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TITLE

An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: a study protocol for a registry-based multicentre randomized controlled trial.

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ABSTRACT

Introduction

Chronic musculoskeletal pain (CMSP) severely affects the individual's quality of life, functioning and ability to work, and comes with significant societal costs for sick leave and productivity loss. After rehabilitation, patients with CMSP often experience lack of support when responsibility for the return to work (RTW) process is taken over by the employer. Therefore, we aim to evaluate the effectiveness of a digital support (SWEPPE) for promoting a sustainable RTW for persons with CMSP and to facilitate the employers' supportive role and responsibilities in the process. The features in SWEPPE are anchored in earlier research.

Methods and analysis

In this registry-based multicentre randomized controlled trial, 360 patients with CMSP will be randomised to either receive the smart phone application SWEPPE (n=180) or to a control group (n=180). The intervention group will use SWEPPE for one year and the control group will not receive any intervention for RTW. Participants will be recruited from approximately ten specialist and primary care level units connected to the Swedish National Quality Registry for Pain Rehabilitation (SQRP) providing Interdisciplinary Pain Rehabilitation programs (IPRP) for CMSP. Eligibility criteria are age 18-65 years and a need for support in RTW or continued support at work for creating a sustainable work situation. Baseline data will be collected when the participants have completed the IPRP. Final assessment will be performed after twelve months. The primary outcome will be number of days with sickness cash benefit. Secondary outcomes and explanatory variables including important domains affected by CMSP such as health-related quality of life, functioning and work ability will be collected.

Ethics and dissemination

The Swedish Ethics Review Board approved the study (Dnr 2020-01593, Dnr 2021-01854). The study findings will be disseminated through publication, national and international conferences, and meetings to be available for patients, health care providers or stakeholders.

Registration details

ClinicalTrials.gov registration number NCT05058547 (Pre-results, not yet recruiting). Version 1. 27 September 2021.

Strengths and limitations of this study

- Using a shared smartphone application (SWEPPE) to facilitate self-management, and communication and collaboration between persons with CMSP and their employer during the return-to-work process is a novel intervention with the potential to support a sustainable work situation.
- A registry-based multicentre randomized trial will provide rigorous evidence regarding clinical effectiveness of the intervention
- In this trial the primary and secondary outcomes are based on recommendation from the Swedish Social Insurance Agency regarding outcomes for return-to-work which ensures capturing relevant aspects of sick-leave.
- It is important to be aware of the risk for selection bias due to patients' self-confidence or willingness to use smartphone applications.

Key words: clinical trials, musculoskeletal disorders, pain management, rehabilitation medicine.

INTRODUCTION

Chronic musculoskeletal pain (CMSP) (i.e., pain duration >3 months) such as chronic neck/shoulder and back pain or generalized widespread pain (including fibromyalgia (FM)) has a prevalence from 10.4%[1] to 20% among adults.[1-3] CMSP negatively impact quality of life, functioning and the ability to work.[2] CMSP also causes considerable costs for the society in terms of sick leave expenses and loss of productivity.[1,2,4-8] Many patients with CMSP participate in Interdisciplinary Pain Rehabilitation Programs (IPRP) to enable self-management of pain and increase the ability to work.[9-11] After completing a rehabilitation program for persons with CMSP the patients can experience lack of support when the employer takes over the responsibility for the return to work (RTW) process.[12] The employers have a crucial role in a successful RTW process[13-15] but may lack knowledge regarding chronic pain and its consequences[16] and how to support the employee with CMSP in the best way during RTW.[12] Barriers for RTW for persons with CMSP are for example lack of support at the workplace, not finding the right fit between the employee's physical abilities and work tasks, or problems with relationships with supervisors or coworkers.[17,18] Key factors for a successful RTW are communication and collaboration between the employer and the employee.[19] Further, employers also need to use active listening skills which means enhancing conversation using open questions and demonstrate effective listening by summary statements.[20] To facilitate the important interaction between employer and employee[21,22] a shared smartphone application may be a tool for increasing a successful outcome in the RTW process.

A primary aim of IPRP is to reach RTW.[9,10] To fill the gap patients with CMSP experience when the RTW process continues after completing IPRP,[12] the digital support A Sustainable WorkEr- digital support for Persons with chronic Pain and their Employers

(SWEPPE) was systematically developed.[23] SWEPPE is a smartphone application for persons with CMSP with the possibility to invite and share information with the employer. SWEPPE was developed by a multidisciplinary project team consisting of health care researchers, a user representative, and a software team. A user-centred agile approach[24] was used with continuous involvement of two reference groups consisting of persons with CMSP and employers providing feedback on the functions and the interface in SWEPPE. Smart phone applications as digital support has shown promising results for persons with chronic pain[25-27] and can be helpful especially in an out-clinic setting.[28] They are easily accessed, can enable management of the condition[29], and reduce pain interference.[30] An evidence-based content and a simple design are key parts for providing a successful digital support.[31] Information provided via apps can improve the level of knowledge among patients.[32] Focusing on self-management and empowerment are other important parts of successful digital support.[32] Self-management among persons with chronic pain include self-monitoring[31,34] and pain education in relation to the neuroscience of pain, medication, stress, depression, and sleep management.[35] Self-monitoring can contribute to learning about consequences of actions and behaviours in daily life.[36] This can lead to making changes in daily activities and a sense of control and motivation for continued use of self-management strategies.[37,38]

Although positive effects of digital support have been shown there are limitations related to low overall quality of smartphone apps for CMSP and lack of rigorous assessment of their effectiveness.[39,40] SWEPPE was found to be useful for self-management for persons with CMSP and for supporting employers, with relevant content, logical and easy to use, and with a nice and clean interface.[23] However, the clinical effectiveness of SWEPPE as a digital support for employees and employers to decrease sick leave in persons with CMSP need to be

investigated. The aim of this paper is to report the study design, aim, outcome assessment and procedures for a planned registry based multicentre randomized controlled trial (R-RCT). The overall objective of the R-RCT is to evaluate the clinical effectiveness of a digital support (SWEPPE) for promoting a sustainable RTW for persons with CMSP and to facilitate the employers' supportive role and responsibilities in the process.

METHODS AND ANALYSIS

Trial design and study setting

This protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[41] The R-RCT will conform with the Consolidated Standards of Reporting Trials (CONSORT).[42,43] This is a two-armed multi-centre registry-based randomized controlled trial. The study will be conducted in specialized and primary level clinics in Sweden providing IPRP and reporting to the Swedish National Quality Registry for Pain Rehabilitation (SQRP). Approximately 360 (n=180 intervention group, n=180 control group) patients with CMSP will be recruited to participate in the study. Study design and enrolment details is presented in figure 1. A completed SPIRIT checklist and the World Health Organization (WHO) trial registration data set[44] can be found in the additional files (S1, S2).

Patient and public involvement

Patients with CMSP were not involved in formulating the research question or setting the research design for the planned study. However, patients with CMSP who had undergone IPRP and employers participated in design and development of the intervention, the digital smart phone application SWEPPE. In addition, a user representative from the Swedish

Rheumatism Association participated as a research partner in the development process of SWEPPE.[23]

Eligibility criteria

Patients entering the trial must have completed an IPRP for CMSP. The principal inclusion criteria for IPRP in Sweden are persistent or intermittent pain lasting ≥3 months, pain affecting daily activities to a large extent, completed systematic assessment and non-pharmacological optimization is completed, and screening for psychosocial risk factors and differential diagnosis completed. In this trial, patients with CMSP will be recruited based on the following criteria: age between 18-65 years, completed IPRP at any of the participating units, having an employment to return to after IPRP or having returned to work but need continued support for creating a sustainable work situation after IPRP. Patients who have completed IPRP but are unemployed or unable to return to work will be excluded.

Recruitment

Units

Units in specialized and primary care level in Sweden providing IPRP based on individualized needs and who are reporting to the SQRP will be included in the study. Two of the researchers (CT, MB) will invite healthcare staff (primarily occupational therapists and physiotherapists but also psychologist/counselor, nurses etc.) at the participating units to online digital information meetings to present the study. A contact person will be appointed at each unit. One researcher (CT) will have continuous contact with the participating units regarding the planned IPRP groups and screening of eligible patients for the study.

Participants

Patients with CMSP participating in IPRP at any of the study units and who is meeting the inclusion criteria will be asked to take part in the study. The recruitment process will start with screening of eligible participants in the IPRP groups. Screening of eligible participants will be performed by the unit coordinators and health care staff providing the IPRP and will be discussed with one of the researchers (CT). The health care staff will collect contact details and information regarding previous sick leave during one year before starting IPRP from the eligible participants and ask for permission to provide this information to the researchers. The participants will at the end of IPRP receive verbal and written information about the study from one of the researchers (CT) and written informed consent will be collected for those willing to participate in the study. The participants will receive detailed information regarding voluntary participation and the right to withdraw from the study at any time.

Sample size

The null hypothesis in this trial is that there will be no difference between the intervention group and the control group concerning the primary outcome sick leave. Based on previous research regarding sick leave[45,46] and the inclusion of participants with the goal to RTW, an estimated difference between the groups of 20 net days and an effect-size of 0.333 was set for rejection of the null hypothesis. To detect this difference with a power of 80% and a significance level of 0.05 a total sample size of approximately 300 participants (150/group) are needed. With an allowance for 20% of participants lost to follow-up we aim to recruit a total sample size of 360 participants (n=180 intervention, n=180 control). To reach the target sample size, participants will be recruited from multiple special and primary care level health care providing IPRP for patients with chronic pain.

Allocation/Randomization

The unit of randomization will be the individual participants who have approved to participate in the study. One of the researchers (CT) will enrol and randomize participants who have given informed consent to participate in the study to either the intervention or control group. As sick leave history is a strong predictor for future sick leave[47] participants will be stratified based on self-reported number of sick leave days during the year before IPRP. Participants will be divided in high (total number of gross sick leave days ≥ 70) or low sick leave absence[47] and then randomized to intervention or control group. Allocation of the participants to intervention or control group will be conducted using a block randomization design with varying block sizes of 2-6.[48-50] The allocation sequence will be computer generated and sealed sequentially numbered opaque sealed envelopes will be prepared by one of the researchers (GL).

Blinding

Due to the nature of the intervention the participants will not be blinded to group allocation. As randomization to intervention or control group is performed at the completion of IPRP the participants will not have further contact with the health care staff responsible for IPRP or other patients. However, the participants will also be instructed by the unit coordinator not to reveal their group allocation to the health care staff responsible for IPRP or other patients if they would have further contact.

Intervention

Participants randomized to the intervention group will receive the smartphone application SWEPPE to use as a digital support during the RTW process. SWEPPE consist of six modules to support self-management:[33] the action plan, daily self-rating of health aspects, self-monitoring graphs of health aspects and goals, the coach, the library, and shared

information with the employer. The action plan includes setting a work-related goal, identification of barriers for RTW, strategies to handle the barriers, identification of support needed from the employer, and weekly evaluation. SWEPPE address pain education[35] and the library provides evidence-based information about CMSP, self-management strategies, and information and tools for RTW.

The intervention starts after completed IPRP with self-rating of work conditions and goal setting in SWEPPE. The participants will use SWEPPE for 12 months. Data registered in SWEPPE by the participant about their goal, work condition and self-rating will be stored in the application and used for self-monitoring and visualizing progress for the participant. The participant invites his/her employer/employers to access the web application SWEPPE depending on what information the participant wants to share with the employer. The employer will receive e-mail reminders to use SWEPPE.

Control

Participants randomized to the control group will follow the regular procedure at any specific unit. As there is no standardized intervention for RTW after IPRP, that will mean that the participants follow their planned RTW process without further support from the IPRP team. However, the patient can initiate and seek other types of health care or support during their RTW process based on their needs.

Outcomes

Outcome assessments in the present trial are intended to capture the complexity of pain[51] based on the biopsychosocial model[52] namely medical, psychological and social (total life situation) factors impacting on the work situation. It has been recommended to include

multiple outcomes in clinical trials for persons with CMSP to capture important domains affected by symptoms such as functioning and health-related quality of life.[53,54]

The primary and secondary outcomes are collected for evaluation of the clinical effectiveness of SWEPPE, and the complementary variables will be collected based on their effect on the outcome. Personal characteristics of the participants will be collected from the SQRP for specialist and primary care respectively and from supplementary questions regarding sex, age, education, currently working/studying (yes, no), work importance in addition to the importance of income (Five alternatives: 1) Very important, 2) Important, 3) Partially important, 4) Hardly no importance, or 5) No importance), diagnosis and pain duration, sick leave during one year before IPRP, and type of work.

Primary outcomes

Primary outcome is days with sickness cash benefit measured according to the Swedish Social Insurance Agency's (SSIA) proposal of outcome measures of return to work:[55]

- Number of gross and net days with sickness cash benefit during the follow-up period (mean and median values).

Secondary outcomes

Secondary outcomes will be collected from SSIA, the SQRP for specialist and primary care respectively, supplementary questionnaires and SWEPPE. An overview of the outcome assessments and data sources is presented in table 1.

Table 1. Overview of the study period, measurement time points (t), primary and secondary outcome assessments and explanatory variables, and data sources *(italics)*.

	Study period			
Time point	**Enrollment**	**Allocation**	**Post-allocation**	
	$-t_1$	**0**	**Baseline**	**t_1**
Enrollment	X			

Eligibility screen	X			
Written and verbal study information	X			
Informed consent	X			
Allocation/randomization		X		
Interventions				
Intervention, SWEPPE (12 months)			X	X
Control (12 months)			X	X
Outcome assessments				
Personal characteristics				
Sex, age, (*SQRP sc and pc*)			X	
Education *(SQRP sc and pc)*			X	
Employment, work importance and type of work *(SQRP sc, supplementary questions for pc)*			X	
Diagnosis, pain duration *(SQRP sc and pc)*			X	
Sick leave during one year before IPRP (*supplementary questionnaire)*			X	
Primary outcomes				
Number of gross and net days with sickness cash benefit during the follow up period (*SSIA*)			X	X
Secondary outcomes				
Return to work (partially or full time) every month (*SSIA*)			X	X
Number of sick-leave spells (per month) (*SSIA*)			X	X
Proportions of a group who returns to full- or part-time work (per month) (*SSIA*)			X	X
Number of days in work before new sick leave during study period (*SSIA*)			X	X
Proportion of a group back to work >28 days (full- or part time) before a new sick-leave spell occurs (*SSIA*)			X	X
Number of sick-leave spells during study period (*SSIA*)			X	X
Length of total sick leave during study period (*SSIA*)			X	X
Pain intensity (last 7 days), NRS (*SQRP sc and pc*)			X	X
Consequences of pain on daily life, MPI-S *(SQRP sc and pc)*			X	X
Overall emotional distress, HADS *(SQRP sc and pc)*			X	X
Physical and mental health, RAND-36, *(SQRP sc, supplementary questionnaire for pc)*			X	X
Goal fulfilment and satisfaction (*supplementary questionnaire)*			X	X
Explanatory variables				
Self-reported fatigue (last 7 days), NRS *(supplementary question)*			X	X
Self-reported level of sleep disturbance, ISI *(SQRP sc, supplementary questionnaire for pc)*			X	X
Self-reported fear of movement, TSK *(SQRP sc, supplementary questionnaire for pc)*			X	X
Self-reported physical activity, *(SQRP sc, supplementary questionnaire for pc)*			X	X
Pain catastrophizing, PCS (*SQRP sc and pc*)			X	X
Perceived work ability, WAI (*SQRP sc and pc*)			X	X
Self-reported demands, control, and support at the workplace, DCSQ *(supplementary questionnaire)*			X	X
Physical work environment *(supplementary questionnaire)*			X	X
Perceived life Satisfaction, LiSat (*Optional questionnaire in SQRP for sc units, supplementary questionnaire for sc units not using it and for pc units*)			X	X

Self-reported work situation during the study period *(supplementary questions)*			X	X
Self-reported workload during the study period *(supplementary questions)*			X	X

Abbreviations: -t^1 = pre recruitment period, t^1 = completed study period and follow-up 12 months after completed interdisciplinary pain rehabilitation program. SQRP= Swedish national Quality Registry for Pain rehabilitation. Sc=specialist care level. Pc=primary care level. NRS = Numeric Pain/Fatigue Rating Scale. MPI-S = Multidimensional Pain Inventory Swedish version. HADS = Hospital anxiety and Depression Scale. TSK = Fear-avoidance Tampa scale for Kinesiophobia. SSIA = Swedish Social Insurance Agency. PCS = Pain Catastrophizing Scale. WAI = Work Ability Index. DCSQ = The Swedish Demand-Control-Support Questionnaire. LiSat = Life Satisfaction Scale.

Secondary outcomes from SSIA:

- Frequencies of individuals in a group who return to full- or part-time work
- Number of sick-leave spells (per month).
- Proportions of a group who returns to full- or part-time work (per month).
- Number of days at work before a new sick-leave spell >14 days occurs (in current diagnosis and in total for all diagnoses).
- Proportions of a group who is back to work >28 days (full- or part time) before a new sick-leave spell occurs.
- Number of new sick-leave spells during the study period.
- Duration of new sick-leave spells per person (gross and net days).[55]

Secondary outcomes from SQRP for specialist and primary care, and supplementary questionnaires:

- Pain intensity during the last seven days estimated with the Numeric Pain Rating Scale (NRS, 0-10).[56]
- Consequences of pain on daily life measured with the Multidimensional Pain Inventory Scale Swedish version, section 1 and 2 (MPI-S, 0 - 6).[57,58]
- Overall emotional distress assessed with the Hospital Anxiety and Depression scale (HADS).[59-61]
- Health related quality of life measured with the RAND-36 health survey.[60,62-64]

- Goal fulfilment inspired by the Canadian Occupational Performance Measure (COPM).[65] The participants will at baseline be asked to report their work-related goal of full- or part-time work for the coming twelve months and rate their present goal fulfilment and satisfaction on a scale ranging from 0, equalling 'far from reaching my goal'/'not satisfied at all', to 10, equalling 'my goal is fulfilled'/'very satisfied'. At twelve months they will be asked to rate their goal fulfilment and satisfaction again.

Explanatory variables

The following explanatory variables, consistent with a biopsychosocial perspective, will be collected from SQRP for specialist and primary care, and supplementary questionnaires:

- Self-reported fatigue during the last seven days estimated with the Numeric Fatigue Rating Scale (0-10).[66-68]
- Patient-reported insomnia measured with the Insomnia Severity Index (ISI).[69,70]
- Fear of movement assessed with Fear-avoidance Tampa scale for Kinesiophobia (17 items).[71]
- Physical activity estimated with the National Board of Health and Welfare's three questions on physical activity (0 - >300 minutes/week), exercise (0 - >120 minutes/week), and sedentary behavior (0 - 15 hours).[72]
- Pain related catastrophizing assessed with the Pain Catastrophizing Scale (PCS).[73]
- Perceived work ability measured with the Work Ability Index (WAI) (0-10).[74]
- Job characteristics influencing psychological well-being estimated with the The Swedish Demand-Control-Support Questionnaire (DCSQ).[75]
- Self-reported physical work environment using a questionnaire inspired by the Swedish Work Environment Authority ergonomics checklist.[76,77]

- Perceived life satisfaction (1 - 6) measured with the Life Satisfaction Scale (LiSat).[78,79]
- Self-reported perceived work situation regarding barriers for RTW, strategies to handle barriers and need of support from the employer.
- Self-reported total workload where the participants register number of hours per day for paid work and unpaid household work.[80-82]

Data collected from SWEPPE

Mobile app usage, for example number of participants using the app, performing daily self-rating, sharing information with the employer, or asking questions to the coach will be retrieved from SWEPPE.

Data collection methods

Data collection for the present trial will start during 2022. Baseline data will be collected when the IPRP is completed and study ending will be at 12 months follow-up after IPRP. Data will be collected from SSIA, the SQRP, supplementary questionnaires to the SQRP, and data registered in SWEPPE (table 1). Data collection for the SQRP is routinely performed when the IPRP is completed and at 12 months follow-up at both primary and specialized care units in Sweden providing IPRP. The supplementary questionnaires will be added to these routine data collections for the SQRP.

Data management

Data will be retrieved from SSIA and from the SQRP and connected to individual-level data retrieved from SWEPPE. The procedure is initiated by sending a file with the participants social security numbers and a consecutive number key to the SSIA who will fill in the ordered

data for each participant. The SSIA will then send the file to SQRP for addition of registry data. The principal investigator will receive the file with consecutive numbered data from SQRP. All data collected in the study will be stored on a safe server at Linköping University. A data management plan (DMP) will be developed by the principal investigator and co-workers and will include a description of research data, information about documentation and quality control of research data, storage and back-up copying of research data, legal and ethical aspects, accessibility and long-term preservation of research data, and responsibility and resources related to the research data.

Statistical analysis

A statistical analysis plan will be developed with details of statistical analyses, handling of missing data and any additional analyses, for example subgroup and adjusted analyses. Descriptive statistical analyses will be performed for reporting of participant characteristics. The clinical effectiveness off SWEPPE will be analysed using uni- and multivariate statistical analyses as a preliminary plan. Data from primary and secondary outcomes will be analysed according to intention-to-treat. All p-values will be presented and a p-value of <0.05 will be considered significant.

Data monitoring

All data in the trial will be monitored regularly. Since no sponsors or competing interests exists, monitoring of data will be performed independently. To ensure proper handling and storing of data (structure, organization, file naming), the data management plan (DMP) will be reviewed regularly by the principal investigator and co-workers.

Harms

SWEPPE can be assumed not to create adverse events and is considered a safe intervention. Nevertheless, all participants will be encouraged to report any adverse events or unintended effects of trial intervention or trial conduct such as unexpected side effects or deterioration of symptoms.[83]

Auditing

To facilitate adherence to the study protocol[84], the project coordinator (CT) will have regular contact (every second week) with the unit coordinators during the study period. Processes to be reviewed are participant screening and eligibility. Documentation of the recruitment and randomization/allocation process, for example eligible patients asked to participate, the number of patients included, excluded or declining participation, performed by CT will be reviewed by the researchers (GL, MB).

ETHICS AND DISSEMINATION

The study is approved by the Swedish Ethics Review Board (Dnr 2020-01593, Dnr 2021-01854) and the trial is registered in ClinicalTrials.gov (NCT05058547). Any important modifications of the study protocol will be communicated to the Swedish Ethics Review Board and to the participants. Informed consent will be collected from all participants by one of the researchers (CT). The consent form is design based on the Ethics committee recommendation and includes written information about the study.

Confidentiality will be protected by coding of individual participants' collected data. Data will be stored at a password protected project server at Linköping University and will not be accessed by unauthorized persons. The study results will be submitted to peer-review journals for publication and will be presented in national and international research networks, clinical settings, and patient associations. The study protocol will be available via Clinicaltrial.gov.

There is no present plan regarding public access of participant-level data set or statistical code.

AUTHOR CONTRIBUTION

MB and GL formed the original research concept. CT, MB and GL contributed to the study design and CT will coordinate the project in cooperation with MB and GL. CT, ML and LV will be responsible for the unit coordinators at each participating unit and the inclusion of participants. All authors will collect and manage data during the trial. CT, MB and GL have written and revised this protocol with critical input from ML and LV. All authors have contributed important intellectual content to the manuscript.

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COMPETING INTERESTS STATEMENT

The authors have no competing interests to declare.

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Figure legends

Figure 1. Time schedule of enrolment, interventions, and assessments.

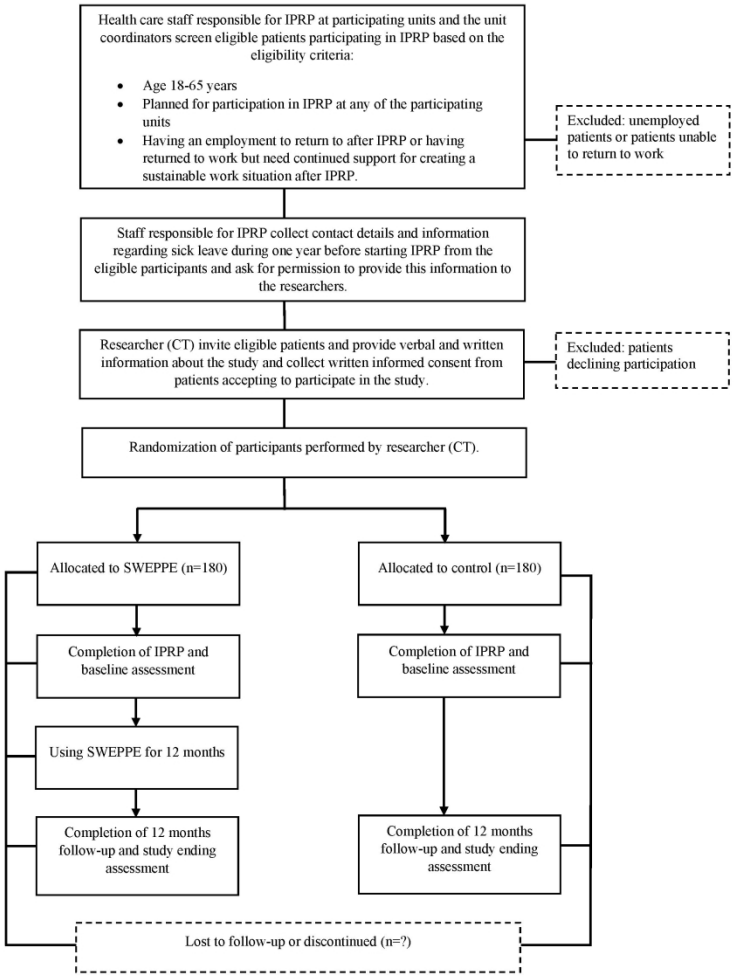

Figure 1. Time schedule of enrolment, interventions, and assessments.

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S1. Overview of the study based on the SPIRIT 2013 checklist.

Section	SPIRIT item number	Item description	Study description	Page number where item can be found.
Title	1	Title	An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: study protocol for a registry-based multicentre randomized controlled trial.	Page 1, manuscript
Trial registration	2a	Trial identifier and registry name	ClinicalTrials.gov registration number NCT05058547	Page 4, manuscript
	2b	All items from the World Health Organization trial registration data set	Supplementary table 2 below.	Page 16, supplementary file
Protocol version	3	Date and version identifier	Version 1. 27 September 2021. NCT05058547	Page 4, manuscript
Funding	4	Sources and types	The Swedish Research Council for Health, Working Life and Welfare: Dnr 2019-01264. Financial.	Page 19, manuscript
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Christina Turesson[1], Gunilla Liedberg[1], Linda Vixner[2], Monica Löfgren[3], Mathilda Björk[4]. MB and GL formed the original research concept. CT, MB and GL contributed to the study design and CT will coordinate the project in cooperation with MB and GL. CT, ML and LV will be responsible for the unit coordinators at each participating unit and the inclusion of participants. All authors will collect and manage data during the trial. CT, MB and GL have written and revised this protocol with critical input from ML and LV. All authors have contributed important intellectual content to the manuscript. **Affiliations:**	Page 1 and 19, manuscript

			1. Division of Prevention, Rehabilitation and Community Medicine, Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden 2. School of Health and Welfare, Dalarna University, Falun, Sweden 3. Karolinska Institutet, Department of Clinical Sciences and Department of Rehabilitation Medicine Danderyd Hospital, 182 88 Stockholm 4. Pain and Rehabilitation Centre, Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden	
	5b	Name and contact information for the trial sponsor	Linköping University 581 83 Linköping Sweden +46 28 10 00	Page 1, manuscript
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A	
	5d	Composition, roles, and responsibilities of the coordinating center, steering	N/A	

		committee, end point adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see item 21a for DMC)		
Introduction Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Chronic musculoskeletal pain (CMSP) severely affects the individual's quality of life, functioning and ability to work, and comes with significant societal costs for sick leave and loss of productivity. After completing an Interdisciplinary Pain Rehabilitation Program (IPRP), patients with CMSP experience a gap in the return to work (RTW) process when the responsibility for RTW is taken over by the employer. The employers have a crucial role in a successful RTW process but may lack knowledge regarding the condition and how to support the employee with CMSP in the best way during RTW. Barriers for RTW for persons with CMSP are for example lack of support at the workplace, not finding the right fit between the employee's physical abilities and work tasks, or problems with relationships with supervisors or coworkers. Key factors for a successful RTW are communication and collaboration between the employer and the employee. To facilitate the important interaction between employer and employee a shared smartphone application may be a tool for increasing a successful outcome in the RTW process. Smart phone applications as digital support has shown promising results for persons with chronic pain and can be helpful especially in an out-clinic setting. They are easily accessed, can enable management of the condition, and reduce pain interference. Focusing on self-management and empowerment are important parts of successful digital support. Self-monitoring can contribute to learning about consequences of actions and behaviours in daily life. Understanding and using own self-monitoring data for making changes in daily activities can give a sense of control and	Page 5-6, manuscript

			motivation for continued use of self-management strategies. Although positive effects of digital support have been shown there are limitations related to low overall quality of smartphone apps for CMSP and lack of rigorous assessment of their effectiveness.	
Objectives	7	Specific objectives or hyptheses	The aim is to evaluate the clinical effectiveness of a digital support (SWEPPE) for promoting a sustainable RTW for persons with CMSP and to facilitate the employers' supportive role and responsibilities in the process. The hypothesis is that using SWEPPE will decrease the need for sick leave.	Page 7, manuscript
Trial design	8	Description of trial design, including type of trial	Registry-based randomized controlled trial with parallel groups.	Page 7, manuscript
Methods Study setting	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Specialist and primary care level health care in Sweden reporting to the Swedish National Quality Registry for Pain Rehabilitation (SQRP). Study cites are listed in the protocol (ClinicalTrials.gov registration number NCT05058547)	Page 7, manuscript
Eligibility criteria	10	Inclusion and exclusion criteria for participants.	Inclusion Criteria: Patients entering the trial must have completed an Interdisciplinary Pain Rehabilitation Program (IPRP). The principal inclusion criteria for IPRP in Sweden are: • persistent or intermittent pain lasting ≥3 months • pain affecting daily activities to a large extent, • completed systematic assessment and non-pharmacological optimization is completed, • screening for psychosocial risk factors and differential diagnosis completed	Page 8, manuscript

			In addition, the following criteria will be applied: • Age 18-65 years • Completed participation in IPRP at any of the participating units. • Having an employment to return to after IPRP or having returned to work but need continued support for creating a sustainable work situation after IPRP. Exclusion criteria: • Completed IPRP but are unemployed or unable to return to work.	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	SWEPPE, a smartphone application where the individual can create an action plan, perform daily registrations of health aspects, self-monitoring of health aspects and goals, have access to a library with evidence-based facts and a coach, and possibility to share information with the employer. The participants will use SWEPPE for 12 months. Participants randomized to the control group will not receive any active intervention for RTW after IPRP.	Page 10-11, manuscript
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)	N/A	
	11c	Strategies to improve adherence to intervention	N/A	

		protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)		
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Outcome assessments in the present trial are intended to capture the complexity of pain based on the biopsychosocial model namely medical, psychological, and social (total life situation) factors impacting on the work situation. It has been recommended to include multiple outcomes in clinical trials for persons with CMSP to capture important domains affected by symptoms such as functioning and health-related quality of life. The primary and secondary outcomes are collected for evaluation of the clinical effectiveness of SWEPPE, and the complementary variables will be collected based on their effect on the outcome.	Page 11-16, manuscript
Participant timeline	13	Time schedule of enrollment,	Figure 1.	Page 7, figure 1

		interventions (including any runins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (Figure).		
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Based on previous research regarding sick leave (45, 46) and the inclusion of participants with the goal to RTW, an estimated difference between the groups of 20 net days and an effect-size of 0.333 was set for rejection of the null hypothesis. To detect this difference with a power of 80% and a significance level of 0.05 a total sample size of 300 participants (150/group) are needed. With an allowance for 20% of participants lost to follow-up we aim to recruit a total sample size of 360 participants (n=180 intervention, n=180 control).	Page 9, manuscript
Recruitment	15	Strategies for achieving adequate participant enrollment to reach target sample size	Participants will be recruited from multiple special and primary care level health care providing IPRP for patients with chronic pain.	Page 9, manuscript
Assignment of interventions Allocation sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random	As sick leave history is a strong predictor for future sick leave (47) participants will be stratified based on self-reported number of sick leave days during the year before IPRP. Participants will be divided in high (total number of gross sick leave days ≥ 70) or low sick leave absence and then randomized to intervention or control group. Allocation of the participants to intervention or control group will be conducted using a block randomization design with varying block sizes of 2-6 (48-50). The allocation sequence will be computer generated and sealed sequentially numbered opaque sealed envelopes will be prepared by one of the researchers (GL).	Page 10, manuscript

		sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions.		
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Sealed sequentially numbered opaque envelopes will be used for implementing the allocation sequence at each participating unit.	Page 10, manuscript
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	The allocation sequence will be generated by a statistician and one of the researchers (GL) will prepare sequentially numbered opaque sealed envelopes. Enrolment and assignment of participants will be performed by one of the researchers (CT) not involved in preparing the allocation sequence or the envelopes.	Page 10, manuscript
Blinding	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers,	Due to the nature of the intervention the participants will not be blinded to group allocation. As randomization to intervention or control group is performed at the completion of IPRP the participants will not have further contact with the health care staff responsible for IPRP or other patients. The participants will be	Page 10, manuscript

		outcome assessors, data analysts), and how	instructed not to reveal their group allocation to the health care staff responsible for IPRP or other patients if they would have further contact.	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A	
Data collection, management, and analysis Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol.	Data collection for the present trial will start when the IPRP is completed (baseline) and at 12 months follow-up (study ending). Data will be collected from the Swedish Social Insurance Agency's SSIA, the SQRP for specialist and primary care level, supplementary questionnaires to the SQRP, and data registered in SWEPPE (table 1).	Page 16, manuscript

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Data collection for the SQRP is routinely performed when the IPRP is completed and at 12 months follow-up at both primary and specialized care units in Sweden providing IPRP. The supplementary questionnaires will be added to these routine data collections for the SQRP.	Page 16, manuscript
Datamanagement	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol.	A data management plan (DMP) will be developed by the principal investigator and co-workers and will include a description of research data, information about documentation and quality control of research data, storage and back-up copying of research data, legal and ethical aspects, accessibility and long-term preservation of research data, and responsibility and resources related to the research data.	Page 16-17, manuscript
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol.	A statistical analysis plan will be developed with details of statistical analyses, handling of missing data and other possible analyses for example subgroups. Descriptive statistical analyses will be performed for reporting of participant characteristics. The clinical effectiveness off SWEPPE will be analysed using uni- and multivariate statistical analyses as a preliminary plan. All p-values will be presented and a p-value of <0.05 will be considered significant.	Page 17, manuscript

	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	A statistical analysis plan will be developed with details of statistical analyses, handling of missing data and any additional analyses, for example subgroup and adjusted analyses.	Page 17, manuscript
	20c	Definition of analysis population relating to protocol nonadherence (e.g., as-randomized analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	Data from primary and secondary outcomes will be analysed according to intention-to-treat.	Page 17, manuscript
Data monitoring	21a	Composition of DMC; summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed.	All data in the trial will be monitored regularly. Since no sponsors or competing interests exists, monitoring of data will be performed independently. To ensure proper handling and storing of data (structure, organization, file naming), the DMP will be reviewed regularly by the principal investigator and co-workers.	Page 17, manuscript
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these	N/A	

		interim results and make the final decision to terminate the trial		
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	SWEPPE can be assumed not to create adverse events and is considered a safe intervention. Nevertheless, all participants will be encouraged to report any adverse events or unintended effects of trial intervention or trial conduct such as unexpected side effects or deterioration of symptoms.	Page 18, manuscript
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	To facilitate adherence to the study protocol the project coordinator (CT) will have regular contact (every second week) with the participating units during the study period. Processes to be reviewed are participant screening and eligibility. Documentation of the recruitment and randomization/allocation process, for example eligible patients asked to participate, the number of patients included, excluded or declining participation, performed by CT will be reviewed by the researchers (GL, MB).	Page 18, manuscript
Ethics and dissemination Research ethics approval	24	Plans for seeking REC/IRB approval	The study is approved by the Swedish Ethics Review Board (Dnr 2020-01593, Dnr 2021-01854).	Page 18, manuscript
Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes,	Any important modifications of the study protocol will be communicated to the Swedish Ethics Review Board and to the participants	Page 18, manuscript

		analyses) to relevant parties (e.g., investigators, RECs/IRBs, trial participants, trial registries, journals, regulators)		
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see item 32)	Informed consent will be collected from all participants by one of the researchers (CT).	Page 18, manuscript
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Confidentiality will be protected by coding of individual participants' collected data.	Page 18, manuscript
Declaration of interest	28	Financial and other competing interests for principal	The authors have no competing interests to declare.	Page 19, manuscript

		investigators for the overall trial and each study site		
Access to data	29	Statement of who will have access to the final trial data set, and disclosure of contractual agreements that limit such access for investigators	Data will be stored at a password protected project server at Linköping University and will not be accessed by unauthorized persons.	Page 18, manuscript
Ancillary and post-treatment care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, health care professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data-sharing arrangements), including any publication restrictions	The study results will be submitted to peer-review journals for publication and will be presented in national and international research networks, clinical settings, and patient associations.	Page 18, manuscript

	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A	
	31c	Plans, if any, for granting public access to the full protocol, participant-level data set, and statistical code	The study protocol will be available via Clinicaltrial.gov. There is no present plan regarding public access of participant-level data set or statistical code.	Page 18-19, manuscript
Appendices Informed consent material	32	Model consent form and other related documentation given to participants and authorized surrogates	The consent form is design based on the Ethics committee recommendation and includes written information about the study.	Page 18, manuscript.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A	

S2. Overview of the study in relation to the World Health Organization (WHO) trial registration data set.

WHO item	Item description	Study description	Page number where item can be found.
1.	Primary registry and trial identifying number	Primary registry at ClinicalTrials.gov registration number NCT05058547	Page 4, manuscript
2.	Date of registration in primary registry	27 September 2021	Page 4, manuscript
3.	Secondary identifying numbers	The Swedish Research Council for Health, Working Life and Welfare: Dnr 2019-01264 The Swedish Ethics Review Board: Dnr 2020-01593, Dnr 2021-01854	Page 18-19, manuscript
4.	Sources of monetary or material support	The Swedish Research Council for Health, Working Life and Welfare: Dnr 2019-01264	Page 19, manuscript
5.	Primary sponsor	Linköping University	Page 1, manuscript
6.	Secondary sponsor(s)	N/A	
7.	Contact for public queries	Mathilda.bjork@liu.se +4611363531 Linköping University 581 83 Linköping Sweden Recruitment status: not yet recruiting	Page 1, manuscript
8.	Contact for scientific queries	Mathilda Björk Mathilda.bjork@liu.se +4611363531 Department of Health, Medicine and Caring Sciences Linköping University 581 83 Linköping Sweden	Page 1, manuscript
9.	Public title	An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a	Page 1, manuscript

		sustainable return to work: a study protocol for a registry-based multicentre randomized controlled trial.	
10.	Scientific title	An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: a study protocol for a registry-based multicentre randomized controlled trial.	Page 1, manuscript
11.	Countries of recruitment	Sweden	Page 7, manuscript
12.	Health condition	Chronic pain	Page 7, manuscript
13.	Intervention	Participants randomized to the intervention group will receive the smartphone application SWEPPE to use as a digital support during the RTW process. SWEPPE is a smartphone application where the individual can create an action plan, perform daily registrations of health aspects, self-monitoring of health aspects and goals, have access to a library with evidence-based facts and a coach, and possibility to share information with the employer. The intervention starts at the end of the IPRP with self-rating of work conditions and goal setting in SWEPPE. The participants will use SWEPPE for 12 months. Data registered in SWEPPE by the participant about their goal, work condition and self-rating will be stored in the application and used for self-monitoring and visualizing progress for the participant. The participant invites his/her employer/employers to access the web application SWEPPE depending on what information the participant wants to share with the employer. The employer will receive e-mail reminders to use SWEPPE. Participants randomized to the control group will not receive any active intervention for RTW after IPRP.	Page 10-11, manuscript
14.	Key inclusion and exclusion criteria	Inclusion Criteria: Patients entering the trial must have completed IPRP[a]. The principal inclusion criteria for IPRP in Sweden are: • persistent or intermittent pain lasting ≥3 months • pain affecting daily activities to a large extent, • completed systematic assessment and non-pharmacological optimization is completed, • screening for psychosocial risk factors and differential diagnosis completed In addition, the following criteria will be applied: • Age 18-65 years	Page 8, manuscript

		• Completed participation in an Interdisciplinary Pain Rehabilitation Program (IPRP) at any of the participating units. • Having an employment to return to after IPRP or having returned to work but need continued support for creating a sustainable work situation after IPRP. Exclusion criteria: • Completed IPRP but are unemployed or unable to return to work.	
15.	Study type	Registry-based randomized controlled trial. Stratification of sick leave history during the year before IPRP and block-randomization, using opaque sealed and numbered envelopes, to intervention (SWEPPE) or control group. Due to the nature of the intervention the participants will not be blinded to group allocation.	Page 7, manuscript
16.	Date of first enrolment	Anticipated to spring 2022.	Page 16, manuscript
17.	Target sample size	Total number of participants: 360	Page 9, manuscript
18.	Recruitment status	Pending	Page 4, manuscript
19.	Primary outcome(s)	Sick leave. Time Frame: 12 months follow up after IPRP. Number of gross and net days with sickness cash benefit	Page 12, manuscript
20.	Key secondary outcome(s)	1. Return to work. Time Frame: 12 months follow up after IPRP. Return to work (partially or full time) every month 2. Sick-leave spells per months. Time Frame: 12 months follow up after IPRP. Number of sick-leave spells (per month) 3. Return to work group level. Time Frame: 12 months follow up after IPRP. Proportions of a group who returns to full- or part-time work (per month) 4. Working days before new sick leave. Time Frame: 12 months follow up after IPRP. Number of days in work before new sick leave during study period 5. Proportion back to work. Time Frame: 12 months follow up after IPRP. Proportion of a group back to work >28 days (full- or part time) before a new sick-leave spell occurs 6. Total sick-leave spells. Time Frame: 12 months follow up after IPRP. Number of sick-leave spells during study period	Page 12-16, manuscript

		7. Length of total sick leave.Time Frame: 12 months follow up after IPRP. Length of total sick leave during study period 8. Pain intensity last 7 days. Time Frame: Baseline and 12 months. Numeric pain rating scale. 9. Consequences of pain on daily life. Time Frame: Baseline and 12 months. Multidimensional Pain Inventory Swedish version. 10. Overall emotional distress. Time Frame: Baseline and 12 months. Hospital Anxiety and Depression Scale Swedish version. 11. Physical and mental health. Time Frame: Baseline and 12 months. RAND-36 Swedish version. 12. Goal fulfilment and satisfaction during the study period. Time Frame: Baseline and 12 months. Explanatory Outcome Measures: 1. Self-reported fatigue the last 7 days. Time Frame: Baseline and 12 months. Numeric fatigue rating scale. 2. Self-reported insomnia. Time Frame: Baseline and 12 months. Insomnia Severity Index Swedish version. 3. Self-reported fear of movement. Time Frame: Baseline and 12 months. Tampa Scale for Kinesiophobia Swedish version. 4. Self-reported physical activity. Time Frame: Baseline and 12 months. The National Board of Health and Welfare's three questions on physical activity, exercise, and sedentary behavior. 5. Pain catastrophizing. Time Frame: Baseline and 12 months. Pain Catastrophizing scale Swedish version. 6. Perceived work ability. Time Frame: Baseline and 12 months. Work Ability Index Swedish version. 7. Self-reported demands, control, and support at the workplace. Time Frame: Baseline and 12 months. Demand Control Support Questionnaire Swedish version. 8. Self-reported physical work environment using a questionnaire inspired by the Swedish Work Environment Authority ergonomics checklist	

		9. Perceived life Satisfaction. Time Frame: Baseline and 12 months. Life satisfaction Scale Swedish version. 10. Self-reported work situation during the study period. Time Frame: Baseline and 12 months. Barriers for return to work, strategies to handle barriers and need of support from the employer reported as text answer. 11. Self-reported workload an average day. Time Frame: Baseline and 12 months. Number of hours per day for paid work and unpaid household work. **Data collected from SWEPPE** Mobile app usage, for example number of participants using the app, performing daily self-rating, sharing information with the employer, or asking questions to the coach will be retrieved from SWEPPE.	
21.	Ethics review	Approved	Page 18, manuscript
22.	Completion date	After the last subject's last visit.	Page 16, manuscript
23.	Summary results	Summary results will be provided when the trial is completed.	Page 18, manuscript
24.	IPD sharing statement (individual clinical trial participant- level data)	Not planned to share individual clinical trial participant- level data (IPD)	Page 18-19, manuscript

BMJ Open

An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: a study protocol for a registry-based multicentre randomized controlled trial.

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TITLE

An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: a study protocol for a registry-based multicentre randomized controlled trial.

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ABSTRACT

Introduction

Chronic musculoskeletal pain severely affects the individual's quality of life, functioning and ability to work, and comes with significant societal costs for sick leave and productivity loss. After rehabilitation, patients with chronic musculoskeletal pain often experience lack of support when responsibility for the return-to-work process is taken over by the employer. Therefore, we aim to evaluate the effectiveness of a digital support (SWEPPE) for promoting a sustainable return-to-work for persons with chronic musculoskeletal pain and to facilitate the employers' supportive role and responsibilities in the process.

Methods and analysis

In this registry-based multicentre randomized controlled trial, 360 patients with chronic musculoskeletal pain will be randomised to either receive the smartphone application SWEPPE (n=180) or to a control group (n=180). The intervention group will use SWEPPE for one year and the control group will not receive any intervention for return to work. Participants will be recruited from approximately ten specialist and primary care level units connected to the Swedish National Quality Registry for Pain Rehabilitation providing interdisciplinary pain rehabilitation programs for chronic musculoskeletal pain. Eligibility criteria are age 18-65 years and a need for support in return to work or continued support at work for creating a sustainable work situation. Baseline data will be collected when the participants have completed the interdisciplinary pain rehabilitation program. Final assessment will be performed after twelve months. The primary outcome will be number of days with sickness cash benefit. Secondary outcomes and explanatory variables including important domains affected by chronic musculoskeletal pain such as health-related quality of life, functioning and work ability will be collected.

Ethics and dissemination

The Swedish Ethics Review Board approved the study (Dnr 2020-01593, Dnr 2021-01854). The study findings will be disseminated through publication, national and international conferences, and meetings to be available for patients, health care providers or stakeholders.

Registration details

ClinicalTrials.gov registration number NCT05058547 (Pre-results, not yet recruiting). Version 1. 27 September 2021.

Strengths and limitations of this study

- Using a shared smartphone application (SWEPPE) to facilitate self-management, and communication and collaboration between persons with chronic musculoskeletal pain and their employer during the return-to-work process is a novel intervention with the potential to support a sustainable work situation.
- A registry-based multicentre randomized trial will provide rigorous evidence regarding clinical effectiveness of the intervention.
- In this trial the primary and secondary outcomes are based on recommendation from the Swedish Social Insurance Agency regarding outcomes for return-to-work which ensures capturing relevant aspects of sick-leave.
- It is important to be aware of the risk for selection bias due to patients' self-confidence or willingness to use smartphone applications.
- A study limitation is the lack of blinding to group allocation and the control groups awareness of not receiving the intervention.

Key words: clinical trials, musculoskeletal disorders, pain management, rehabilitation medicine.

INTRODUCTION

Chronic musculoskeletal pain (CMSP) (i.e., pain duration >3 months) such as chronic neck/shoulder and back pain or generalized widespread pain (including fibromyalgia (FM)) has a prevalence from 10.4% [1] to 20% among adults.[1-3] CMSP negatively impact quality of life, functioning and the ability to work.[2] CMSP also causes considerable costs for the society in terms of sick leave expenses and loss of productivity.[1,2,4-8] Many patients with CMSP participate in Interdisciplinary Pain Rehabilitation Programs (IPRP) to enable self-management of pain and increase the ability to work.[9-11] After completing a rehabilitation program for persons with CMSP the patients can experience lack of support when the employer takes over the responsibility for the return to work (RTW) process.[12] The employers have a crucial role in a successful RTW process [13-15] but may lack knowledge regarding chronic pain and its consequences [16] and how to support the employee with CMSP in the best way during RTW.[12] Barriers for RTW for persons with CMSP are for example lack of support at the workplace, not finding the right fit between the employee's physical abilities and work tasks, or problems with relationships with supervisors or coworkers.[17,18] Key factors for a successful RTW are communication and collaboration between the employer and the employee.[19] Further, employers also need to use active listening skills which means enhancing conversation using open questions and demonstrate effective listening by summary statements.[20] To facilitate the important interaction between employer and employee[21,22] a shared smartphone application may be a tool for increasing a successful outcome in the RTW process.

A primary aim of IPRP is to reach RTW.[9,10] To fill the gap patients with CMSP experience when the RTW process continues after completing IPRP [12], the digital support A Sustainable WorkEr- digital support for Persons with chronic Pain and their Employers

(SWEPPE) was systematically developed.[23] SWEPPE is a smartphone application for persons with CMSP with the possibility to invite and share information with the employer. SWEPPE was developed by a multidisciplinary project team consisting of health care researchers, a user representative, and a software team. A user-centred agile approach [24] was used with continuous involvement of two reference groups consisting of persons with CMSP and employers providing feedback on the functions and the interface in SWEPPE. Smart phone applications as digital support has shown promising results for persons with chronic pain [25-27] and can be helpful especially in an out-clinic setting.[28] They are easily accessed, can enable management of the condition [29], and reduce pain interference.[30] An evidence-based content and a simple design are key parts for providing a successful digital support.[31] Information provided via apps can improve the level of knowledge among patients.[32] Focusing on self-management and empowerment are other important parts of successful digital support.[33] Self-management among persons with chronic pain include self-monitoring [31,34] and pain education in relation to the neuroscience of pain, medication, stress, depression, and sleep management.[35] Self-monitoring can contribute to learning about consequences of actions and behaviours in daily life.[36] This can lead to making changes in daily activities and a sense of control and motivation for continued use of self-management strategies.[37,38]

Although positive effects of digital support have been shown there are limitations related to low overall quality of smartphone apps for CMSP and lack of rigorous assessment of their effectiveness.[39,40] SWEPPE was found to be useful for self-management for persons with CMSP and for supporting employers, with relevant content, logical and easy to use, and with a nice and clean interface.[23] However, the clinical effectiveness of SWEPPE as a digital support for employees and employers to decrease sick leave in persons with CMSP need to be

investigated. The aim of this paper is to report the study design, aim, outcome assessment and procedures for a planned registry based multicentre randomized controlled trial (R-RCT). The overall objective of the R-RCT is to evaluate the clinical effectiveness of a digital support (SWEPPE) for promoting a sustainable RTW for persons with CMSP and to facilitate the employers' supportive role and responsibilities in the process.

METHODS AND ANALYSIS

Trial design and study setting

This protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[41] The R-RCT will conform with the Consolidated Standards of Reporting Trials (CONSORT).[42,43] This is a two-armed multi-centre registry-based randomized controlled trial. The study will be conducted in specialized and primary level clinics in Sweden providing IPRP and reporting to the Swedish National Quality Registry for Pain Rehabilitation (SQRP). Approximately 360 (n=180 intervention group, n=180 control group) patients with CMSP will be recruited to participate in the study. Study design and enrollment details is presented in figure 1. A completed SPIRIT checklist and the World Health Organization (WHO) trial registration data set [44] can be found in the supplementary files (S1 and S2).

Patient and public involvement

Patients with CMSP were not involved in formulating the research question or setting the research design for the planned study. However, patients with CMSP who had undergone IPRP and employers participated in design and development of the intervention, the digital smart phone application SWEPPE. In addition, a user representative from the Swedish

Rheumatism Association participated as a research partner in the development process of SWEPPE.[23]

Participants

Eligibility criteria for the study is that patients entering the trial must have completed an IPRP for CMSP. The principal inclusion criteria for IPRP in Sweden are persistent or intermittent pain lasting ≥3 months, pain affecting daily activities to a large extent, completed systematic assessment and non-pharmacological optimization, and screening for psychosocial risk factors and differential diagnosis completed. In this trial, patients with CMSP will be recruited based on the following criteria: age between 18-65 years, completed IPRP at any of the participating units, having an employment to return to after IPRP or having returned to work but need continued support for creating a sustainable work situation after IPRP. Patients who have completed IPRP but are unemployed or unable to return to work will be excluded.

Recruitment

Units in specialized and primary care level in Sweden providing IPRP based on individualized needs and who are reporting to the SQRP will be included in the study. Two of the researchers (CT, MB) will invite healthcare staff (primarily occupational therapists and physiotherapists but also psychologist/counselor, nurses etc.) at the participating units to online digital information meetings to present the study. A contact person will be appointed at each unit. One researcher (CT) will have continuous contact with the participating units regarding the planned IPRP groups and screening of eligible patients for the study.

Patients with CMSP participating in IPRP at any of the study units and who is meeting the inclusion criteria will be asked to take part in the study. The recruitment process will start

with screening of eligible participants in the IPRP groups. Screening of eligible participants will be performed by the health care staff providing the IPRP and will be discussed with one of the researchers (CT). The health care staff will collect contact details and information regarding previous sick leave during one year before starting IPRP from the eligible participants and ask for permission to provide this information to the researchers. The participants will at the end of IPRP receive verbal and written information about the study from one of the researchers (CT) and written informed consent (S3) will be collected for those willing to participate in the study. The participants will receive detailed information regarding voluntary participation and the right to withdraw from the study at any time.

Intervention

The participants will be assigned to the intervention group or the control group. Participants in both groups will follow the plan for return to work that has been established at the end of IPRP.

Intervention group receiving SWEPPE

Participants randomized to the intervention group will receive the smartphone application SWEPPE to use as a digital support during the RTW process. SWEPPE consist of six modules to support self-management:[33] the action plan, daily self-rating of health aspects, self-monitoring graphs of health aspects and goals, the coach, the library, and shared information with the employer. The action plan includes setting a work-related goal, identification of barriers for RTW, strategies to handle the barriers, identification of support needed from the employer, and weekly evaluation. SWEPPE address pain education [35] and the library provides evidence-based information about CMSP, self-management strategies, and information and tools for RTW.

The intervention starts after completed IPRP with self-rating of work conditions and goal setting in SWEPPE. The participants will use SWEPPE for 12 months. Data registered in SWEPPE by the participant about their goal, work condition and self-rating will be stored in the application and used for self-monitoring and visualizing progress for the participant. The participant invites his/her employer/employers to access the web application SWEPPE depending on what information the participant wants to share with the employer. The employer will receive e-mail reminders to use SWEPPE.

Control group

Participants randomized to the control group will not be blinded to treatment allocation as it is not feasible. They will follow the regular procedure at any specific unit and as there is no standardized intervention for RTW after IPRP, that will mean the participants follow their planned RTW process without further support from the IPRP team. However, the patient can initiate and seek other types of health care or support during their RTW process based on their needs.

Allocation/Randomization

The unit of randomization will be the individual participants who have approved to participate in the study. One of the researchers (CT) will enroll and randomize participants who have given informed consent (S3) to participate in the study to either the intervention or control group. As sick leave history is a strong predictor for future sick leave [45] participants will be stratified into high or low sick leave history based on self-reported number of sick leave days during the year before IPRP. It has been shown that patients with low sick leave history to a larger extent are younger, have an employment, higher education and are more confident regarding recovery.[45] Participants will therefore be divided in high (total number of gross

sick leave days ≥ 70) or low sick leave absence [45] and then randomized to intervention or control group. Allocation of the participants to intervention or control group will be conducted using a block randomization design with varying block sizes of 2-6.[46-48] The allocation sequence will be computer generated and sealed sequentially numbered opaque sealed envelopes will be prepared by one of the researchers (GL).

Blinding

Due to the nature of the intervention the participants will not be blinded to group allocation. As the intervention is a smartphone application it is not feasible to give a sham intervention to the control group. Randomization to intervention or control group is performed at the completion of IPRP and the participants will not have further contact with the health care staff responsible for IPRP or other patients. However, the participants will also be instructed by the health care staff not to reveal their group allocation to the health care staff responsible for IPRP or other patients if they would have further contact.

Sample size

The null hypothesis in this trial is that there will be no difference between the intervention group and the control group concerning the primary outcome sick leave. Since there is no established minimal clinical important difference regarding sick leave, the sample size calculation was inspired by previous research regarding patterns of sick leave after IPRP [49, 50]. It has been shown that the distribution of sick leave among persons with chronic pain change over time from full-time to partial sick leave after IPRP [49] and sick leave are reduced with approximately 16 net days from one year before to two years after IPRP.[50] Therefore, an estimated difference between the groups of 20 net days with a standard deviation of 60 and an effect-size of 0.333 was set for rejection of the null hypothesis. To

detect this difference with a power of 80% and a significance level of 0.05 a total sample size of approximately 300 participants (150/group) are needed. With an allowance for 20% of participants lost to follow-up we aim to recruit a total sample size of 360 participants (n=180 intervention, n=180 control). To reach the target sample size, participants will be recruited from multiple special and primary care level health care providing IPRP for patients with chronic pain.

Outcomes

Outcome assessments in the present trial are intended to capture the complexity of pain [51] based on the biopsychosocial model [52] namely medical, psychological, and social (total life situation) factors impacting on the work situation. It has been recommended to include multiple outcomes in clinical trials for persons with CMSP to capture important domains affected by symptoms such as functioning and health-related quality of life.[53,54]

The primary and secondary outcomes are collected for evaluation of the clinical effectiveness of SWEPPE, and the complementary variables will be collected based on their effect on the outcome. Personal characteristics of the participants will be collected from the SQRP for specialist and primary care respectively and from supplementary questions regarding sex, age, education, currently working/studying (yes, no), work importance in addition to the importance of income (Five alternatives: 1) Very important, 2) Important, 3) Partially important, 4) Hardly no importance, or 5) No importance), diagnosis and pain duration, sick leave during one year before IPRP, and type of work.

Primary outcomes

Primary outcome is days with sickness cash benefit measured according to the Swedish Social Insurance Agency's (SSIA) proposal of outcome measures of return to work:[55]

- Number of gross and net days with sickness cash benefit during the follow-up period (mean and median values).

Secondary outcomes

Secondary outcomes will be collected from SSIA, the SQRP for specialist and primary care respectively, supplementary questionnaires and SWEPPE. An overview of the outcome assessments and data sources is presented in table 1.

Table 1. Overview of the study period, measurement time points (t), primary and secondary outcome assessments and explanatory variables, and data sources *(italics)*.

	Study period			
Time point	**Enrollment**	**Allocation**	**Post-allocation**	
	$-t_1$	**0**	**Baseline**	**t_1**
Enrollment	X			
Eligibility screen	X			
Written and verbal study information	X			
Informed consent	X			
Allocation/randomization		X		
Interventions				
Intervention, SWEPPE (12 months)			X	X
Control (12 months)			X	X
Outcome assessments				
Personal characteristics				
Sex, age, (*SQRP sc and pc*)			X	
Education *(SQRP sc and pc)*			X	
Employment, work importance and type of work *(SQRP sc, supplementary questions for pc)*			X	
Diagnosis, pain duration *(SQRP sc and pc)*			X	
Sick leave during one year before IPRP (*supplementary questionnaire)*			X	
Primary outcomes				
Number of gross and net days with sickness cash benefit during the follow up period (*SSIA*)			X	X
Secondary outcomes				
Return to work (partially or full time) every month (*SSIA*)			X	X
Number of sick-leave spells (per month) (*SSIA*)			X	X
Proportions of a group who returns to full- or part-time work (per month) (*SSIA*)			X	X
Number of days in work before new sick leave during study period (*SSIA*)			X	X
Proportion of a group back to work >28 days (full- or part time) before a new sick-leave spell occurs (*SSIA*)			X	X
Number of sick-leave spells during study period (*SSIA*)			X	X

Length of total sick leave during study period (*SSIA*)			X	X
Pain intensity (last 7 days), NRS (*SQRP sc and pc*)			X	X
Consequences of pain on daily life, MPI-S *(SQRP sc and pc)*			X	X
Overall emotional distress, HADS *(SQRP sc and pc)*			X	X
Physical and mental health, RAND-36, *(SQRP sc, supplementary questionnaire for pc)*			X	X
Goal fulfilment and satisfaction (*supplementary questionnaire)*			X	X
Explanatory variables				
Self-reported fatigue (last 7 days), NRS *(supplementary question)*			X	X
Self-reported level of sleep disturbance, ISI *(SQRP sc, supplementary questionnaire for pc)*			X	X
Self-reported fear of movement, TSK *(SQRP sc, supplementary questionnaire for pc)*			X	X
Self-reported physical activity, *(SQRP sc, supplementary questionnaire for pc)*			X	X
Pain catastrophizing, PCS (*SQRP sc and pc*)			X	X
Perceived work ability, WAI (*SQRP sc and pc*)			X	X
Self-reported demands, control, and support at the workplace, DCSQ *(supplementary questionnaire)*			X	X
Physical work environment *(supplementary questionnaire)*			X	X
Perceived life Satisfaction, LiSat (*Optional questionnaire in SQRP for sc units, supplementary questionnaire for sc units not using it and for pc units*)			X	X
Self-reported work situation during the study period *(supplementary questions)*			X	X
Self-reported workload during the study period *(supplementary questions)*			X	X

Abbreviations: -t^1 = pre recruitment period, t^1 = completed study period and follow-up 12 months after completed interdisciplinary pain rehabilitation program. SQRP= Swedish national Quality Registry for Pain rehabilitation. Sc=specialist care level. Pc=primary care level. NRS = Numeric Pain/Fatigue Rating Scale. MPI-S = Multidimensional Pain Inventory Swedish version. HADS = Hospital anxiety and Depression Scale. TSK = Fear-avoidance Tampa scale for Kinesiophobia. SSIA = Swedish Social Insurance Agency. PCS = Pain Catastrophizing Scale. WAI = Work Ability Index. DCSQ = The Swedish Demand-Control-Support Questionnaire. LiSat = Life Satisfaction Scale.

Secondary outcomes from SSIA:

- Frequencies of individuals in a group who return to full- or part-time work.
- Number of sick-leave spells (per month).
- Proportions of a group who returns to full- or part-time work (per month).
- Number of days at work before a new sick-leave spell >14 days occurs (in current diagnosis and in total for all diagnoses).
- Proportions of a group who is back to work >28 days (full- or part time) before a new sick-leave spell occurs.
- Number of new sick-leave spells during the study period.

- Duration of new sick-leave spells per person (gross and net days).[55]

Secondary outcomes from SQRP for specialist and primary care, and supplementary questionnaires:

- Pain intensity during the last seven days estimated with the Numeric Pain Rating Scale (NRS, 0-10).[56]
- Consequences of pain on daily life measured with the Multidimensional Pain Inventory Scale Swedish version, section 1 and 2 (MPI-S, 0 - 6).[57,58]
- Overall emotional distress assessed with the Hospital Anxiety and Depression scale (HADS).[59-61]
- Health related quality of life measured with the RAND-36 health survey.[60,62-64]
- Goal fulfilment inspired by the Canadian Occupational Performance Measure (COPM).[65] The participants will at baseline be asked to report their work-related goal of full- or part-time work for the coming twelve months and rate their present goal fulfilment and satisfaction on a scale ranging from 0, equalling 'far from reaching my goal'/'not satisfied at all', to 10, equalling 'my goal is fulfilled'/'very satisfied'. At twelve months they will be asked to rate their goal fulfilment and satisfaction again.

Explanatory variables

The following explanatory variables, consistent with a biopsychosocial perspective, will be collected from SQRP for specialist and primary care, and supplementary questionnaires:

- Self-reported fatigue during the last seven days estimated with the Numeric Fatigue Rating Scale (0-10).[66-68]
- Patient-reported insomnia measured with the Insomnia Severity Index (ISI).[69,70]

- Fear of movement assessed with Fear-avoidance Tampa scale for Kinesiophobia (17 items).[71]
- Physical activity estimated with the National Board of Health and Welfare's three questions on physical activity (0 - >300 minutes/week), exercise (0 - >120 minutes/week), and sedentary behavior (0 - 15 hours).[72]
- Pain related catastrophizing assessed with the Pain Catastrophizing Scale (PCS).[73]
- Perceived work ability measured with the Work Ability Index (WAI) (0-10).[74]
- Job characteristics influencing psychological well-being estimated with the The Swedish Demand-Control-Support Questionnaire (DCSQ).[75]
- Self-reported physical work environment using a questionnaire inspired by the Swedish Work Environment Authority ergonomics checklist.[76,77]
- Perceived life satisfaction (1 - 6) measured with the Life Satisfaction Scale (LiSat).[78,79]
- Self-reported perceived work situation regarding barriers for RTW, strategies to handle barriers and need of support from the employer.
- Self-reported total workload where the participants register number of hours per day for paid work and unpaid household work.[80-82]

Data collected from SWEPPE

Mobile app usage, for example number of participants using the app, performing daily self-rating, sharing information with the employer, or asking questions to the coach will be retrieved from SWEPPE.

Data collection methods

Data collection for the present trial will start during 2022. Baseline data will be collected when the IPRP is completed and study ending will be at 12 months follow-up after IPRP. Data will be collected from SSIA, the SQRP, supplementary questionnaires to the SQRP, and data registered in SWEPPE (table 1). Data collection for the SQRP is routinely performed when the IPRP is completed and at 12 months follow-up at both primary and specialized care units in Sweden providing IPRP. The supplementary questionnaires will be added to these routine data collections for the SQRP.

Data management

Data will be retrieved from SSIA and from the SQRP and connected to individual-level data retrieved from SWEPPE. The procedure is initiated by sending a file with the participants social security numbers and a consecutive number key to the SSIA who will fill in the ordered data for each participant. The SSIA will then send the file to SQRP for addition of registry data. The principal investigator will receive the file with consecutive numbered data from SQRP. All data collected in the study will be stored on a safe server at Linköping University. A data management plan (DMP) will be developed by the principal investigator and co-workers and will include a description of research data, information about documentation and quality control of research data, storage and back-up copying of research data, legal and ethical aspects, accessibility and long-term preservation of research data, and responsibility and resources related to the research data.

Data monitoring

All data in the trial will be monitored regularly. Since no sponsors or competing interests exists, monitoring of data will be performed independently. To ensure proper handling and

storing of data (structure, organization, file naming), the data management plan (DMP) will be reviewed regularly by the principal investigator and co-workers.

Statistical analysis

A statistical analysis plan will be developed with details of statistical analyses, handling of missing data and any additional analyses, for example subgroup and adjusted analyses. Descriptive statistical analyses will be performed for transparent reporting of participant characteristics. The clinical effectiveness off SWEPPE will be analysed using effect-size and uni- and multivariate statistical analyses as a preliminary plan. Data from primary and secondary outcomes will be analysed according to intention-to-treat. Data from SWEPPE will be analysed using repeated measures analyses. All p-values will be presented and a p-value of <0.05 will be considered significant.

Harms

SWEPPE can be assumed not to create adverse events and is considered a safe intervention. Nevertheless, all participants will be encouraged to report any adverse events or unintended effects of trial intervention or trial conduct such as unexpected side effects or deterioration of symptoms.[83]

Auditing

To facilitate adherence to the study protocol [84], the project coordinator (CT) will have regular contact (every second week) with the unit coordinators during the study period. Processes to be reviewed are participant screening and eligibility. Documentation of the recruitment and randomization/allocation process, for example eligible patients asked to

participate, the number of patients included, excluded or declining participation, performed by CT will be reviewed by the researchers (GL, MB).

ETHICS AND DISSEMINATION

The study is approved by the Swedish Ethics Review Board (Dnr 2020-01593, Dnr 2021-01854) and the trial is registered in ClinicalTrials.gov (NCT05058547). Any important modifications of the study protocol will be communicated to the Swedish Ethics Review Board and to the participants. Informed consent (S3) will be collected from all participants by one of the researchers (CT). The consent form is design based on the Ethics committee recommendation and includes written information about the study.

Confidentiality will be protected by coding of individual participants' collected data. Data will be stored at a password protected project server at Linköping University and will not be accessed by unauthorized persons. The study results will be submitted to peer-review journals for publication and will be presented in national and international research networks, clinical settings, and patient associations. The study protocol is available via Clinicaltrial.gov (NCT05058547). There is no present plan regarding public access of participant-level data set or statistical code.

AUTHOR CONTRIBUTION

MB and GL formed the original research concept. CT, MB and GL contributed to the study design and CT will coordinate the project in cooperation with MB and GL. CT, ML and LV will be responsible for the unit coordinators at each participating unit and the inclusion of participants. All authors will collect and manage data during the trial. CT, MB and GL have written and revised this protocol with critical input from ML and LV. All authors have contributed important intellectual content to the manuscript.

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COMPETING INTERESTS STATEMENT

The authors have no competing interests to declare.

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Figure legends

Figure 1. Time schedule of enrollment, interventions, and assessments.

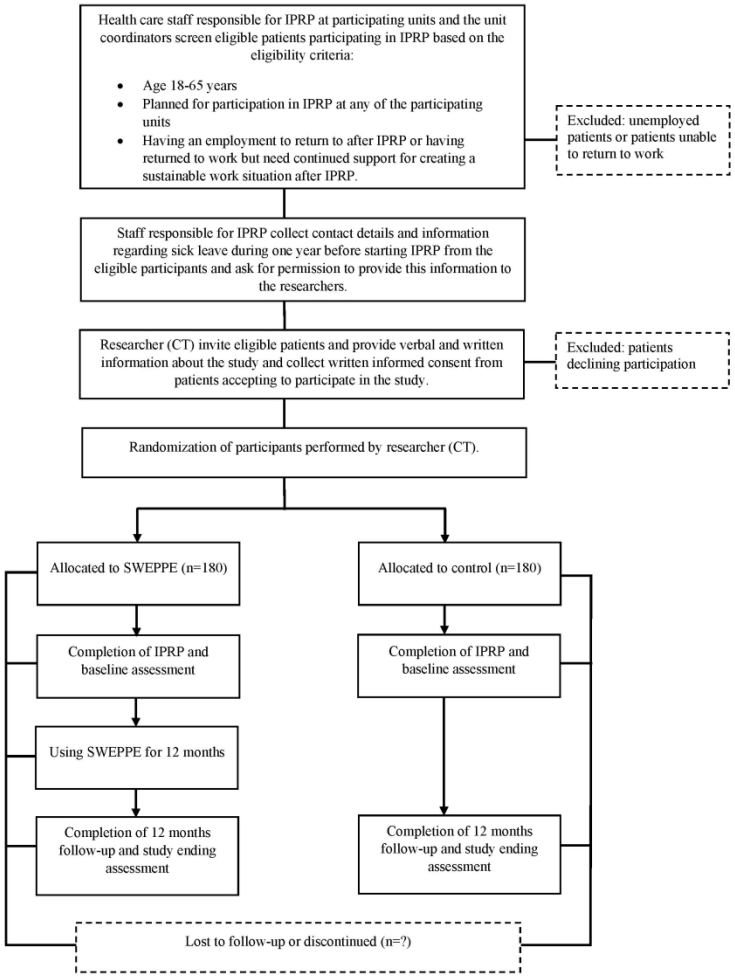

Figure 1. Time schedule of enrolment, interventions, and assessments.

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S1. Overview of the study based on the SPIRIT 2013 checklist.

Section	SPIRIT item number	Item description	Study description	Page number where item can be found.
Title	1	Title	An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: study protocol for a registry-based multicentre randomized controlled trial.	Page 1, manuscript file
Trial registration	2a	Trial identifier and registry name	ClinicalTrials.gov registration number NCT05058547	Page 4, manuscript file
	2b	All items from the World Health Organization trial registration data set	Supplementary table S2.	Supplementary file S2
Protocol version	3	Date and version identifier	Version 1. 27 September 2021. NCT05058547	Page 4, manuscript file
Funding	4	Sources and types	The Swedish Research Council for Health, Working Life and Welfare: Dnr 2019-01264. Financial.	Page 19, manuscript file
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Christina Turesson[1], Gunilla Liedberg[1], Linda Vixner[2], Monica Löfgren[3], Mathilda Björk[4]. MB and GL formed the original research concept. CT, MB and GL contributed to the study design and CT will coordinate the project in cooperation with MB and GL. CT, ML and LV will be responsible for the unit coordinators at each participating unit and the inclusion of participants. All authors will collect and manage data during the trial. CT, MB and GL have written and revised this protocol with critical input from ML and LV. All authors have contributed important intellectual content to the manuscript. **Affiliations:**	Page 1 and 19, manuscript file

			1. Division of Prevention, Rehabilitation and Community Medicine, Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden 2. School of Health and Welfare, Dalarna University, Falun, Sweden 3. Karolinska Institutet, Department of Clinical Sciences and Department of Rehabilitation Medicine Danderyd Hospital, 182 88 Stockholm 4. Pain and Rehabilitation Centre, Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden	
	5b	Name and contact information for the trial sponsor	Linköping University 581 83 Linköping Sweden +46 28 10 00	Page 1, manuscript file
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A	
	5d	Composition, roles, and responsibilities of the coordinating center, steering	N/A	

		committee, end point adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see item 21a for DMC)		
Introduction Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Chronic musculoskeletal pain (CMSP) severely affects the individual's quality of life, functioning and ability to work, and comes with significant societal costs for sick leave and loss of productivity. After completing an Interdisciplinary Pain Rehabilitation Program (IPRP), patients with CMSP experience a gap in the return to work (RTW) process when the responsibility for RTW is taken over by the employer. The employers have a crucial role in a successful RTW process but may lack knowledge regarding the condition and how to support the employee with CMSP in the best way during RTW. Barriers for RTW for persons with CMSP are for example lack of support at the workplace, not finding the right fit between the employee's physical abilities and work tasks, or problems with relationships with supervisors or coworkers. Key factors for a successful RTW are communication and collaboration between the employer and the employee. To facilitate the important interaction between employer and employee a shared smartphone application may be a tool for increasing a successful outcome in the RTW process. Smart phone applications as digital support has shown promising results for persons with chronic pain and can be helpful especially in an out-clinic setting. They are easily accessed, can enable management of the condition, and reduce pain interference. Focusing on self-management and empowerment are important parts of successful digital support. Self-monitoring can contribute to learning about consequences of actions and behaviours in daily life. Understanding and using own self-monitoring data for making changes in daily activities can give a sense of control and	Page 5-6, manuscript file

			motivation for continued use of self-management strategies. Although positive effects of digital support have been shown there are limitations related to low overall quality of smartphone apps for CMSP and lack of rigorous assessment of their effectiveness.	
Objectives	7	Specific objectives or hyptheses	The aim is to evaluate the clinical effectiveness of a digital support (SWEPPE) for promoting a sustainable RTW for persons with CMSP and to facilitate the employers' supportive role and responsibilities in the process. The hypothesis is that using SWEPPE will decrease the need for sick leave.	Page 7, manuscript file
Trial design	8	Description of trial design, including type of trial	Registry-based randomized controlled trial with parallel groups.	Page 7, manuscript file
Methods Study setting	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Specialist and primary care level health care in Sweden reporting to the Swedish National Quality Registry for Pain Rehabilitation (SQRP). Study cites are listed in the protocol (ClinicalTrials.gov registration number NCT05058547)	Page 7, manuscript file
Eligibility criteria	10	Inclusion and exclusion criteria for participants.	Inclusion Criteria: Patients entering the trial must have completed an Interdisciplinary Pain Rehabilitation Program (IPRP). The principal inclusion criteria for IPRP in Sweden are: • persistent or intermittent pain lasting ≥3 months • pain affecting daily activities to a large extent, • completed systematic assessment and non-pharmacological optimization is completed, • screening for psychosocial risk factors and differential diagnosis completed	Page 8, manuscript file

			In addition, the following criteria will be applied: • Age 18-65 years • Completed participation in IPRP at any of the participating units. • Having an employment to return to after IPRP or having returned to work but need continued support for creating a sustainable work situation after IPRP. Exclusion criteria: • Completed IPRP but are unemployed or unable to return to work.	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	SWEPPE, a smartphone application where the individual can create an action plan, perform daily registrations of health aspects, self-monitoring of health aspects and goals, have access to a library with evidence-based facts and a coach, and possibility to share information with the employer. The participants will use SWEPPE for 12 months. Participants randomized to the control group will not receive any active intervention for RTW after IPRP.	Page 9-10, manuscript file
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)	N/A	
	11c	Strategies to improve adherence to intervention	N/A	

		protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)		
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	The participants can initiate and seek other types of health care or support during their RTW process based on their needs.	Page 10, manuscript file
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Outcome assessments in the present trial are intended to capture the complexity of pain based on the biopsychosocial model namely medical, psychological, and social (total life situation) factors impacting on the work situation. It has been recommended to include multiple outcomes in clinical trials for persons with CMSP to capture important domains affected by symptoms such as functioning and health-related quality of life. The primary and secondary outcomes are collected for evaluation of the clinical effectiveness of SWEPPE, and the complementary variables will be collected based on their effect on the outcome.	Page 12-16, manuscript file
Participant timeline	13	Time schedule of enrollment,	Figure 1.	Page 7, figure 1

		interventions (including any runins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (Figure).		
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Since there is no established minimal clinical important difference regarding sick leave, the sample size calculation was inspired by previous research regarding patterns of sick leave after IPRP [45,46]. It has been shown that the distribution of sick leave change over time from full-time to partial sick leave after IPRP [45] and sick leave are reduced with approximately 16 net days from one year before to two years after IPRP. [46] Therefore, an estimated difference between the groups of 20 net days with a standard deviation of 60 and an effect-size of 0.333 was set for rejection of the null hypothesis. To detect this difference with a power of 80% and a significance level of 0.05 a total sample size of 300 participants (150/group) are needed. With an allowance for 20% of participants lost to follow-up we aim to recruit a total sample size of 360 participants (n=180 intervention, n=180 control).	Page 11, manuscript file
Recruitment	15	Strategies for achieving adequate participant enrollment to reach target sample size	Participants will be recruited from multiple special and primary care level health care providing IPRP for patients with chronic pain.	Page 8-9, manuscript file
Assignment of interventions Allocation sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of	As sick leave history is a strong predictor for future sick leave (47) participants will be stratified based on self-reported number of sick leave days during the year before IPRP. Participants will be divided in high (total number of gross sick leave days ≥ 70) or low sick leave absence and then randomized to intervention or control group. Allocation of the participants to intervention or control group will be	Page 10, manuscript file

		any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions.	conducted using a block randomization design with varying block sizes of 2-6 (48-50). The allocation sequence will be computer generated and sealed sequentially numbered opaque sealed envelopes will be prepared by one of the researchers (GL).	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Sealed sequentially numbered opaque envelopes will be used for implementing the allocation sequence at each participating unit.	Page 10, manuscript file
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	The allocation sequence will be generated by a statistician and one of the researchers (GL) will prepare sequentially numbered opaque sealed envelopes. Enrollment and assignment of participants will be performed by one of the researchers (CT) not involved in preparing the allocation sequence or the envelopes.	Page 10, manuscript file

Blinding	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	Due to the nature of the intervention the participants will not be blinded to group allocation. As randomization to intervention or control group is performed at the completion of IPRP the participants will not have further contact with the health care staff responsible for IPRP or other patients. The participants will be instructed not to reveal their group allocation to the health care staff responsible for IPRP or other patients if they would have further contact.	Page 11, manuscript file
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A	
Data collection, management, and analysis Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and	Data collection for the present trial will start when the IPRP is completed (baseline) and at 12 months follow-up (study ending). Data will be collected from the Swedish Social Insurance Agency's SSIA, the SQRP for specialist and primary care level, supplementary questionnaires to the SQRP, and data registered in SWEPPE (table 1).	Page 16, manuscript file

		validity, if known. Reference to where data collection forms can be found, if not in the protocol.		
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Data collection for the SQRP is routinely performed when the IPRP is completed and at 12 months follow-up at both primary and specialized care units in Sweden providing IPRP. The supplementary questionnaires will be added to these routine data collections for the SQRP.	Page 16, manuscript file
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol.	A data management plan (DMP) will be developed by the principal investigator and co-workers and will include a description of research data, information about documentation and quality control of research data, storage and back-up copying of research data, legal and ethical aspects, accessibility and long-term preservation of research data, and responsibility and resources related to the research data.	Page 17, manuscript file
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes. Reference to where	A statistical analysis plan will be developed with details of statistical analyses, handling of missing data and other possible analyses for example subgroups. Descriptive statistical analyses will be performed for transparent reporting of participant characteristics. The clinical effectiveness off SWEPPE will be analysed using	Page 17-18, manuscript file

		other details of the statistical analysis plan can be found, if not in the protocol.	effect-size and uni- and multivariate statistical analyses as a preliminary plan. Data from SWEPPE will be analysed using repeated measures analyses. All p-values will be presented and a p-value of <0.05 will be considered significant.	
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	A statistical analysis plan will be developed with details of statistical analyses, handling of missing data and any additional analyses, for example subgroup and adjusted analyses.	Page 17-18, manuscript file
	20c	Definition of analysis population relating to protocol nonadherence (e.g., as-randomized analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	Data from primary and secondary outcomes will be analysed according to intention-to-treat.	Page 17-18, manuscript file
Data monitoring	21a	Composition of DMC; summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed.	All data in the trial will be monitored regularly. Since no sponsors or competing interests exists, monitoring of data will be performed independently. To ensure proper handling and storing of data (structure, organization, file naming), the DMP will be reviewed regularly by the principal investigator and co-workers.	Page 17, manuscript file

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	SWEPPE can be assumed not to create adverse events and is considered a safe intervention. Nevertheless, all participants will be encouraged to report any adverse events or unintended effects of trial intervention or trial conduct such as unexpected side effects or deterioration of symptoms.	Page 18, manuscript file
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	To facilitate adherence to the study protocol the project coordinator (CT) will have regular contact (every second week) with the participating units during the study period. Processes to be reviewed are participant screening and eligibility. Documentation of the recruitment and randomization/allocation process, for example eligible patients asked to participate, the number of patients included, excluded or declining participation, performed by CT will be reviewed by the researchers (GL, MB).	Page 18, manuscript file
Ethics and dissemination Research ethics approval	24	Plans for seeking REC/IRB approval	The study is approved by the Swedish Ethics Review Board (Dnr 2020-01593, Dnr 2021-01854).	Page 18-19, manuscript file

Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, RECs/IRBs, trial participants, trial registries, journals, regulators)	Any important modifications of the study protocol will be communicated to the Swedish Ethics Review Board and to the participants	Page 18-19, manuscript file
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see item 32)	Informed consent will be collected from all participants by one of the researchers (CT). See also the model consent form in S3.	Page 18, manuscript file.
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect	Confidentiality will be protected by coding of individual participants' collected data.	Page 18-19, manuscript file

		confidentiality before, during, and after the trial		
Declaration of interest	28	Financial and other competing interests for principal investigators for the overall trial and each study site	The authors have no competing interests to declare.	Page 19, manuscript file
Access to data	29	Statement of who will have access to the final trial data set, and disclosure of contractual agreements that limit such access for investigators	Data will be stored at a password protected project server at Linköping University and will not be accessed by unauthorized persons.	Page 19, manuscript file
Ancillary and post-treatment care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, health care professionals, the public, and other relevant groups (e.g., via publication, reporting in results	The study results will be submitted to peer-review journals for publication and will be presented in national and international research networks, clinical settings, and patient associations.	Page 19, manuscript file

		databases, or other data-sharing arrangements), including any publication restrictions		
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A	
	31c	Plans, if any, for granting public access to the full protocol, participant-level data set, and statistical code	The study protocol is available via Clinicaltrial.gov. There is no present plan regarding public access of participant-level data set or statistical code.	Page 18-19, manuscript file
Appendices Informed consent material	32	Model consent form and other related documentation given to participants and authorized surrogates	The consent form is design based on the Swedish Ethics Review Board recommendation and includes written information about the study, supplementary file S3.	Page 18, manuscript file and page 21 in supplemental file
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A	

S2. Overview of the study in relation to the World Health Organization (WHO) trial registration data set.

WHO item	Item description	Study description	Page number where item can be found.
1.	Primary registry and trial identifying number	Primary registry at ClinicalTrials.gov registration number NCT05058547	Page 4, manuscript
2.	Date of registration in primary registry	27 September 2021	Page 4, manuscript
3.	Secondary identifying numbers	The Swedish Research Council for Health, Working Life and Welfare: Dnr 2019-01264 The Swedish Ethics Review Board: Dnr 2020-01593, Dnr 2021-01854	Page 18-19, manuscript
4.	Sources of monetary or material support	The Swedish Research Council for Health, Working Life and Welfare: Dnr 2019-01264	Page 19, manuscript
5.	Primary sponsor	Linköping University	Page 1, manuscript
6.	Secondary sponsor(s)	N/A	
7.	Contact for public queries	Mathilda.bjork@liu.se +4611363531 Linköping University 581 83 Linköping Sweden Recruitment status: not yet recruiting	Page 1, manuscript
8.	Contact for scientific queries	Mathilda Björk Mathilda.bjork@liu.se +4611363531 Department of Health, Medicine and Caring Sciences Linköping University 581 83 Linköping Sweden	Page 1, manuscript
9.	Public title	An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a	Page 1, manuscript

		sustainable return to work: a study protocol for a registry-based multicentre randomized controlled trial.	
10.	Scientific title	An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: a study protocol for a registry-based multicentre randomized controlled trial.	Page 1, manuscript
11.	Countries of recruitment	Sweden	Page 7, manuscript
12.	Health condition	Chronic pain	Page 7, manuscript
13.	Intervention	Participants randomized to the intervention group will receive the smartphone application SWEPPE to use as a digital support during the RTW process. SWEPPE is a smartphone application where the individual can create an action plan, perform daily registrations of health aspects, self-monitoring of health aspects and goals, have access to a library with evidence-based facts and a coach, and possibility to share information with the employer. The intervention starts at the end of the IPRP with self-rating of work conditions and goal setting in SWEPPE. The participants will use SWEPPE for 12 months. Data registered in SWEPPE by the participant about their goal, work condition and self-rating will be stored in the application and used for self-monitoring and visualizing progress for the participant. The participant invites his/her employer/employers to access the web application SWEPPE depending on what information the participant wants to share with the employer. The employer will receive e-mail reminders to use SWEPPE. Participants randomized to the control group will not receive any active intervention for RTW after IPRP.	Page 9-10, manuscript
14.	Key inclusion and exclusion criteria	Inclusion Criteria: Patients entering the trial must have completed IPRP[a]. The principal inclusion criteria for IPRP in Sweden are: • persistent or intermittent pain lasting ≥3 months • pain affecting daily activities to a large extent, • completed systematic assessment and non-pharmacological optimization is completed, • screening for psychosocial risk factors and differential diagnosis completed In addition, the following criteria will be applied: • Age 18-65 years	Page 8, manuscript

		• Completed participation in an Interdisciplinary Pain Rehabilitation Program (IPRP) at any of the participating units. • Having an employment to return to after IPRP or having returned to work but need continued support for creating a sustainable work situation after IPRP. Exclusion criteria: • Completed IPRP but are unemployed or unable to return to work.	
15.	Study type	Registry-based randomized controlled trial. Stratification of sick leave history during the year before IPRP and block-randomization, using opaque sealed and numbered envelopes, to intervention (SWEPPE) or control group. Due to the nature of the intervention the participants will not be blinded to group allocation.	Page 7, manuscript
16.	Date of first enrollment	Anticipated to spring 2022.	Page 16, manuscript
17.	Target sample size	Total number of participants: 360	Page 11, manuscript
18.	Recruitment status	Pending	Page 4, manuscript
19.	Primary outcome(s)	Sick leave. Time Frame: 12 months follow up after IPRP. Number of gross and net days with sickness cash benefit	Page 12, manuscript
20.	Key secondary outcome(s)	1. Return to work. Time Frame: 12 months follow up after IPRP. Return to work (partially or full time) every month 2. Sick-leave spells per months. Time Frame: 12 months follow up after IPRP. Number of sick-leave spells (per month) 3. Return to work group level. Time Frame: 12 months follow up after IPRP. Proportions of a group who returns to full- or part-time work (per month) 4. Working days before new sick leave. Time Frame: 12 months follow up after IPRP. Number of days in work before new sick leave during study period 5. Proportion back to work. Time Frame: 12 months follow up after IPRP. Proportion of a group back to work >28 days (full- or part time) before a new sick-leave spell occurs 6. Total sick-leave spells. Time Frame: 12 months follow up after IPRP. Number of sick-leave spells during study period	Page 13-16, manuscript

		7. Length of total sick leave. Time Frame: 12 months follow up after IPRP. Length of total sick leave during study period 8. Pain intensity last 7 days. Time Frame: Baseline and 12 months. Numeric pain rating scale. 9. Consequences of pain on daily life. Time Frame: Baseline and 12 months. Multidimensional Pain Inventory Swedish version. 10. Overall emotional distress. Time Frame: Baseline and 12 months. Hospital Anxiety and Depression Scale Swedish version. 11. Physical and mental health. Time Frame: Baseline and 12 months. RAND-36 Swedish version. 12. Goal fulfilment and satisfaction during the study period. Time Frame: Baseline and 12 months. Explanatory Outcome Measures: 1. Self-reported fatigue the last 7 days. Time Frame: Baseline and 12 months. Numeric fatigue rating scale. 2. Self-reported insomnia. Time Frame: Baseline and 12 months. Insomnia Severity Index Swedish version. 3. Self-reported fear of movement. Time Frame: Baseline and 12 months. Tampa Scale for Kinesiophobia Swedish version. 4. Self-reported physical activity. Time Frame: Baseline and 12 months. The National Board of Health and Welfare's three questions on physical activity, exercise, and sedentary behavior. 5. Pain catastrophizing. Time Frame: Baseline and 12 months. Pain Catastrophizing scale Swedish version. 6. Perceived work ability. Time Frame: Baseline and 12 months. Work Ability Index Swedish version. 7. Self-reported demands, control, and support at the workplace. Time Frame: Baseline and 12 months. Demand Control Support Questionnaire Swedish version. 8. Self-reported physical work environment using a questionnaire inspired by the Swedish Work Environment Authority ergonomics checklist	

		9. Perceived life Satisfaction. Time Frame: Baseline and 12 months. Life satisfaction Scale Swedish version. 10. Self-reported work situation during the study period. Time Frame: Baseline and 12 months. Barriers for return to work, strategies to handle barriers and need of support from the employer reported as text answer. 11. Self-reported workload an average day. Time Frame: Baseline and 12 months. Number of hours per day for paid work and unpaid household work. **Data collected from SWEPPE** Mobile app usage, for example number of participants using the app, performing daily self-rating, sharing information with the employer, or asking questions to the coach will be retrieved from SWEPPE.	
21.	Ethics review	Approved	Page 18, manuscript
22.	Completion date	After the last subject's last visit.	Page 16, manuscript
23.	Summary results	Summary results will be provided when the trial is completed.	Page 18, manuscript
24.	IPD sharing statement (individual clinical trial participant- level data)	Not planned to share individual clinical trial participant- level data (IPD)	Page 19, manuscript