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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 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 treatment¹⁶, 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

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3 selections vary among healthcare professionals, which may result in less efficient care for
4 patients with CMP.
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8 Besides the different perspectives regarding CMP, general practitioners (GPs) in primary care
9 and rehabilitation physicians (RPs) in secondary and tertiary care refer patients mostly based on
10 their anamnesis and clinical experience. However, it appears to be difficult for GPs to identify
11 the impact of all psychosocial factors on chronic low back pain patients, one of the most
12 frequently encountered CMP problems.¹⁸ Recently, different tools became available to support
13 GPs in the decision-making process concerning (initial) treatment options for patients with
14 chronic low back pain and fibromyalgia, especially focusing on the impact of psychosocial
15 components.¹⁹⁻²² However, these decision-making tools are not implemented in daily care yet in
16 the Netherlands. In the Dutch health care system, patients with moderate to severe levels of
17 disability and associated influencing psychosocial factors are seen by a RP. To support decision
18 making by RPs, an evidence-based objective tool to classify patients objectively and
19 transparently for a specific treatment is needed. Earlier studies have shown that the interrater
20 reliability of the method currently used by RPs to classify the level of disability (WPN
21 classification) is at least questionable.^{23 24} In addition, healthcare professionals indicate a lack of
22 overview regarding the complete supply of treatment methods, resulting in inadequate
23 referrals.²⁵
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35 Ideally, after assessing the level of disability, the patient receives a treatment matching the
36 complexity of the pain problem in line with the biopsychosocial profile. As in most situations, no
37 cure for CMP is possible and evidence-based treatments are multicomponent pain rehabilitation
38 with a biopsychosocial focus on being active and living a valuable life despite pain.^{5 26-28} In
39 primary care physiotherapy, cognitive-behavioural interventions and interventions focusing on
40 biopsychosocial factors have shown long-term effects on patient outcomes.^{29 30} Moreover, even
41 positive effects were found when advice combined with pain education alone is given by GPs or
42 therapists to patients with CMP.³¹⁻³³ In secondary and tertiary care, multidisciplinary pain
43 rehabilitation programs with physical, psychological, and/or social/work related components, like
44 Acceptance Commitment Therapy (ACT), Graded Activity (GA), and Exposure in vivo (EXP),
45 are more effective than treatments focusing on one aspect of the biopsychosocial model for
46 decreasing pain and disability in patients with disabling chronic low back pain.³⁴⁻³⁹
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3 Despite this knowledge of the effective components of multidisciplinary rehabilitation programs,
4 a wide variety of treatment approaches in various dosages are currently applied in regular
5 rehabilitation programs in different private and public rehabilitation centres.⁴⁰ To overcome the
6 different points of view as well as the lack of overview about treatment options, objective
7 decision-making tools, and variety of treatments in the Netherlands, a national care standard for
8 chronic pain was presented in 2017.¹¹ In this standard, a stepped and person-centred care
9 approach for patients with CMP was proposed.
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16 To implement care as part of the national care standard, a transmurial network could be
17 designed in which different healthcare professionals collaborate in providing person-centred
18 rehabilitation care. Recently, different transmurial integrated care health networks, for example
19 for Parkinson's disease and palliative care, have been successfully developed and implemented
20 in the Netherlands.^{41 42} In line with these findings, a transmurial pain rehabilitation network can
21 provide a shared vision regarding CMP, including early recognition of subacute pain patients
22 followed by suitable person-centred treatment and referral, is supposed to improve patients'
23 levels of functioning despite pain and to prevent medical shopping of patients with CMP.¹¹ It
24 should have an unambiguous view, stepped care, and a person-centred approach with
25 guidelines for referral and treatment, coordination, and a continuous focus on improvement of
26 care to increase the effectiveness, quality, and efficiency of healthcare for patients with CMP.⁴³
27 This approach fits with the advice of the World Health Organisation to focus on stimulating
28 functioning when designing rehabilitation care.^{44 45}
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38 The Network Pain Rehabilitation Limburg (NPRL), in the province of Limburg, the Netherlands,
39 will be designed striving to fulfil the Quadruple Aim, in which the improvement of population
40 health, experience of care by patients, and work life satisfaction for physicians and staff, as well
41 as a reduction in costs are important aspects to be taken into account.^{46 47} Before evaluation the
42 Quadruple Aim outcomes, as a first step a feasibility study will be performed aiming to explore
43 the barriers and facilitators of the development, implementation, and transferability of NPRL.
44 Following the UK Medical Research Council framework⁴⁸ for developing complex interventions
45 will be useful as NPRL is a complex intervention because of the number of practices and
46 integrated healthcare settings targeted in the NPRL and the number and variability of outcomes.
47 This paper describes the study protocol of the feasibility study of NPRL for adults with CMP.
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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 transmurial 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.

Inclusion	Exclusion
Having a practice in the pilot area of NPRL.	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.
Willingness to attend the meetings and to implement the different elements of NPRL.	Are not able to implement the protocols or assessment tool of NPRL in their own practice.
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 .	

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.	
Having musculoskeletal pain that is (suspected to be) chronic.	Any suspicion of a (underlying) psychiatric disease, for which psychiatric treatment is better suited, according to the expert opinion of the GP and RP.
Treatment aim of the patient is to improve functioning despite the pain.	Pregnancy.
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

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3 besides physical exercise) or multidisciplinary treatment in secondary or tertiary care.
4 Collaboration will be supported by facilitating communication between patients and all
5 healthcare professionals involved in the trajectory of an individual patient by E-health.⁵¹ In
6 addition, the collaboration between healthcare professionals in different practices and
7 organisations will be further supported by informative meetings and education days.
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12 In order to facilitate the joint focus on improving the level of functioning despite pain, the
13 following elements are integrated in NPRL:
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17 *Integral focus on assessment and referral: assessment tools*
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19 To support the healthcare professionals in their decision making for problem mapping and
20 treatment selection, two evidence-based objective assessment tools will support the
21 assessment of complexity of the pain problem; one tool for GPs and primary care therapists and
22 one tool for RPs. The assessment tool for primary care is based on the Start Back Tool²⁰ and
23 will help to advise patient treatment matched to the patient's biopsychosocial profile. The
24 options are: advice only, treatments in primary care, or for decision making by a RP (Figure 2).
25 The GP can also decide to advise patients for a treatment outside NPRL (psychiatrist, specific
26 healthcare specialist, etc.). Since 2006, patients in the Netherlands can visit a primary care
27 therapist without a referral of a GP,⁵² so these therapists will also use this assessment tool. In
28 this situation, a primary care therapist of NPRL will advise the patient to visit the GP for
29 additional assessment and referral if needed as the GP is the gatekeeper to secondary and
30 tertiary care.
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39 When a patient visits a RP, the assessment tool for specialised rehabilitation care is used for
40 decision making. This tool will assess the patient's view as well as the RP's view of the
41 biopsychosocial problem and consists of two parts. The first part will guide the anamnesis of the
42 RP and is based on two different ways to score disability related complexity, namely the Case
43 Complexity Index and INTERMED method.^{24 53 54} First, a standardised scoring method for
44 assessing the biopsychosocial profile and care for the past and current situations will be used
45 by the RP. Second, a set of CMP related questionnaires assessing anxiety, depression,
46 catastrophising, fatigue, pain level, participation level, and general health will be completed by
47 the patient. After completion of these questionnaires, scores will be interpreted by the RP.
48 Based on scoring in both parts of the RP-assessment tool, patients will be categorised by
49 profile, representing the patient's level of disability. In addition to primary and interdisciplinary
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3 primary care, the second tool will assist the RP to further differentiate between available
4 secondary or tertiary multidisciplinary rehabilitation programs (Figure 2).
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8 *Integral focus on treatment content and duration: treatment protocols*

9 When the patient receives treatment, an individualised treatment plan based on their current
10 needs will be made. Protocols will be based on the most recent evidence-based treatment
11 methods such as GA, EXP, and ACT^{34-37 39} and these will be used in all healthcare settings. As
12 these evidence-based methods are developed for secondary and tertiary care, they will be
13 adjusted for primary care. During evaluations in phase 1 and 2, healthcare professionals will be
14 invited to provide feedback on the treatment protocols. As a result, adjustments to the content
15 and duration of treatment protocols will be made if these adjustments are in line with the
16 evidence-based treatment methods.
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24 *Integral focus on self-management: E-health application*

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

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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).

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 transmurals 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	<p><u>Focus groups and interviews</u> <i>Healthcare professionals</i></p> <ul style="list-style-type: none"> 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 <p><u>Questionnaire</u> <i>Healthcare professionals</i></p> <ul style="list-style-type: none"> Current views and thoughts regarding patients with CMP Referral pattern Patient characteristics 	<p><u>Focus groups and interviews</u> <i>Healthcare professionals</i></p> <ul style="list-style-type: none"> Views on working in NPRL Current experiences (satisfaction) with working in NPRL Implications and recommendations of the implementation strategy for practise Barriers and facilitators 	<p><u>Focus groups and interviews</u> <i>Healthcare professionals</i></p> <ul style="list-style-type: none"> 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 <p><u>Focus group</u> <i>+/- 10 patients</i></p> <ul style="list-style-type: none"> Perceived quality of care Experiences with NPRL Barriers and facilitators <p><u>Questionnaire</u> <i>Healthcare professionals</i></p> <ul style="list-style-type: none"> Referral pattern Patient characteristics
	<p><u>Questionnaire start and end of treatment (T0 and T2)</u> <i>Patients</i></p> <ul style="list-style-type: none"> Health status 		

- Quality of care
- Usability of the SanaCoach Pain Rehabilitation

Questionnaire after referral (T1)

Patients

- Quality and satisfaction with referral and care

Questionnaire or logbook of treatment

Healthcare specialists

- Barriers and facilitators of the treatment protocol per patient

Notes

- 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,

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

34 The Consolidated Framework for Implementation Research (CFIR) protocol according to
35 Damschroder *et al*⁵⁵ will be used to develop this feasibility evaluation and analysis plan. This
36 explanatory framework with theory-based constructs and mechanisms will be used to help
37 explain whether an implementation may or may not succeed and to identify barriers and
38 facilitators. In this iterative design, the results of each phase will be used to adapt the
39 intervention for the next phase.
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46 All field notes and logbooks will be collected. Additionally, the focus groups and interviews will
47 be audio recorded and transcribed verbatim. Qualitative data will be analysed using the NVivo
48 software (NVivo.version 11.1.0.411) following a directed content analysis method.⁵⁶ The
49 analysis will be deductive (e.g. the identified themes will derive from existing theory). After
50 familiarisation with the data, definitions for the CFIR constructs will be made based on the
51 intervention in collaboration with the project team. Next, the different constructs will be assigned
52 to the fewest codes possible. After developing analytic summaries and matrices, the data will be
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3 compared to derive barriers and facilitators. A researcher with expertise in qualitative research
4 without any involvement in the project will peer review the analysis by verification of the analysis
5 of 20% of the interviews and focus groups. Also, a cross-check for interim findings with
6 respondents will be performed.
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11 Quantitative data will be analysed concurrently with the qualitative data. Descriptive statistics
12 will be denoted as mean (standard deviation) or median (range) and number (%) for continuous
13 and categorical data, respectively, with the use of IBM SPSS Statistics 24.
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16 17 **ETHICS AND DISSIMINATION**

18 Informed consent will be obtained from all participants. Ethical approval for this study was
19 granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133. The results of
20 this feasibility study will form the base for refinement of NPRL and planning of a large-scale
21 process and effect evaluation on the Quadruple Aim outcomes. Dissemination will include
22 publications and presentations at national and international conferences.
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28 29 **DISCUSSION**

30 This study will provide insight into the feasibility of NPRL, a transmural integrated healthcare
31 network for CMP rehabilitation. The aim is to provide integrated care for patients with CMP in
32 order to improve their level of functioning despite pain by stimulating a biopsychosocial
33 approach for all involved healthcare professionals. It is expected that the study will provide
34 information on barriers and facilitators, perceived value, acceptability, and implementation
35 strategies for the development, implementation, and transferability for further develop and
36 refinement of the NPRL. If the study results suggest that NPRL is feasible and preliminary
37 outcomes are positive, a large-scale process and effective evaluation of the Quadruple Aim
38 outcomes will be performed.
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46 The process of developing NPRL is in accordance with the Medical Research Council guidance
47 on how to develop and evaluate complex interventions.⁴⁸ In the development process, existing
48 evidence together with collected evidence based on the expertise of healthcare professionals
49 was combined to develop the first version of NPRL. This first version of NPRL will be
50 implemented on a restricted scale to test the feasibility. The evidence generated from this
51 feasibility study will not only help to adjust the design and content of NPRL but will also inform
52 future methodological studies on developing and implementing a transmural network in
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3 healthcare. It is expected that this bottom-up development in combination with the limited
4 number of participating healthcare professionals will lead to a successful implementation of the
5 network. Nijkrake *et al*⁴² did indicate this approach as one of the success factors of
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7 ParkinsonNet, a successful and cost-effective network in the Netherlands for patients with
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9 Parkinson's disease.
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12 In conclusion, there is need for a transmural network in which different healthcare professionals
13 collaborate in providing integrated healthcare for patients with CMP. The aim of NPRL is to
14 improve the level of functioning of individual patients despite pain, experience of care by
15 patients, and work life satisfaction for physicians and staff, as well as a reduction in costs.
16
17 Therefore, this feasibility study will be conducted to explore the barriers and facilitators of the
18 development, implementation, and transferability of NPRL. The results will be applied to refine a
19 large-scale process and effective evaluation of the Quadruple Aim outcomes.
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41 AUTHORS CONTRIBUTIONS

42 JAMCFV, IPJH, and AJK conceived the original idea and outline of the study, and CL, MEK,
43 IPJH, JAMCFV, and DR contributed to designing the study. JAMCFV, IPJH, and AJK were
44 responsible for developing the intervention. CL was the primary writer of the study protocol in
45 collaboration with MEK and IPJH. All authors discussed and commented on draft versions and
46 approved the final version.
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51

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54 The funding bodies had no role in the design of the study or writing the manuscript
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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;

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

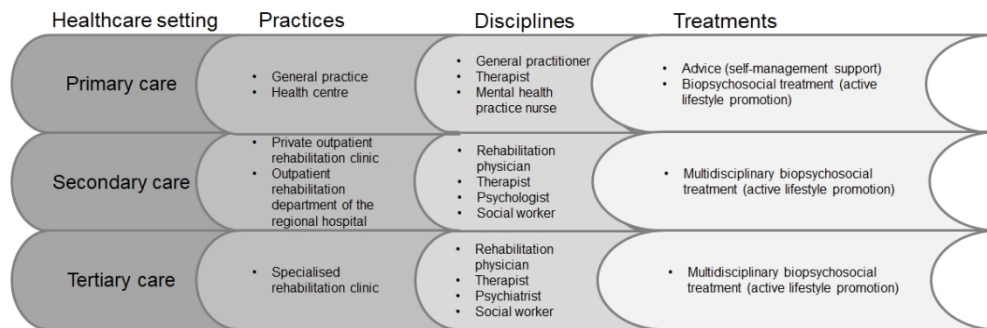


Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

321x106mm (96 x 96 DPI)

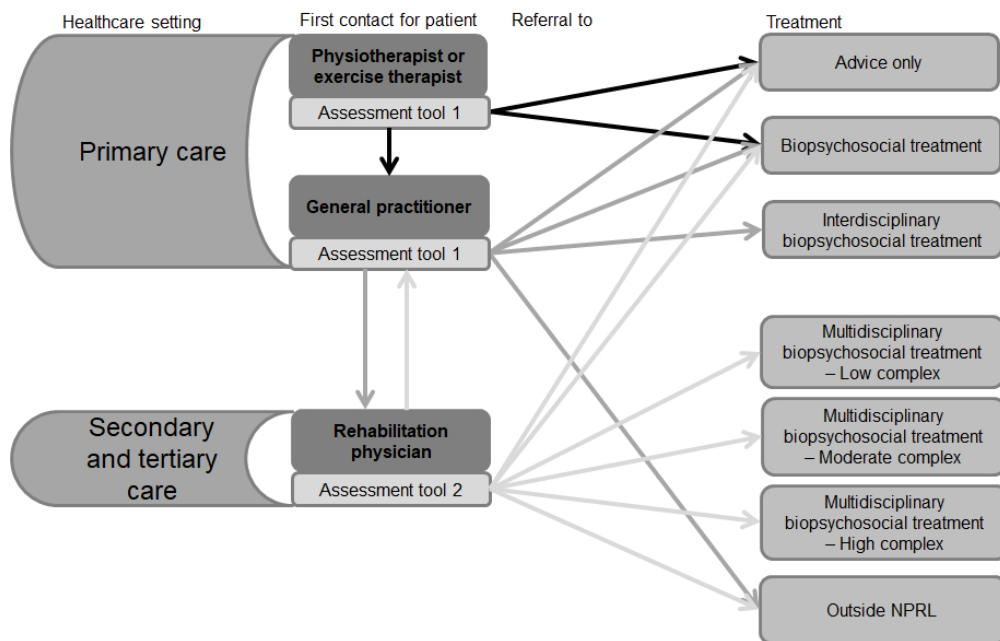


Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

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BMJ Open

Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol

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Manuscripts

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 transmurally 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, transmurally 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 treatment¹⁶, 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

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3 selections vary among healthcare professionals, which may result in less efficient care for
4 patients with CMP.
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8 Besides the different perspectives regarding CMP, general practitioners (GPs) in primary care
9 and rehabilitation physicians (RPs) in secondary and tertiary care refer patients mostly based on
10 their anamnesis and clinical experience. However, it appears to be difficult for GPs to identify
11 the impact of all psychosocial factors on chronic low back pain patients, one of the most
12 frequently encountered CMP problems.¹⁹ Recently, different tools became available to support
13 GPs in the decision-making process concerning (initial) treatment options for patients with
14 chronic low back pain and fibromyalgia, especially focusing on the impact of psychosocial
15 components.²⁰⁻²³ However, these decision-making tools are not implemented in daily care yet in
16 the Netherlands. In the Dutch health care system, patients with moderate to severe levels of
17 disability and associated influencing psychosocial factors are seen by a RP. To support decision
18 making by RPs, an evidence-based objective tool to classify patients objectively and
19 transparently for a specific treatment is needed. Earlier studies have shown that the interrater
20 reliability of the method currently used by RPs to classify the level of disability (WPN
21 classification) is at least questionable.^{24 25} In addition, healthcare professionals indicate a lack of
22 overview regarding the complete supply of treatment methods, resulting in inadequate
23 referrals.²⁶
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35 Ideally, after assessing the level of disability, the patient receives a treatment matching the
36 complexity of the pain problem in line with the biopsychosocial profile. As in most situations, no
37 cure for CMP is possible and evidence-based treatments are multicomponent pain rehabilitation
38 with a biopsychosocial focus on being active and living a valuable life despite pain.^{5 27-29} In
39 primary care physiotherapy, cognitive-behavioural interventions and interventions focusing on
40 biopsychosocial factors have shown long-term effects on patient outcomes.^{30 31} Moreover, even
41 positive effects were found when advice combined with pain education alone is given by GPs or
42 therapists to patients with CMP.³²⁻³⁴ In secondary and tertiary care, multidisciplinary pain
43 rehabilitation programs with physical, psychological, and/or social/work related components, like
44 Acceptance Commitment Therapy (ACT), Graded Activity (GA), and Exposure in vivo (EXP),
45 are more effective than treatments focusing on one aspect of the biopsychosocial model for
46 decreasing pain and disability in patients with disabling chronic low back pain.³⁵⁻⁴⁰
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3 Despite this knowledge of the effective components of multidisciplinary rehabilitation programs,
4 a wide variety of treatment approaches in various dosages are currently applied in regular
5 rehabilitation programs in different private and public rehabilitation centres.⁴¹ To overcome the
6 different points of view as well as the lack of overview about treatment options, objective
7 decision-making tools, and variety of treatments in the Netherlands, a national care standard for
8 chronic pain was presented in 2017.¹¹ In this standard, a stepped and person-centred care
9 approach for patients with CMP was proposed.
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16 To implement care as part of the national care standard, a transmurals network could be
17 designed in which different healthcare professionals collaborate in providing person-centred
18 rehabilitation care. Recently, different transmurals integrated care health networks, for example
19 for Parkinson's disease and palliative care, have been successfully developed and implemented
20 in the Netherlands.^{42 43} In line with these findings, a transmurals pain rehabilitation network can
21 provide a shared vision regarding CMP, including early recognition of subacute pain patients
22 followed by suitable person-centred treatment and referral, is supposed to improve patients'
23 levels of functioning despite pain and to prevent medical shopping of patients with CMP.¹¹ It
24 should have an unambiguous view, stepped care, and a person-centred approach with
25 guidelines for referral and treatment, coordination, and a continuous focus on improvement of
26 care to increase the effectiveness, quality, and efficiency of healthcare for patients with CMP.⁴⁴
27 This approach fits with the advice of the World Health Organisation to focus on stimulating
28 functioning when designing rehabilitation care.^{45 46}
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38 The Network Pain Rehabilitation Limburg (NPRL), a transmurals integrated healthcare network
39 for CMP rehabilitation, will be designed to ultimately fulfil the Quadruple Aim in the province of
40 Limburg, the Netherlands.^{47 48} The aim is to provide integrated care for patients with CMP in
41 order to improve their level of functioning despite pain by stimulating a biopsychosocial
42 approach for all involved healthcare professionals. As a first step a feasibility study will be
43 performed. This study provides insight into the barriers and facilitators, perceived value,
44 acceptability, and implementation strategies for the development, implementation, and
45 transferability of the NPRL. This paper describes the study protocol of the feasibility study of
46 NPRL for adults with CMP.
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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 framework⁵¹ 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.	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.
Willingness to attend the meetings and to implement the different elements of NPRL.	Are not able to implement the protocols or assessment tool of NPRL in their own practice.
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	
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.

Inclusion	Exclusion
Age \geq 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.	
Having musculoskeletal pain that is (suspected to be) chronic.	Any suspicion of a (underlying) psychiatric disease, for which psychiatric treatment is better suited, according to the expert opinion of the GP and RP.
Treatment aim of the patient is to improve functioning despite the pain.	Pregnancy.
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.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.

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

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

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30 *Integral focus on assessment and referral: assessment tools*

31 To support the healthcare professionals in their decision making for problem mapping and
32 treatment selection, two evidence-based objective assessment tools will be used. These tools
33 will support the assessment of the complexity of the pain problem; one tool for GPs and primary
34 care therapists and one tool for RPs. The assessment tool for primary care is based on the Start
35 Back Tool²⁰ and will help to advise patient treatment matched to the patient's biopsychosocial
36 profile. The options are: advice only, treatments in primary care, or for decision making by a RP
37 (Figure 2). The GP can also decide to advise patients for a treatment outside NPRL
38 (psychiatrist, specific healthcare specialist, etc.). Since 2006, patients in the Netherlands can
39 visit a primary care therapist without a referral of a GP,⁵⁶ so these therapists will also use this
40 assessment tool. In this situation, a primary care therapist of NPRL will advise the patient to visit
41 the GP for additional assessment and referral if needed as the GP is the gatekeeper to
42 secondary and tertiary care.

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52 When a patient visits a RP, the assessment tool for specialised rehabilitation care is used for
53 decision making. This tool will assess the patient's view as well as the RP's view of the
54 biopsychosocial problem and consists of two parts. The first part will guide the anamnesis of the
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3 RP and is based on two different ways to score disability related complexity, namely the Case
4 Complexity Index and INTERMED method.^{25 57 58} First, a standardised scoring method for
5 assessing the biopsychosocial profile and care for the past and current situations will be used
6 by the RP. Second, a set of CMP related questionnaires assessing anxiety, depression,
7 catastrophising, fatigue, pain level, participation level, and general health will be completed by
8 the patient. After completion of these questionnaires, scores will be interpreted by the RP.
9 Based on scoring in both parts of the RP-assessment tool, patients will be categorised by
10 profile, representing the patient's level of disability. In addition to primary and interdisciplinary
11 primary care, the second tool will assist the RP to further differentiate between available
12 secondary or tertiary multidisciplinary rehabilitation programs (Figure 2).
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21 *Integral focus on treatment content and duration: treatment protocols*

22 When the patient receives treatment, an individualised treatment plan based on their current
23 needs will be made. The patient decides the treatment aim when he visits a healthcare
24 professional. In case this is necessary, the practitioner will support the patient in setting
25 functional goals. Protocols will be based on the most recent evidence-based treatment methods
26 such as GA, EXP, and ACT^{35-38 40} and these will be used in all healthcare settings. As these
27 evidence-based methods are developed for secondary and tertiary care, they will be adjusted
28 for primary care. During evaluations in phase 1 and 2, healthcare professionals will be invited to
29 provide feedback on the treatment protocols. As a result, adjustments to the content and
30 duration of treatment protocols will be made if these adjustments are in line with the evidence-
31 based treatment methods.
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40 *Integral focus on self-management: E-health application*

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

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 transmurial 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,	<u>Focus groups and interviews</u> <i>Healthcare professionals</i>	<u>Focus groups and interviews</u> <i>Healthcare professionals</i>	<u>Focus groups and interviews</u> <i>Healthcare professionals</i>

<p>respondents, and outcomes</p>	<ul style="list-style-type: none"> 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 <p><u>Questionnaire</u> <i>Healthcare professionals</i></p> <ul style="list-style-type: none"> Current views and thoughts regarding patients with CMP Referral pattern Patient characteristics 	<ul style="list-style-type: none"> Views on working in NPRL Current experiences (satisfaction) with working in NPRL Implications and recommendations of the implementation strategy for practise Barriers and facilitators 	<ul style="list-style-type: none"> 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 <p><u>Focus group</u> <i>+/- 10 patients</i></p> <ul style="list-style-type: none"> Perceived quality of care Experiences with NPRL Barriers and facilitators <p><u>Questionnaire</u> <i>Healthcare professionals</i></p> <ul style="list-style-type: none"> Referral pattern Patient characteristics
<p><u>Questionnaire start and end of treatment (T0 and T2)</u></p> <p><i>Patients</i></p> <ul style="list-style-type: none"> Health status Quality of care Usability of the SanaCoach Pain Rehabilitation <p><u>Questionnaire after referral (T1)</u></p> <p><i>Patients</i></p> <ul style="list-style-type: none"> Quality and satisfaction with referral and care <p><u>Questionnaire or logbook of treatment</u></p> <p><i>Healthcare specialists</i></p> <ul style="list-style-type: none"> Barriers and facilitators of the treatment protocol per patient <p><u>Notes</u></p> <ul style="list-style-type: none"> Current views regarding NPRL Barriers and facilitators <p>NPRL = Network Pain Rehabilitation Limburg; CMP= chronic musculoskeletal pain</p>			

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3 During the informative meetings and education days, field notes will be made in order to collect
4 information about the views on NPRL and its elements out of the perspectives of the healthcare
5 professionals involved. At the end of each phase, focus groups and/or interviews will take place
6 with (a selection of) the healthcare professionals involved. During the evaluation of phase 1,
7 healthcare professionals will be asked about the barriers and facilitators they perceived while
8 working in NPRL. Therefore, more information will be collected about expectations, views,
9 experiences, and satisfaction. Also, experiences and opinions about the informative meetings
10 and education days will be collected. Healthcare professionals will fill in an electronic
11 questionnaire in phase 1 concerning decision making, treatments, and characteristics of the
12 patients involved in the study. This information will give more insight into potential changes in
13 referral policy between the situation in usual care and the situation within NPRL. Moreover, the
14 questionnaire also asks for knowledge and perspectives regarding patients with CMP.
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24 In phases 2 and 3, more emphasis will be put on the added value of NPRL including barriers
25 and facilitators for implementation. This information will be used for recommendations for
26 practise and future research. Also in these phases, information will be gained about the
27 experiences and satisfaction with NPRL during a focus group with healthcare professionals.
28 Moreover, in phase 3 (transferability), they will fill in an electronic questionnaire concerning
29 decision making, treatments, and characteristics of the patients involved in the study. As part of
30 the evaluation of phase 3, a focus group with a sample of 6 to 10 patients with CMP who are
31 being treated by participating healthcare professionals will take place. During this focus group,
32 the emphasis will be on the satisfaction of care and experiences, leading to barriers and
33 facilitators with NPRL.
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41 Besides this information, the research team will keep up a logbook to get insight into the barriers
42 and facilitators of NPRL. The field notes in this logbook will be the results of discussions with
43 different healthcare professionals, patients, and stakeholders, as well as researchers.
44 Additionally, patients will be asked to complete study-related questionnaires about the quality
45 and their satisfaction with the decision making, treatment and education, and usability of the
46 SanaCoach Pain Rehabilitation in order to further improve different elements of NPRL. Besides
47 this feasibility data, also some questions about their work status, general health, and
48 participation level will be asked as preliminary data on efficiency to objectify the progress of the
49 treatment. They will receive this questionnaire at the start of the treatment (T0) and at the end of
50 the treatment (T2). Patients referred to another healthcare professional will receive an extra
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3 questionnaire after the referral (T1) regarding the quality of and satisfaction with the decision
4 making. Additionally, after completion of the treatment, a small questionnaire or logbook about
5 the treatment of each patient separately must be handed in by the healthcare professionals.
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7 This information will be used to discover barriers and facilitators and desired adjustments of the
8 treatment protocols.
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11 12 **Data Analysis**

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14 In this iterative design with key principles of user-centered design, the results will be gathered in
15 daily practice from the healthcare professional and patient perspective. The results of each
16 phase will be used to adapt the intervention for the next phase. The Consolidated Framework
17 for Implementation Research (CFIR) protocol according to Damschroder *et al*⁵² will be used to
18 develop this feasibility evaluation and analysis plan of the results. This explanatory framework
19 with theory-based constructs and mechanisms will be used to explain whether an
20 implementation may or may not succeed and to identify barriers and facilitators.
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26 All field notes and logbooks will be collected. Additionally, the focus groups and interviews will
27 be audio recorded and transcribed verbatim. Qualitative data will be analysed using the NVivo
28 software (NVivo.version 11.1.0.411) following a directed content analysis method.⁵⁹ The
29 analysis will be deductive (e.g. the identified themes will derive from existing theory). After
30 familiarisation with the data, definitions for the CFIR constructs will be made based on the
31 intervention in collaboration with the project team. Next, the different constructs will be assigned
32 to the fewest codes possible. After developing analytic summaries and matrices, the data will be
33 compared to derive barriers and facilitators. A researcher with expertise in qualitative research
34 without any involvement in the project will peer review the analysis by verification of the analysis
35 of 20% of the interviews and focus groups. Also, a cross-check for interim findings with
36 respondents will be performed.
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46 Quantitative data will be analysed concurrently with the qualitative data. Descriptive statistics
47 will be denoted as mean (standard deviation) or median (range) and number (%) for continuous
48 and categorical data, respectively, with the use of IBM SPSS Statistics 24.
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51 52 **ETHICS AND DISSEMINATION**

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54 Informed consent will be obtained from all participants. Ethical approval for this study was
55 granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133. The results of
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3 this feasibility study will form the base for refinement of NPRL and planning of a large-scale
4 process and effect evaluation on the Quadruple Aim outcomes. Dissemination will include
5 publications and presentations at national and international conferences.
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8 9 **DISCUSSION**

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11 This study will provide insight into the feasibility of NPRL, a transmural integrated healthcare
12 network for CMP rehabilitation. The aim is to provide integrated care for patients with CMP in
13 order to improve their level of functioning despite pain by stimulating a biopsychosocial
14 approach for all involved healthcare professionals. It is expected that the study will provide
15 information on barriers and facilitators, perceived value, acceptability, and implementation
16 strategies for the development, implementation, and transferability for further develop and
17 refinement of the NPRL. If the study results suggest that NPRL is feasible and preliminary
18 outcomes are positive, a large-scale process and effective evaluation of the Quadruple Aim
19 outcomes will be performed.
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27 The process of developing NPRL is in accordance with the Medical Research Council guidance
28 on how to develop and evaluate complex interventions.⁵¹ In the development process, existing
29 evidence together with collected evidence based on the expertise of healthcare professionals
30 was combined to develop the first version of NPRL. This first version of NPRL will be
31 implemented on a restricted scale to test the feasibility. The evidence generated from this
32 feasibility study will not only help to adjust the design and content of NPRL but will also inform
33 future methodological studies on developing and implementing a transmural network in
34 healthcare. It is expected that this bottom-up development in combination with the limited
35 number of participating healthcare professionals will lead to a successful implementation of the
36 network. Nijkrake *et al*⁴³ did indicate this approach as one of the success factors of
37 ParkinsonNet, a successful and cost-effective network in the Netherlands for patients with
38 Parkinson's disease.
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47 In conclusion, there is need for a transmural network in which different healthcare professionals
48 collaborate in providing integrated healthcare for patients with CMP. The aim of NPRL is to
49 improve the level of functioning of individual patients despite pain, experience of care by
50 patients, and work-life satisfaction for physicians and staff, as well as a reduction in costs.
51 Therefore, this feasibility study will be conducted to explore the barriers and facilitators of the
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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

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28 JAMCFV, IPJH, and AJK conceived the original idea and outline of the study, and CL, MEK,
29 IPJH, JAMCFV, and DR contributed to designing the study. JAMCFV, IPJH, and AJK were
30 responsible for developing the intervention. CL was the primary writer of the study protocol in
31 collaboration with MEK and IPJH. All authors discussed and commented on draft versions and
32 approved the final version.
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10 11 **ETHICS APPROVAL**

12 Approval from the Medical Ethics Committee Z, the Netherlands, METC 17-N-133.
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29 **Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg**
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32 **Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain**
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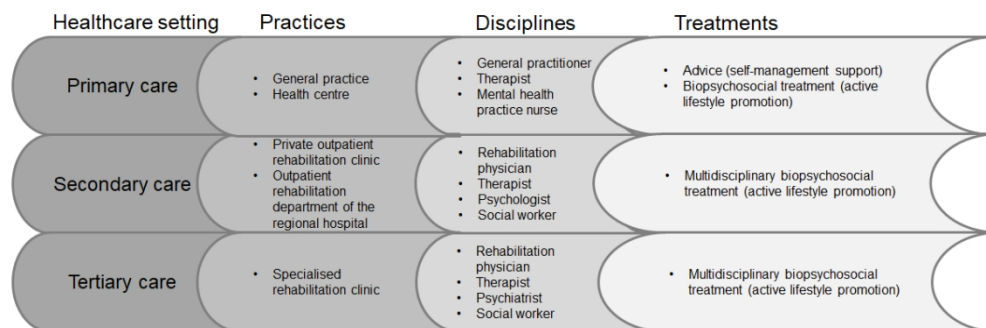


Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

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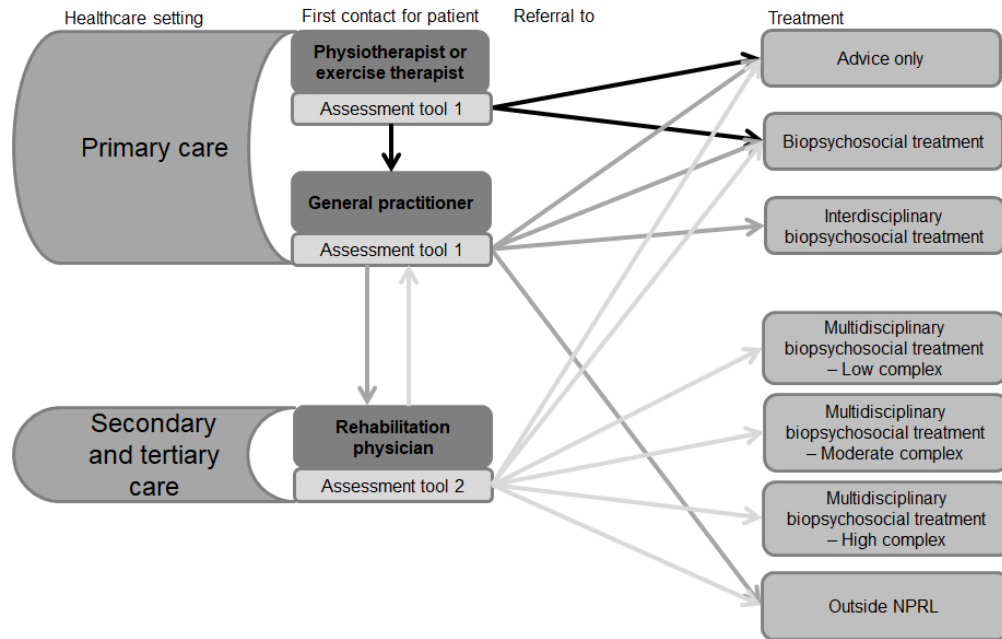


Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

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Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol

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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 treatment¹⁶, 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

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3 selections vary among healthcare professionals, which may result in less efficient care for
4 patients with CMP.
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8 Besides the different perspectives regarding CMP, general practitioners (GPs) in primary care
9 and rehabilitation physicians (RPs) in secondary and tertiary care refer patients mostly based on
10 their anamnesis and clinical experience. However, it appears to be difficult for GPs to identify
11 the impact of all psychosocial factors on chronic low back pain patients, one of the most
12 frequently encountered CMP problems.¹⁹ Recently, different tools became available to support
13 GPs in the decision-making process concerning (initial) treatment options for patients with
14 chronic low back pain and fibromyalgia, especially focusing on the impact of psychosocial
15 components.²⁰⁻²³ However, these decision-making tools are not implemented in daily care yet in
16 the Netherlands. In the Dutch health care system, patients with moderate to severe levels of
17 disability and associated influencing psychosocial factors are seen by a RP. To support decision
18 making by RPs, an evidence-based objective tool to classify patients objectively and
19 transparently for a specific treatment is needed. Earlier studies have shown that the interrater
20 reliability of the method currently used by RPs to classify the level of disability (WPN
21 classification) is at least questionable.^{24 25} In addition, healthcare professionals indicate a lack of
22 overview regarding the complete supply of treatment methods, resulting in inadequate
23 referrals.²⁶
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35 Ideally, after assessing the level of disability, the patient receives a treatment matching the
36 complexity of the pain problem in line with the biopsychosocial profile. As in most situations, no
37 cure for CMP is possible and evidence-based treatments are multicomponent pain rehabilitation
38 with a biopsychosocial focus on being active and living a valuable life despite pain.^{5 27-29} In
39 primary care physiotherapy, cognitive-behavioural interventions and interventions focusing on
40 biopsychosocial factors have shown long-term effects on patient outcomes.^{30 31} Moreover, even
41 positive effects were found when advice combined with pain education alone is given by GPs or
42 therapists to patients with CMP.³²⁻³⁴ In secondary and tertiary care, multidisciplinary pain
43 rehabilitation programs with physical, psychological, and/or social/work related components, like
44 Acceptance Commitment Therapy (ACT), Graded Activity (GA), and Exposure in vivo (EXP),
45 are more effective than treatments focusing on one aspect of the biopsychosocial model for
46 decreasing pain and disability in patients with disabling chronic low back pain.³⁵⁻⁴⁰
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3 Despite this knowledge of the effective components of multidisciplinary rehabilitation programs,
4 a wide variety of treatment approaches in various dosages are currently applied in regular
5 rehabilitation programs in different private and public rehabilitation centres.⁴¹ To overcome the
6 different points of view as well as the lack of overview about treatment options, objective
7 decision-making tools, and variety of treatments in the Netherlands, a national care standard for
8 chronic pain was presented in 2017.¹¹ In this standard, a matched and person-centred care
9 approach for patients with CMP was proposed.⁴²
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16 To implement care as part of the national care standard, a transmurals network could be
17 designed in which different healthcare professionals collaborate in providing person-centred
18 rehabilitation care. Recently, different transmurals integrated care health networks, for example
19 for Parkinson's disease and palliative care, have been successfully developed and implemented
20 in the Netherlands.^{43 44} In line with these findings, a transmurals pain rehabilitation network can
21 provide a shared vision regarding CMP, including early recognition of subacute pain patients
22 followed by suitable person-centred treatment and referral, is supposed to improve patients'
23 levels of functioning despite pain and to prevent medical shopping of patients with CMP.¹¹ It
24 should have an unambiguous view, matched care, and a person-centred approach with
25 guidelines for referral and treatment, coordination, and a continuous focus on improvement of
26 care to increase the effectiveness, quality, and efficiency of healthcare for patients with CMP.⁴⁵
27 This approach fits with the advice of the World Health Organisation to focus on stimulating
28 functioning when designing rehabilitation care.^{46 47}
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38 The Network Pain Rehabilitation Limburg (NPRL), a transmurals healthcare network for CMP
39 rehabilitation, will be designed to ultimately fulfil the Quadruple Aim in the province of Limburg,
40 the Netherlands.^{48 49} NPRL provides integrated care for patients with CMP in order to improve
41 their level of functioning despite pain by stimulating a biopsychosocial approach for all involved
42 healthcare professionals. As a first step a feasibility study will be performed. This study aims to
43 provide insight into the barriers and facilitators, perceived value, acceptability, and
44 implementation strategies for the development, implementation, and transferability of the NPRL.
45 This paper describes the study protocol of the feasibility study of NPRL for adults with CMP.
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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 framework⁵² 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.	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.
Willingness to attend the meetings and to implement the different elements of NPRL.	Are not able to implement the protocols or assessment tool of NPRL in their own practice.
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	
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.

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.	
Having musculoskeletal pain that is (suspected to be) chronic.	Any suspicion of a (underlying) psychiatric disease, for which psychiatric treatment is better suited, according to the expert opinion of the GP and RP.
Treatment aim of the patient is to improve functioning despite the pain.	Pregnancy.
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

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3 healthcare professionals. This should accomplish the Quadruple Aim: improvement of CMP
4 patient functioning, experiences of care, and work life satisfaction of physicians and staff, as
5 well as a reduction of healthcare costs of patients with CMP.
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9 Each patient will receive the treatment needed to reach his/her optimal level of functioning. In
10 order to reach this, a matched care approach will be used for every individual patient.
11 Depending on the level of disability and biopsychosocial factors involved, this will either include;
12 1) education only and no further treatment, 2) monodisciplinary treatment in primary care, 3)
13 multidisciplinary treatment in primary care (collaboration between GPs, primary care therapists,
14 and mental health practice nurses in assessing and treating patients with CMP who need
15 mental support besides physical exercise), 4) interdisciplinary treatment in secondary or 5)
16 interdisciplinary treatment in tertiary care. Collaboration will be supported by facilitating
17 communication between patients and all healthcare professionals involved in the trajectory of an
18 individual patient by E-health.⁵⁶ In addition, the collaboration between healthcare professionals
19 in different practices and organisations will be further supported by informative meetings and
20 education days. All healthcare professionals with different specialisms will participate together in
21 the meetings and education days. This ensures a common understanding of the
22 biopsychosocial approach and rehabilitation treatment options. In order to facilitate this in daily
23 practice, the following elements are integrated in NPRL:
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34 *Integral focus on assessment and referral: assessment tools*

35 To support the healthcare professionals in their decision making for problem mapping and
36 treatment selection, two evidence-based objective assessment tools will be used. These tools
37 will support the assessment of the complexity of the pain problem; one tool for GPs and primary
38 care therapists and one tool for RPs. The assessment tool for primary care is based on the Start
39 Back Tool²⁰ and will help to advise patient treatment matched to the patient's biopsychosocial
40 profile. The options are: advice only, treatments in primary care, or for decision making by a RP
41 (Figure 2). The GP can also decide to advise patients for a treatment outside NPRL
42 (psychiatrist, specific healthcare specialist, etc.). Since 2006, patients in the Netherlands can
43 visit a primary care therapist without a referral of a GP,⁵⁷ so these therapists will also use this
44 assessment tool. In this situation, a primary care therapist of NPRL will advise the patient to visit
45 the GP for additional assessment and referral if needed as the GP is the gatekeeper to
46 secondary and tertiary care.
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3 When a patient visits a RP, the assessment tool for specialised rehabilitation care is used for
4 decision making. This tool will assess the patient's view as well as the RP's view of the
5 biopsychosocial problem and consists of two parts. The first part will guide the anamnesis of the
6 RP and is based on two different ways to score disability related complexity, namely the Case
7 Complexity Index and INTERMED method.^{25 58 59} First, a standardised scoring method for
8 assessing the biopsychosocial profile and care for the past and current situations will be used
9 by the RP. Second, a set of CMP related questionnaires assessing anxiety, depression,
10 catastrophising, fatigue, pain level, participation level, and general health will be completed by
11 the patient. After completion of these questionnaires, scores will be interpreted by the RP.
12 Based on scoring in both parts of the RP-assessment tool, patients will be categorised by
13 profile, representing the patient's level of disability. In addition to primary and interdisciplinary
14 primary care, the second tool will assist the RP to further differentiate between available
15 secondary or tertiary multidisciplinary rehabilitation programs (Figure 2).
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Integral focus on treatment content and duration: treatment protocols

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26 When the patient receives treatment, an individualised treatment plan based on their current
27 needs will be made. The patient decides the treatment aim when he visits a healthcare
28 professional. In case this is necessary, the practitioner will support the patient in setting
29 functional goals. Protocols will be based on the most recent evidence-based treatment methods
30 such as GA, EXP, and ACT^{35-38 40} and these will be used in all healthcare settings. As these
31 evidence-based methods are developed for secondary and tertiary care, they will be adjusted
32 for primary care. During evaluations in phase 1 and 2, healthcare professionals will be invited to
33 provide feedback on the treatment protocols. As a result, adjustments to the content and
34 duration of treatment protocols will be made if these adjustments are in line with the evidence-
35 based treatment methods.
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Integral focus on self-management: E-health application

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45 All professionals and patients participating in the NPRL will make use of an E-health application:
46 SanaCoach Pain Rehabilitation.⁵⁶ Also, primary care patients who receive 'advice only' can
47 make use of this SanaCoach Pain Rehabilitation. The coach has different functions and goals in
48 the treatment process. The primary goal is to support self-management. The main function of
49 the coach is to provide pain education based on the education modules. Different eLearning
50 modules are developed for the patients in order to teach them about the biopsychosocial
51 aspects of pain. Furthermore, diaries are integrated into the coach in which patients can give
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3 feedback on changes in pain intensity, level of activity over time, and the interrelation between
4 these variables. Moreover, healthcare professionals can use scores from these diaries to adjust
5 treatment to individual patients. The coach also consists of a chat function between the patient
6 and healthcare professionals to ensure short communication lines. All healthcare professionals
7 involved in the care process of a patient have access to this chat function with that patient.
8 Additionally, the assessment tool for primary care is integrated, which makes these results
9 available for all involved healthcare professionals. For this study, the questionnaires for patients
10 are also available via the coach. Based on the level of complexity of disability, the functions in
11 the SanaCoach Pain Rehabilitation will be adjusted to the patient, such as the number of diaries
12 and level of education.
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20 **Patient and Public Involvement**

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

37 In this study, the feasibility of the development, implementation, and transferability of NPRL for
38 adults with CMP will be investigated. Therefore, different data collection techniques such as
39 observations, interviews, focus groups, and questionnaires will be combined to get more insight
40 into the barriers and facilitators of NPRL (Table 3).
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47 Phase	1	2	3
48 Time period	October 2017–February 2018	February 2018–June 2018	June 2018–October 2018
49 Goal project	50 Exploration of context will take 51 place in order to develop the 52 design of the NPRL and to 53 educate the involved healthcare 54 professionals.	55 Specification of the content to 56 adjust the design of the 57 transmurial network to daily 58 practise.	59 Organisation of care in daily practise 60 and barriers and facilitators for implementation in other practices and organisations.

1 2 3 4 5 6	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.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36	Data collection method, respondents, and outcomes	<p><u>Focus groups and interviews</u></p> <p><i>Healthcare professionals</i></p> <ul style="list-style-type: none"> 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 <p><u>Questionnaire</u></p> <p><i>Healthcare professionals</i></p> <ul style="list-style-type: none"> Current views and thoughts regarding patients with CMP Referral pattern Patient characteristics 	<p><u>Focus groups and interviews</u></p> <p><i>Healthcare professionals</i></p> <ul style="list-style-type: none"> Views on working in NPRL Current experiences (satisfaction) with working in NPRL Implications and recommendations of the implementation strategy for practise Barriers and facilitators 	<p><u>Focus groups and interviews</u></p> <p><i>Healthcare professionals</i></p> <ul style="list-style-type: none"> 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 <p><u>Focus group</u></p> <p><i>+/- 10 patients</i></p> <ul style="list-style-type: none"> Perceived quality of care Experiences with NPRL Barriers and facilitators <p><u>Questionnaire</u></p> <p><i>Healthcare professionals</i></p> <ul style="list-style-type: none"> Referral pattern Patient characteristics
37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56		<p><u>Questionnaire start and end of treatment (T0 and T2)</u></p> <p><i>Patients</i></p> <ul style="list-style-type: none"> Health status Quality of care Usability of the SanaCoach Pain Rehabilitation <p><u>Questionnaire after referral (T1)</u></p> <p><i>Patients</i></p> <ul style="list-style-type: none"> Quality and satisfaction with referral and care <p><u>Questionnaire or logbook of treatment</u></p> <p><i>Healthcare specialists</i></p> <ul style="list-style-type: none"> Barriers and facilitators of the treatment protocol per patient <p><u>Notes</u></p> <ul style="list-style-type: none"> Current views regarding NPRL Barriers and facilitators 		

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

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8 During the informative meetings and education days, field notes will be made in order to collect
9 information about the views on NPRL and its elements out of the perspectives of the healthcare
10 professionals involved. At the end of each phase, focus groups and/or interviews will take place
11 with (a selection of) the healthcare professionals involved. During the evaluation of phase 1,
12 healthcare professionals will be asked about the barriers and facilitators they perceived while
13 working in NPRL. Therefore, more information will be collected about expectations, views,
14 experiences, and satisfaction. Also, experiences and opinions about the informative meetings
15 and education days will be collected. Healthcare professionals will fill in an electronic
16 questionnaire in phase 1 concerning decision making, treatments, and characteristics of the
17 patients involved in the study. This information will give more insight into potential changes in
18 referral policy between the situation in usual care and the situation within NPRL. Moreover, the
19 questionnaire also asks for knowledge and perspectives regarding patients with CMP.
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28 In phases 2 and 3, more emphasis will be put on the added value of NPRL including barriers
29 and facilitators for implementation. This information will be used for recommendations for
30 practise and future research. Also in these phases, information will be gained about the
31 experiences and satisfaction with NPRL during a focus group with healthcare professionals.
32 Moreover, in phase 3 (transferability), they will fill in an electronic questionnaire concerning
33 decision making, treatments, and characteristics of the patients involved in the study. As part of
34 the evaluation of phase 3, a focus group with a sample of 6 to 10 patients with CMP who are
35 being treated by participating healthcare professionals will take place. During this focus group,
36 the emphasis will be on the satisfaction of care and experiences, leading to barriers and
37 facilitators with NPRL.
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45 Besides this information, the research team will keep up a logbook to get insight into the barriers
46 and facilitators of NPRL. The field notes in this logbook will be the results of discussions with
47 different healthcare professionals, patients, and stakeholders, as well as researchers.

48 Additionally, patients will be asked to complete study-related questionnaires about the quality
49 and their satisfaction with the decision making, treatment and education, and usability of the
50 SanaCoach Pain Rehabilitation in order to further improve different elements of NPRL. Besides
51 this feasibility data, also some questions about their work status, general health, and
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3 participation level will be asked as preliminary data on efficiency to objectify the progress of the
4 treatment. They will receive this questionnaire at the start of the treatment (T0) and at the end of
5 the treatment (T2). Patients referred to another healthcare professional will receive an extra
6 questionnaire after the referral (T1) regarding the quality of and satisfaction with the decision
7 making. Additionally, after completion of the treatment, a small questionnaire or logbook about
8 the treatment of each patient separately must be handed in by the healthcare professionals.
9 This information will be used to discover barriers and facilitators and desired adjustments of the
10 treatment protocols.
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16 17 **Data Analysis**

18 In this iterative design with key principles of user-centered design, the results will be gathered in
19 daily practice from the healthcare professional and patient perspective. The results of each
20 phase will be used to adapt the intervention for the next phase. The Consolidated Framework
21 for Implementation Research (CFIR) protocol according to Damschroder *et al*⁵³ will be used to
22 develop this feasibility evaluation and analysis plan of the results. This explanatory framework
23 with theory-based constructs and mechanisms will be used to explain whether an
24 implementation may or may not succeed and to identify barriers and facilitators.
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31 All field notes and logbooks will be collected. Additionally, the focus groups and interviews will
32 be audio recorded and transcribed verbatim. Qualitative data will be analysed using the NVivo
33 software (NVivo.version 11.1.0.411) following a directed content analysis method.⁶⁰ The
34 analysis will be deductive (e.g. the identified themes will derive from existing theory). After
35 familiarisation with the data, definitions for the CFIR constructs will be made based on the
36 intervention in collaboration with the project team. Next, the different constructs will be assigned
37 to the fewest codes possible. After developing analytic summaries and matrices, the data will be
38 compared to derive barriers and facilitators. A researcher with expertise in qualitative research
39 without any involvement in the project will peer review the analysis by verification of the analysis
40 of 20% of the interviews and focus groups. Also, a cross-check for interim findings with
41 respondents will be performed.
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50 Quantitative data will be analysed concurrently with the qualitative data. Descriptive statistics
51 will be denoted as mean (standard deviation) or median (range) and number (%) for continuous
52 and categorical data, respectively, with the use of IBM SPSS Statistics 24.
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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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AUTHORS CONTRIBUTIONS

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37 JAMCFV, IPJH, and AJK conceived the original idea and outline of the study, and CL, MEK,
38 IPJH, JAMCFV, and DR contributed to designing the study. JAMCFV, IPJH, and AJK were
39 responsible for developing the intervention. CL was the primary writer of the study protocol in
40 collaboration with MEK and IPJH. All authors discussed and commented on draft versions and
41 approved the final version.
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48 The funding bodies had no role in the design of the study or writing the manuscript
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51

COMPETING INTERESTS

52
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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

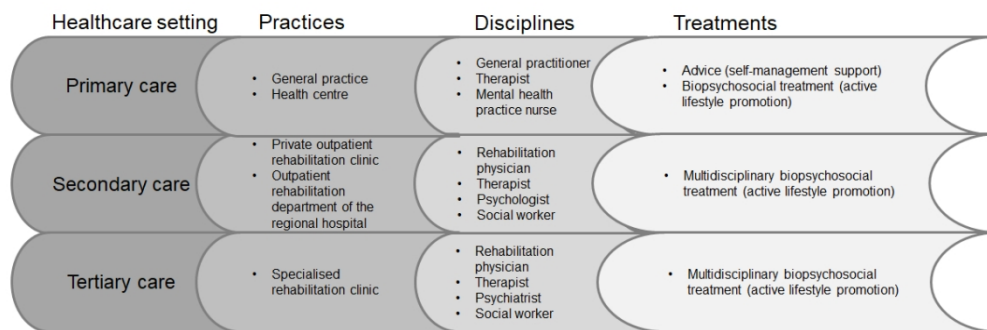


Figure 1 Construction of the health care system in Network Pain Rehabilitation Limburg

102x34mm (300 x 300 DPI)

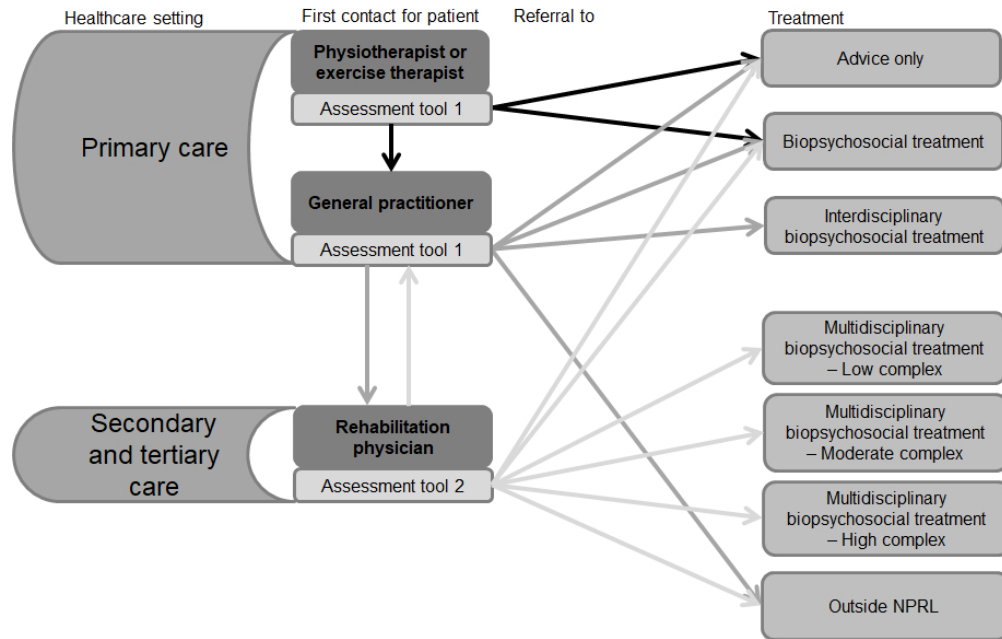


Figure 2 First patient contact and referral options per healthcare setting and discipline. NPRL = Network Pain Rehabilitation Limburg

77x49mm (300 x 300 DPI)