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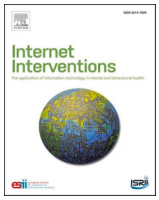

From the identification of biopsychosocial risk factors to an increase in pain-related self-efficacy (IDRIS) – The online-based conveyance of an explanatory model for chronic back pain: Study protocol of a cohort multiple randomized controlled trial

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ABSTRACT

Background: Back pain has a high global prevalence and carries a substantial risk for chronification. Biopsychosocial factors are assumed to be critical in the transition from acute to chronic back pain. Digital interventions are a promising tool to educate patients about their complaints. Thus, providing patients with an explanatory model regarding their individual risk factors in the early stage of their complaints via the internet might thus be a valuable approach in treatment.

Objectives: The objectives of the present online study are to investigate the influence of a personalized psychoeducational intervention on self-efficacy and functioning and to examine biopsychosocial risk factors for symptom chronification. The intervention is based on a current model summarizing the empirical knowledge on relevant factors for persistent somatic symptoms, which has not been studied in back pain patients yet.

Methods: An observational cohort of patients with acute and subacute back pain ($N = 564$) will be asked about biopsychosocial risk factors via online survey at baseline, 4-week, and 12-week follow-up. Within this cohort, a randomly selected group of 132 participants (intervention group) with psychological burden (MCS-12 score of the SF-12 ≤ 50) and relevant somatic symptom intensity and interference (mean sum score of two numeric rating scales ≥ 5) and no prior psychotherapeutic treatment will be offered a personalized explanatory model in the form of an animated psychoeducational video. The video will be personalized in terms of participants' individual symptom profile and will be made accessible to watch online for 7 days. Participants will be compared to a control group receiving no treatment regarding change in pain-specific self-efficacy after 1 month as primary outcome, and change in functioning after 1 and 3 months, respectively, as secondary outcomes. Acceptance and usefulness of the intervention will be evaluated using the number of video views and a numeric rating scale.

Discussion: This is the first investigation of a personalized, video-animated online psychoeducation based on patients' individual risk factors for the chronification of back pain and the first systematic evaluation of the risk factors included in a comprehensive aetiological model on persistent somatic symptoms in back pain patients. This way, this study contributes to the understanding of cross-disorder psychopathological factors and a stronger consideration of biopsychosocial factors in the treatment of persistent somatic symptoms. If proven effective, the internet-based intervention will make an important contribution to the early treatment of back pain.

Ethical approval: The study was approved by the Local Psychological Ethics Committee (LPEK) at the Center for Psychosocial Medicine of the University Medical Center Hamburg-Eppendorf.

Trial registration: The study was registered at the German Clinical Trials Register in December 2021 (registration trial number: DRKS00025445).

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1. Introduction

Back pain is one of the most common medical symptoms worldwide, resulting in substantial patient impairment as well as excessive costs for the healthcare system (World Health Organization, 2021). A recent cross-sectional survey shows that 61.3 % of the German population suffered from back pain within the last 12 months (von der Lippe et al., 2020). Although back pain often takes a favorable course, a significant proportion of patients develop chronic back pain (Costa et al., 2012). Despite these facts, many patients do not receive treatment concordant with current guidelines (Stevans et al., 2021). For instance, a central element in back pain management according to national and international guidelines is to provide information on health-conscious behavior and to convey a biopsychosocial model early in the treatment process (National Guideline Centre UK, 2016; Bundesärztekammer (BÄK), 2017). Studies have shown, though, that this is often impeded not only due to patients', but also healthcare professionals' biomedical focuses and beliefs (Darlow et al., 2012).

Research in the past decades has demonstrated that psychological and psychosocial risk factors are consistently more crucial for the chronification of back pain than biomedical risk factors (Vargas-Prada and Coggon, 2015). In a systematic review, Chou and Shekelle (2010) identified maladaptive pain coping behaviors, non-organic signs (defined as psychological components or intentionally misreported or exaggerated symptoms (Waddell et al., 1980)), functional impairment, general health status, and comorbid psychological disorders as the strongest predictors of chronic back pain, accordingly.

However, there is still little consensus regarding the cross-disorder aetiology of persistent somatic symptoms (PSS), including chronic back pain, in general. Current aetiological models assume that biopsychosocial risk factors contribute to the chronification of somatic symptoms and that higher-level mechanisms of action are valid regardless of the "explainability" of complaints from an organ pathological perspective (Klaus et al., 2013). A recently published comprehensive vulnerability-stress model summarizes the current evidence regarding predisposing, triggering, and maintaining factors in the transition from acute symptoms to PSS (Henningsen et al., 2018). As a result, a variety of potentially relevant factors have been identified that may influence patients' perceptions of their somatic symptoms. At the same time, these factors are thought to affect the intensity of symptoms, expectations regarding symptom development, as well as the constellation in which biopsychosocial factors influence the course of somatic symptoms (Deary et al., 2007; Rief and Martin, 2014). In a large German research unit (SOMACROSS (Löwe et al., 2022)), the model provides the basis for developing a deeper disorder-specific understanding of psychopathological risk factors across different medical disciplines, while identifying higher-level mechanisms and exploring opportunities for change. Despite the great relevance of chronic back pain within the field of PSS, the model has not yet been specifically studied in this patient group.

One key mechanism regarding the experience of pain and disability is patients' pain-related self-efficacy (Woby et al., 2007). It has been found to be even more relevant than fear of movement (Costa et al., 2011). According to current research and clinical practice, promoting patients' self-efficacy with regard to their symptoms is the primary goal in therapy, providing the best positive long-term effects (Schiltenwolf and Henningsen, 2018). There are different approaches to promote patients' self-efficacy within a biopsychosocial framework. A central element of cognitive behavioral therapy (CBT), which has been well studied for its efficacy in chronic back pain (Kröner-Herwig, 2018), is the development of an individual explanatory model. In CBT, the conveyance of disorder-specific information with the aim of empowering patients and promoting self-efficacy is often summarized under the term psychoeducation. A Cochrane review showed that an average of 2.5 h of psychoeducation was sufficient to improve the treatment outcome of subacute back pain and to enable an earlier return to work (Engers et al., 2008).

In the same study, the authors noted that the way psychoeducation was delivered could have a strong influence on effectiveness, and further criticized that none of the included studies had specified which theoretical model the psychoeducation was based on (Engers et al., 2008). It therefore seems conceivable that shorter interventions might also be beneficial to back pain patients if they are theory-based and delivered in a user-oriented way, e.g., by using digital media. In a recently published study, for instance, a brief psychoeducational intervention has shown significant symptom improvement in somatic symptom disorder (Johnson et al., 2022). Notably, internet-based interventions have several advantages: Besides being easy to deliver and administer, they are convenient for users, cost-effective, scalable, and provide the ability to personalize content to meet individual needs (Borrelli and Ritterband, 2015). Technology-based interventions have been shown to positively affect PSS including chronic pain (Vugts et al., 2018). At the same time, content quality of public back pain websites or videos on streaming platforms like YouTube has been found to be low (Costa et al., 2020; Hornung et al., 2022). Accordingly, there is a need for higher quality information on back pain on the internet.

Experimental studies and evidence-based recommendations on health communication point out that the information provided should meet personal needs (Hollands and Marteau, 2013), be presented in lay language (Lühnen et al., 2015), and allow patients an active choice in content selection (Kreuter and Wray, 2003). Even though such a personalized approach has been recommended for digital interventions (O'Connor et al., 2016), tailoring is often not implemented in interventions for back pain (Nicholl et al., 2017).

In summary, back pain patients are oftentimes not provided with biopsychosocial psychoeducation in order to prevent chronification and foster patients' self-efficacy. The biopsychosocial risk factors of a current evidence-based aetiological model on PSS have not yet been studied in chronic back pain. Existing psychoeducational interventions often lack both a theoretical foundation as well as individual tailoring in terms of symptomatology. Since internet-based interventions are a promising tool for patient education, we assume that a patient-oriented conveyance of personalized psychoeducation on back pain via the internet can increase self-efficacy of those affected and consequently prevent chronification (see Fig. 1). In this study, we thus want to assess the influence of a video-animated psychoeducation on patients' pain-related self-efficacy by developing animated videos that help patients to understand contributing factors regarding their back pain, and show ways to improve behavioral, cognitive, and affective components. This effect will be further strengthened by elements of personalization, i.e., the selection of those components that are relevant to the patient, rather than generally applicable, based on the patient's individual symptom score with regard to a predefined selection of potential risk factors for the chronification of back pain. In addition, we will examine the effect of the personalized psychoeducation on functioning as well as investigate further biopsychosocial risk factors for the development and maintenance of chronic back pain according to a current aetiological model. To the best of our knowledge, no online study to date has examined the effect of individualized psychoeducation on self-efficacy and functioning in back pain patients.

1.1. Objectives

The primary aim of the IDRIS study (full title: From the identification of biopsychosocial risk factors to an increase in pain-related self-efficacy – The online-based conveyance of an explanatory model for chronic back pain) is to examine if patients' pain-related self-efficacy can be altered by the presentation of a personalized, animated psychoeducational online intervention at the early stage of symptoms. Second, it will assess the effect of the intervention on functioning. In addition, the study will investigate the biopsychosocial risk factors of an evidence-based aetiological model for the development and maintenance of chronic back

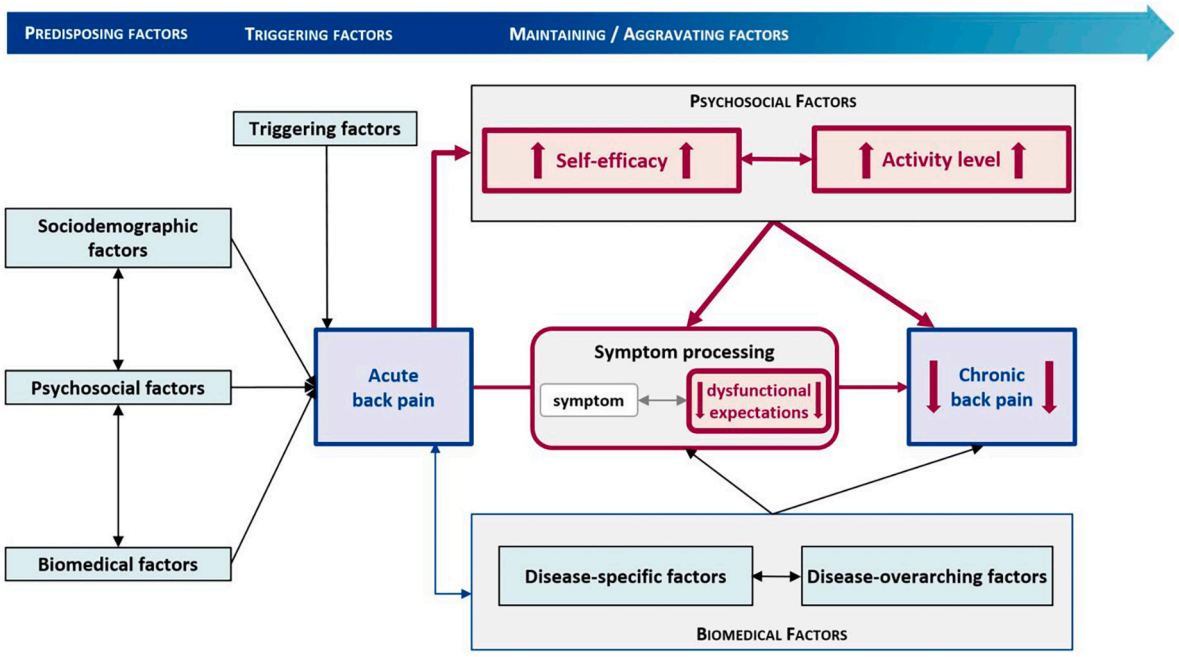

Fig. 1. Schematic illustration of the hypothesized mechanisms of action of conveying a personalized psychoeducation to back pain patients, based on the working model of the research unit SOMACROSS (Löwe et al., 2022).

pain.

2. Methods and analysis

2.1. Study design

The IDRIS trial is designed as an internet-based study on patients with acute and subacute back pain, which will be conducted nationwide in Germany. According to the "cohort multiple randomized controlled trial" design (Relton et al., 2010), a total observational cohort of patients in the early phase of their complaints (duration ≤ 12 weeks) will be collected. At baseline (T0), 4-week (T1), and 12-week (T2) follow-up, patients will be asked about biopsychosocial risk factors with regard to a possible chronification of their complaints via an online survey using the software REDCap (Harris et al., 2019). Subsequently, an explorative comparison of the severity of risk factors in those patients with and without chronic back pain will be carried out. From the total cohort, a group of eligible study participants will be randomly selected and offered a personalized psychoeducation to evaluate the influence of a personalized explanatory intervention on pain-related self-efficacy and on functioning (randomized controlled trial cohort). The term personalized refers to the inclusion of only those risk factors in each participant's intervention video that are relevant to that individual person. Accordingly, the selection of videos to create a personalized intervention for participants will be based on the individual data collected at T0. Participants will receive a link to access their personalized animation video for 7 days. The intervention group will then be compared with a randomly selected eligible control group, with respect to the primary and secondary outcomes. Data collection and management will be in accordance with the European General Data Protection Regulation as well as German law.

2.2. Study procedures

2.2.1. Recruitment

The complete study will be conducted online. $N = 564$ participants will be recruited from the general population via the internet, i.e., social media, internet forums, and professional associations, as well as in specific therapeutic settings, e.g., physiotherapy practices. All recruitment ways will lead to an open access study website, which contains detailed information on the study, data safety procedures, the study team, and contact information. Interested applicants will be asked to provide online informed consent and to complete the T0 assessment thereafter.

2.2.2. Inclusion and exclusion criteria

We will include participants aged between 18 and 67 years who have been suffering from back pain for a maximum of 12 weeks. Exclusion criteria are chronic back pain (duration >12 weeks), a severe acute somatic back injury (herniated disc, surgical intervention, etc.), insufficient knowledge of the German language, a self-reported substance use disorder, and insufficient self-reported mental or physical health for study participation.

Explicit inclusion criteria for participation in the randomized controlled trial (RCT) cohort are a minimum burden due to psychological distress operationalized as score of ≤50 in the Mental Composite Scale (MCS-12) of the Short Form 12 (SF-12) (Ware et al., 1996) and a minimum burden in terms of symptom intensity and symptom interference corresponding to a mean sum score of ≥5 on two numerical rating scales (NRS; range: 0–10) (Rief et al., 2017). The MCS-12 score of ≤50 was chosen as it is the general population mean (Ware et al., 1996) and has been recommended as a screening cut-off for mental disorders (Gill et al., 2007). For chronic pain patients, scores between 34 (Díaz-Arribas et al., 2017) and 40 (Piontek et al., 2019) have been found, but due to our target population of patients in the early phase of their complaints, a liberal inclusion criterion seemed appropriate. Explicit exclusion criteria for participation in the RCT cohort are a current or previous inpatient psychosomatic hospital or rehabilitation treatment and a current or previous outpatient psychotherapy due to back pain. Eligibility criteria will be assessed within a self-report online survey at T0.

2.2.3. Randomization

All included participants from the total cohort ($N = 564$) will be screened to determine if they meet the criteria for the RCT cohort. Eligible participants included in the RCT cohort will be randomly

assigned to either the intervention or the control group. Randomization within the RCT cohort will take place directly after inclusion, based on a random number system and a web-based randomization tool. According to the sample size/power calculation, $n = 264$ participants who meet the inclusion criteria for the RCT cohort are required. Fig. 2 provides a detailed overview of the study flow.

2.3. Variables and instruments

All participants will complete online questionnaires on potential risk factors for the chronification of back pain at baseline, 4-week, and 12-week follow-up. An overview of all instruments employed at baseline and follow-up is provided in Table 1.

2.3.1. Self-efficacy and functioning

The primary outcome of the RCT will be change in patients' pain-specific self-efficacy after 1 month, determined via the German adaptation of the Pain Self-Efficacy Questionnaire ("Fragebogen zur Erfassung der schmerzspezifischen Selbstwirksamkeit"; ΔFESS) (Mangels et al., 2009). Secondary outcomes will be change in functioning after 1 and 3 months. Symptom intensity and symptom interference will be assessed using two numerical rating scales according to the recommendations of EURONET-SOMA (Rief et al., 2017). Symptom-related disability will be measured using an adapted version of the Pain Disability Index (Dillmann et al., 1994) and health-related quality of life using the SF-12 (Ware et al., 1996). Further variables included in the study are summarized in Table 1. Further information on the corresponding instruments can be found in the study protocol of SOMACROSS (Löwe et al., 2022).

2.3.2. Acceptance and usefulness of the intervention

The total number of video views within the 7 days will be used to quantitatively estimate acceptance and feasibility of the intervention. Perceived usefulness of the intervention will be measured using five NRS (range: 0–10).

2.3.3. Sample characterization

In order to describe the study sample, sociodemographic information on age, gender, nationality, martial status, living situation, insurance, education, occupational status, healthcare utilization, smoking, weight, height, and data on symptom onset, pain intensity, and medication will be collected online via self-report at T0. Data will also include somatic and mental comorbidities: Depression will be measured using the Patient Health Questionnaire (PHQ-8) (Löwe et al., 2004), anxiety via the Generalized Anxiety Disorder Scale 7 (GAD-7) (Spitzer et al., 2006).

2.4. Intervention group

The personalized and visualized psychoeducation will be made available for the intervention group immediately after randomization. After receiving a link to access their personalized animated video, participants will be able to watch the video for 7 days on any digital device (computer, tablet, smartphone, etc.). Participants will be informed that the video has been created based on their own data entries and is tailored to their individual symptom profile. They will further be informed that the video includes information on factors influencing their back pain and on how to potentially address these factors. In order to benefit the most from all the information provided, participants will be advised to watch their personalized video several times, e.g., once a day. Length of the intervention will depend on the number of factors identified to be relevant for the individual participant.

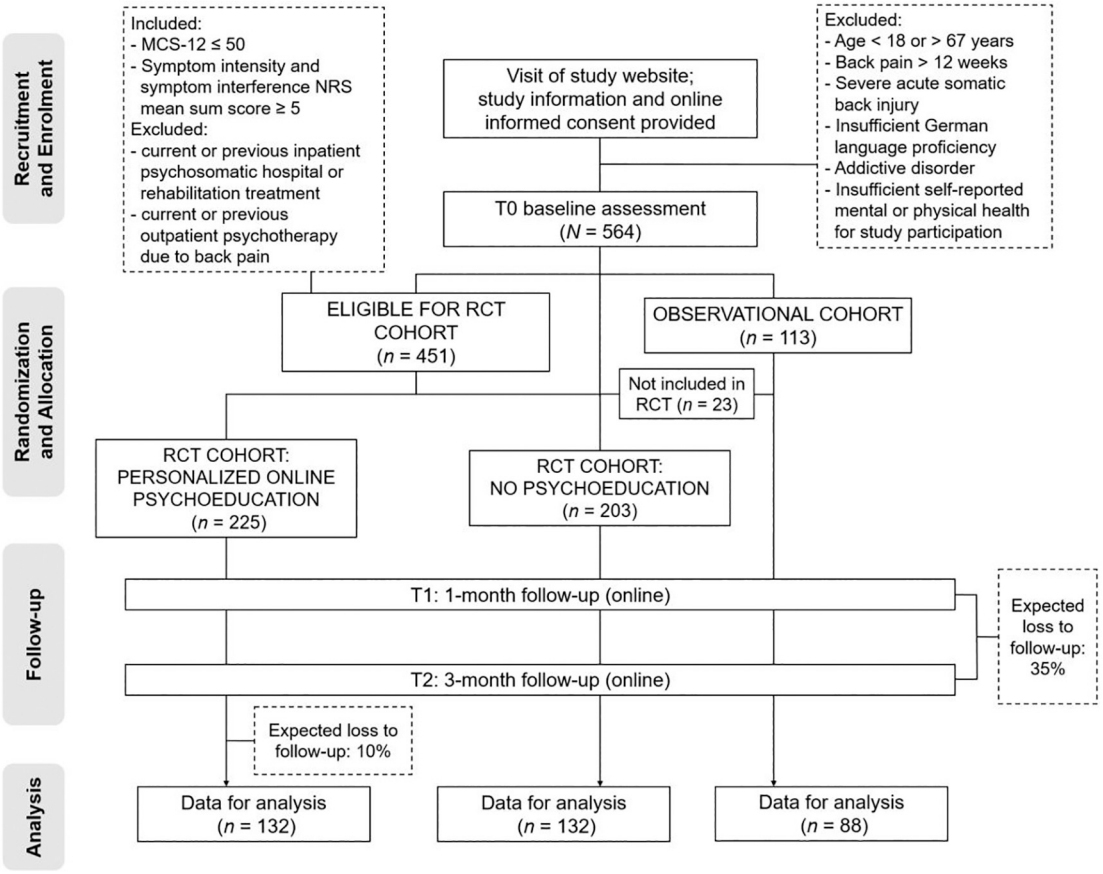

Fig. 2. Flow chart of the IDRIS study.

Table 1
Overview of instruments employed in the IDRIS study.

Risk factors and mechanisms (assessed via self-report)						
Predisposing, triggering, and maintaining/aggravating factors	Single constructs	Instrument	Items	Months		
				0	1	3
Sociodemographic factors	Gender, age, nationality, height, weight, marital status, migration status, current housing situation, insurance, education, occupational status, smoking	Single items	20	X		
	Health care utilization	Single items	2	X	X	X
	SARS-CoV-2 infection and Long COVID	Single items	7	X	X	X
Psychosocial factors	(Complex) PTSD	International Trauma Questionnaire (ITQ)	18	X		
	Negative affectivity	Positive and Negative Affectivity Schedule (PANAS)	20	X		
	Life stressors	Perceived Stress Scale (PSS-10)	10	X		
	Perceived stigmatization	Single items	2	X		
Cognitive-perceptual and emotional mechanisms	Somatosensory amplification	Somatosensory Amplification Scale (SSAS)	10	X	X	X
	Catastrophizing	Coping Strategies Questionnaire - Catastrophizing Subscale (CSQ-CAT)	6	X	X	X
	Treatment expectations	Treatment Expectation Questionnaire (TEX-Q)	17	X	X	X
	Expectation of symptom severity	Numeric Rating Scale	1	X	X	X
	Expectation of symptom burden	Numeric Rating Scale	1	X	X	X
	Expectation of coping with symptoms	Numeric Rating Scale	1	X	X	X
	Illness-related worries	Whiteley-Index Short Version (WI-7)	7	X	X	X
	Symptom perception	Illness perception questionnaire (B-IPQ)	8	X	X	X
	Anxiety severity	Generalized Anxiety Disorder-7 (GAD-7)	7	X	X	X
	Depression severity	Patient Health Questionnaire-8 (PHQ-8)	8	X	X	X
	Alexithymia	Toronto Alexithymia Scale (TAS-20)	20	X		
	Emotion regulation	Emotion Regulation Questionnaire (ERQ)	10	X		
	COVID-19 anxiety	Single item	1	X	X	X
Behavioral factors	Physical inactivity	International Physical Activity Questionnaire (IPAQ-SF)	7	X	X	X
	Pain avoidance/endurance	Avoidance-Endurance Fast Screening (AE-FS)	9	X	X	X
	Fear of movement	Tampa Scale for Kinesiophobia (TSK-GV)	11	X	X	X
Biomedical and treatment-related factors	(Prior) organic disease/comorbidity	Self-Administered Comorbidity Questionnaire (SCQ)	16	X		X
	Medication adherence	Medication Adherence Report Scale (MARS-D)	5	X	X	X
	Treatment side effects	Numeric Rating Scale	1	X	X	X
	Treatment experience	Numeric Rating Scale	2	X	X	X
	Symptom duration	Single item	1	X		
	Pain severity	Classification of von Korff et al.	8	X		X
	Medication	Single item	2	X		X
	Somatic symptom burden	Patient Health Questionnaire (PHQ-15)	15	X	X	X
Outcome variables (assessed via self-report)						
Primary outcome: self-efficacy	Self-efficacy	Fragebogen zur Erfassung der schmerzspezifischen Selbstwirksamkeit (FESS)	10	X	X	X
Secondary outcomes: functioning	Symptom intensity	EURONET-SOMA Numeric Rating Scale	1	X	X	X
	Symptom interference	EURONET-SOMA Numeric Rating Scale	1	X	X	X
	Symptom-related disability	Pain Disability Index – adapted (PDI)	7	X	X	X
	Health-related quality of life	Short Form Health Survey (SF-12)	12	X	X	X
Acceptance and usefulness of the intervention (RCT cohort only)	Use of the individualized video	Number of video views within 7 days	N/A		X	
	Perceived usefulness of the intervention	Numeric Rating Scale	5			X
TOTAL (self-report items)			289			

2.4.1. Development and design of the intervention

The intervention development and implementation consists of three sub-steps. In the first step, animated short films will be created for a total of eight selected risk factors which have been identified in the literature as particularly relevant for the chronification of back pain and which can also be operationalized as elements of the aetiological model by Henningsen et al. (2018), using the software Adobe After Effects 2022 (version 22.1.1) (Adobe After Effects, 2022). The videos will be made explicitly for the patient target population, using lay language and compromised information from research findings. Besides information on biopsychosocial factors, potential for change will be illustrated in order to promote an increase in self-efficacy. In the second step, those risk factors that are relevant for the individual patient will be determined algorithmically by means of questionnaires, using cut-off scores at baseline. Thus, if a patient's baseline questionnaire score reaches a predefined cut-off, the risk factor assessed by the questionnaire is considered to be relevant to the patient so that he/she will receive the corresponding animated short film on that factor as part of his/her individual psychoeducation. For an overview of the eight risk factors potentially addressed in the intervention, core elements of the intervention modules, as well as corresponding questionnaires and cut-off scores see Table 2. Out of each short film, one complete personalized film will be compiled for each participant in the intervention group in the third step. This film will be sent to the patient via a link and made available online for 7 days.

Table 2
Risk factors for the chronification of back pain potentially addressed in the intervention based on cut-off scores in the corresponding questionnaires and core elements of the intervention modules.

Risk factor	Instrument	Cut-off score	Core elements of the intervention module
Depression severity	PHQ-8	≥5	• Symptoms of a depressive episode • Vicious cycle of depression and back pain • Building positive activities and dealing with negative thoughts
Health anxiety	WI-7	≥2	• Physiological effects of anxiety • Connection between anxiety and pain • Relaxation and breathing techniques
Catastrophizing	CSQ-CAT	≥10	• Examples of catastrophizing thoughts • Effects of catastrophizing on pain persistence • Attention redirection and inner distancing by developing helpful, realistic thoughts
Pain endurance	AE-FS	PPS subscale ≥3	• Balance between inactivity and overload • Recognition of personal limits • Temporary acceptance of reduced mobility
Fear of movement and physical inactivity	TSK-GV IPAQ-SF	≥25 ≤Moderate physical activity	• Vicious cycle of avoidance behavior and pain • Graded exposure • Movement exercises
Symptom and treatment expectations	TEX-Q	Positive expectations ≤6 Negative expectations ≥5	• Placebo/nocebo effect • Development of expectations • Challenging expectations
	NRS (EXPECT 1, 2, 3)	Mean score ≥ 5	
Traumatic experiences	ITQ	≥13	• Link between early trauma and pain • Role of pain memory • Stabilization tools
Emotion regulation deficits	ERQ	Reappraisal ≤4.0 Suppression ≥3.5	• Distinction between bodily sensations and emotions • Association between emotion regulation deficits and pain • Stimulation of emotional perception

Note. PHQ-8 = Patient Health Questionnaire-8, WI-7 = Whiteley-Index Short Version, CSQ-CAT = Coping Strategies Questionnaire - Subscale, AE-FS = Avoidance-Endurance Fast Screening, TSK-GV = Tampa Scale for Kinesiophobia, IPAQ-SF = International Physical Activity Questionnaire, TEX-Q = Treatment Expectation Questionnaire, NRS = Numeric Rating Scale, ITQ = International Trauma Questionnaire, ERQ = Emotion Regulation Questionnaire.

2.4.2. Control group

Participants in the control condition will receive no animated psychoeducation. Their data will be used for comparison with the intervention group.

2.5. Sample size/power calculation

An explorative approach was chosen for the identification of risk factors within the total study cohort. The RCT is powered with regard to the difference in change of pain-related self-efficacy between the intervention and the control group as effect of the intervention, thus forming our primary objective. As the intervention to be tested is a brief intervention in the initial stage of symptoms in untreated patients and based on previous findings (Nicholl et al., 2017), we assume a small effect $f = .15$ (Cohen, 2013). We further assume a correlation of $r = 0.5$ between the primary outcome of change in self-efficacy (Δ FESS) and fear of movement (Δ TSK-GV). Fear of movement will be included as a covariate in the design, allowing for a magnification of the expected effect to $f = .173$ (Lipsey, 1990). To be able to detect this effect size with a two-group analysis of covariance (F-test) and a covariate with $\alpha = 0.05$ and power $= 1\text{-}\beta = 0.8$, a sample size of $n = 132$ in each the intervention and control group is required. The sample size calculation was performed using G*Power (Faul et al., 2009).

Based on our recent experience with another online-based study for patients with depression (Sikorski et al., 2021), we assume an estimated dropout rate of 35 %. Based on data from our outpatient clinic and surveys in the general population (Toussaint et al., 2020), we estimate that a majority (80 %) will meet the specific inclusion criteria in addition to the general ones. Of the eligible participants randomized to the intervention, a majority (90 %) are assumed to participate due to the small amount of additional effort (namely, clicking on a video link and watching the video). This results in a targeted total number of participants of $N = 564$. In order to reach this number, strategies for recruitment optimization will be applied (Darmawan et al., 2020) and incentives of 20 EUR per participant will be paid.

2.6. Handling of missing values

In case of missing data at either baseline or follow-up, cases will be analyzed according to intention-to-treat principles if a minimum of 75 % of data is present. Participants with ≥25 % missing baseline scores will not be included in the study. To reduce missing data, online questionnaires will check for completeness before submitting. If patients do not respond to the email invitation or the link to the intervention, they will be registered as dropouts after at least 5 attempts of being reached via email reminders. Systematic differences between participants and dropouts will be examined using the provided data.

2.7. Statistical analyses

Since normal distribution can be assumed for sum scores of self-efficacy and functioning, mean score and standard deviation will be used as descriptive characteristic. To test the primary hypothesis (psychoeducational intervention improving pain-related self-efficacy), an ANCOVA with experimental group (personalized psychoeducation vs. no psychoeducation) as independent variable and change in self-efficacy at 1-month follow-up as dependent variable (ΔFESS) will be employed, with covariates age, gender, change in fear of movement, and self-efficacy at baseline. For the second hypothesis (the psychoeducational intervention reduces functional impairment), an ANCOVA with experimental group (personalized psychoeducation vs. no psychoeducation) as independent variable and change in functioning at 1- and 3-month follow-up as dependent variables will be employed, with covariates age, gender, and functioning at baseline. For evaluation of the third hypothesis, namely the influence of risk factors on the persistence of back pain, linear regression analyses will be conducted. Results will be reported using regression coefficients corresponding 95-%-confidence intervals and *p*-values. Statistical analyses will be performed using IMB SPSS Version 27.

2.8. Methods to reduce bias

Selection bias is minimized by the inclusion of a control group and the use of a web-based randomization tool. Presentation of the intervention will be standardized by the use of online videos. The videos on each risk factor will be created with the attempt to maximize comparability in terms of length, amount of content, and visual representation. In order to potentially identify invalid entries, the first online survey will comprise the following two questions as validity checks: "Are you participating in the study seriously?" and "Have you already participated in this study?". The full recruitment process will be documented according to CONSORT reporting standards (Moher et al., 2012).

2.9. Study registration

The study was registered at the German Clinical Trials Register (Deutsches Register Klinischer Studien (DRKS), registration trial number DRKS00025445), and thereby automatically submitted to the World Health Organization International Clinical Trials Registry Platform.

3. Discussion

The aim of the IDRIS study is to investigate if patients' pain-related self-efficacy can be modified by means of a personalized and visualized internet-based psychoeducation. Additionally, the influence of the personalized psychoeducation on core symptoms as well as the empirical value of biopsychosocial risk factors of a current aetiological model for the development of PSS in patients with back pain will be examined. The animated conveyance of a personalized psychoeducation based on individually meaningful factors is hypothesized to improve pain-related self-efficacy at 1-month follow up as well as to reduce functional impairment at 1-month and 3-month follow-up compared to a control group. It is further hypothesized that biological, psychological, and social factors contribute to the chronification of back pain (duration >12 weeks).

To our knowledge, this study is the first systematic evaluation of the risk factors of the aetiological model by Henningsen et al. (2018) on PSS in patients with back pain. It is also the first personalized approach to employ a video-animated online psychoeducation developed specifically for this patient population. Enhancing self-efficacy by conveying a personalized explanatory intervention based on patients' individual risk factors is a promising approach to counteract a possible chronification of back pain at an early stage. Previous work has already shown that the early conveyance of patient-oriented explanatory models is positively accepted by patients and can improve processes with regard to expectations and communication (Hüsing et al., 2021). Despite the high relevance of back pain for the healthcare sector and guideline recommendations to provide patients with a biopsychosocial model, online or traditional face-to-face psychoeducation of those affected has so far often neither been theory-based nor personalized with respect to the consideration of individual risk factors (Engers et al., 2008; Nicholl et al., 2017).

3.1. Strengths and limitations

Despite the presented possible benefits of the planned study, several limitations have to be considered. The intervention will not address all potential risk factors for the chronification of back pain, but will be focused on psychological (and not, for example, sociological) factors with the most empirical evidence found in the literature. In order to enhance self-efficacy, a special emphasis will be placed on modifiable factors that can be assessed by means of questionnaires. The mere use of self-report instruments is another limitation. Medical aspects (e.g., previous examinations and diagnostic procedures) will thus only be collected through information provided by the participants and will not additionally be verified by physicians' reports or patient records. The personalization of the intervention is limited to the incorporation of individual symptom profiles and does not include, for instance, further aspects of personalization such as participant names or other personal information. This could be a next step in future studies. The deployment of an online intervention might also be a barrier for some patients. However, internet-based tools are becoming more common in the treatment of back pain (Vugts et al., 2018; Nicholl et al., 2017) and offer various benefits (Borrelli and Ritterband, 2015) that also apply to the IDRIS trial. Beyond that, in view of the COVID-19 pandemic and possible future pandemics, the empirical investigation of digital therapeutic applications has a special relevance. Thus, the planned intervention is intended as complementary to other, multimodal therapeutic approaches that are often difficult to access for non-chronic back pain patients. If proven effective, it will make an important contribution to the early treatment of back pain. Overall, the IDRIS study is a well-designed trial based on the combination of clinical and scientific expertise as well as current empirical evidence on biopsychosocial factors in back pain.

3.2. Conclusion

This study contributes to the understanding of evidence-based and cross-disorder psychopathological factors and complies with the current trend towards a stronger consideration of biopsychosocial factors in the treatment of PSS (Gureje, 2015). By testing the effectiveness of an economic and decentralizable mechanism-based online intervention, we strive to make a contribution to changing patients' and healthcare professionals' biomedical beliefs (Darlow et al., 2012). The feasible, convenient, and cost-effective online intervention can for example be used as part of a stepped-care program.

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Ethics and dissemination

The study procedure was reviewed and approved by the Local Psychological Ethics Committee (LPEK) at the Center for Psychosocial Medicine of the University Medical Center Hamburg-Eppendorf (approved on December 9th, 2021; LPEK-0393). Results from this study will be published in peer-reviewed journals and presented at national and international conferences. Before participation, patients will receive detailed information about the nature, purpose, and possible consequences of the trial. Participants will be required to give written informed consent to participate in the study.

Data sharing statement

Individual participant data will be shared and include data that underlie the results reported in this article after deidentification (text, tables, figures, and appendices). Further, the study protocol will be published and made available publicly. Data will be made available 3 months after publication and end 5 years following article publication.

CRediT authorship contribution statement

PH and BL developed the concept and design of the study, and have acquired the funding. PE wrote the draft of this manuscript, PH and BL provided revisions. All authors contributed to the further writing and approved the final version of the manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be shared with researchers who provide a methodologically sound proposal; proposals should be directed to p.huesing@uke.de. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (https://data.mendeley.com/).

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