the decision making, treatment and education, and usability of the SanaCoach Pain Rehabilitation in order to further improve different elements of NPRL. Besides this feasibility data, also some questions about their work status, general health, and

participation level will be asked as preliminary data on efficiency to objectify the progress of the treatment. They will receive this questionnaire at the start of the treatment (T0) and at the end of the treatment (T2). Patients referred to another healthcare professional will receive an extra questionnaire after the referral (T1) regarding the quality of and satisfaction with the decision making. Additionally, after completion of the treatment, a small questionnaire or logbook about the treatment of each patient separately must be handed in by the healthcare professionals. This information will be used to discover barriers and facilitators and desired adjustments of the treatment protocols.

Data Analysis

In this iterative design with key principles of user-centered design, the results will be gathered in daily practice from the healthcare professional and patient perspective. The results of each phase will be used to adapt the intervention for the next phase. The Consolidated Framework for Implementation Research (CFIR) protocol according to Damschroder *et al*[53] will be used to develop this feasibility evaluation and analysis plan of the results. This explanatory framework with theory-based constructs and mechanisms will be used to explain whether an implementation may or may not succeed and to identify barriers and facilitators.

All field notes and logbooks will be collected. Additionally, the focus groups and interviews will be audio recorded and transcribed verbatim. Qualitative data will be analysed using the NVivo software (NVivo.version 11.1.0.411) following a directed content analysis method.[60] The analysis will be deductive (e.g. the identified themes will derive from existing theory). After familiarisation with the data, definitions for the CFIR constructs will be made based on the intervention in collaboration with the project team. Next, the different constructs will be assigned to the fewest codes possible. After developing analytic summaries and matrices, the data will be compared to derive barriers and facilitators. A researcher with expertise in qualitative research without any involvement in the project will peer review the analysis by verification of the analysis of 20% of the interviews and focus groups. Also, a cross-check for interim findings with respondents will be performed.

Quantitative data will be analysed concurrently with the qualitative data. Descriptive statistics will be denoted as mean (standard deviation) or median (range) and number (%) for continuous and categorical data, respectively, with the use of IBM SPSS Statistics 24.

ETHICS AND DISSEMINATION

Informed consent will be obtained from all participants. Ethical approval for this study was granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133. The results of this feasibility study will form the base for refinement of NPRL and planning of a large-scale process and effect evaluation on the Quadruple Aim outcomes. Dissemination will include publications and presentations at national and international conferences.

DISCUSSION

This study will provide insight into the feasibility of NPRL, a transmural integrated healthcare network for CMP rehabilitation. The aim is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. It is expected that the study will provide information on barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability for further develop and refinement of the NPRL. If the study results suggest that NPRL is feasible and preliminary outcomes are positive, a large-scale process and effective evaluation of the Quadruple Aim outcomes will be performed.

The process of developing NPRL is in accordance with the Medical Research Council guidance on how to develop and evaluate complex interventions.[52] In the development process, existing evidence together with collected evidence based on the expertise of healthcare professionals was combined to develop the first version of NPRL. This first version of NPRL will be implemented on a restricted scale to test the feasibility. The evidence generated from this feasibility study will not only help to adjust the design and content of NPRL but will also inform future methodological studies on developing and implementing a transmural network in healthcare. It is expected that this bottom-up development in combination with the limited number of participating healthcare professionals will lead to a successful implementation of the network. Nijkrake *et al*[44] did indicate this approach as one of the success factors of ParkinsonNet, a successful and cost-effective network in the Netherlands for patients with Parkinson's disease.

In conclusion, there is need for a transmural network in which different healthcare professionals collaborate in providing integrated healthcare for patients with CMP. The aim of NPRL is to improve the level of functioning of individual patients despite pain, experience of care by

patients, and work-life satisfaction for physicians and staff, as well as a reduction in costs. Therefore, this feasibility study will be conducted to explore the barriers and facilitators of the development, implementation, and transferability of NPRL. The results will be applied to refine a large-scale process and effective evaluation of the Quadruple Aim outcomes.

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Reference Table 1

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AUTHORS CONTRIBUTIONS

JAMCFV, IPJH, and AJK conceived the original idea and outline of the study, and CL, MEK, IPJH, JAMCFV, and DR contributed to designing the study. JAMCFV, IPJH, and AJK were responsible for developing the intervention. CL was the primary writer of the study protocol in collaboration with MEK and IPJH. All authors discussed and commented on draft versions and approved the final version.

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COMPETING INTERESTS

CL, MEK and DR have nothing to disclose. AJK, JAMCFV, and IPJH report grants from Health Insurance Companies CZ, VGZ and Achmea, during the conduct of the study;

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ETHICS APPROVAL

Approval from the Medical Ethics Committee Z, the Netherlands, METC 17-N-133.

Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

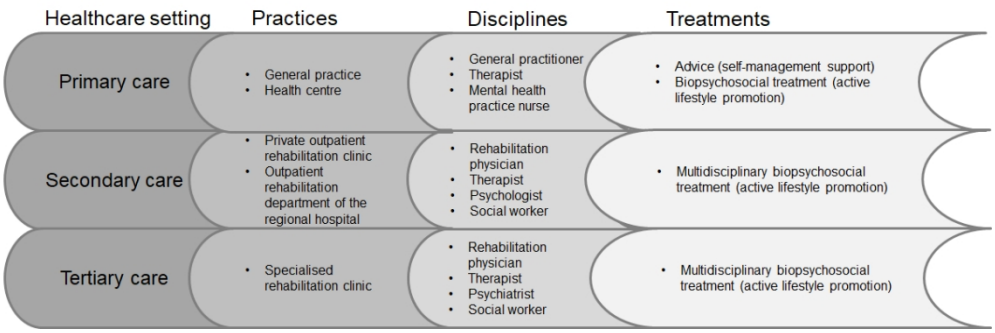

Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

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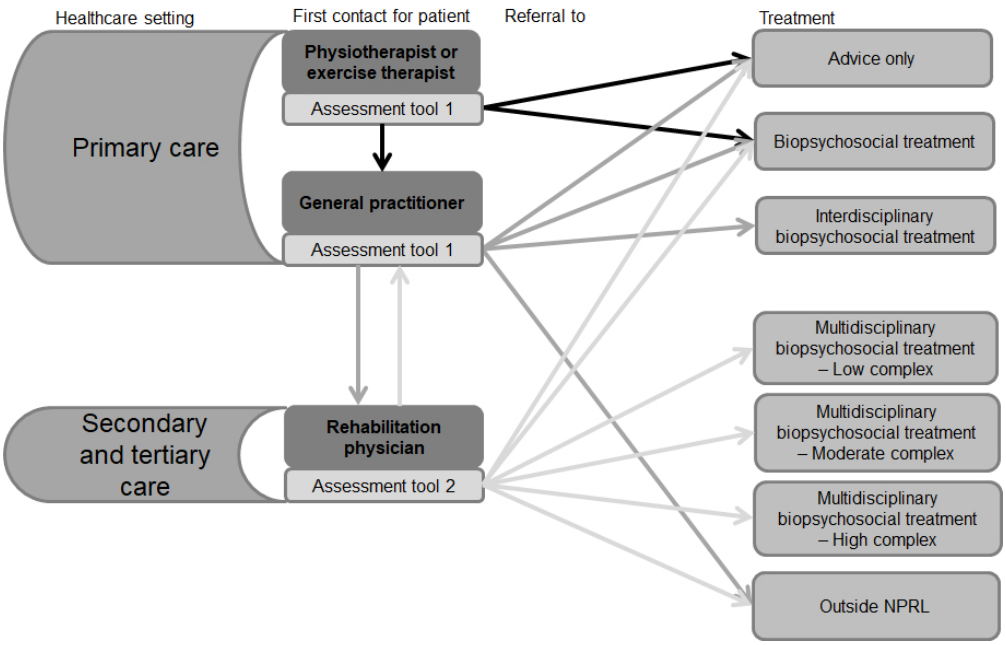

Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

77x49mm (300 x 300 DPI)