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ORIGINAL RESEARCH

Evaluating an early Interdisciplinary Multimodal Assessment for Patients at Risk of Developing Chronic Pain: Results of a Multicentre RCT in Germany

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ABSTRACT

***Introduction*:** Patients at risk of developing chronic pain are often significantly impaired in their daily, social and work activities. An early interdisciplinary multimodal assessment (IMA) includes a systematically integrated view of medical, psychosocial and functional factors to direct patients to need-based treatment services. This multicentre, randomised, controlled trial examined the effects of an IMA on preventing chronic pain and improving care for adult patients.

***Methods*:** The intervention group (IG) received an IMA in accordance with standardised guidelines. The control group (CG) was offered a unimodal medical pain assessment (MPA). Data from the Characteristic Pain Intensity (PI) and Disability Score (DS), as primary outcomes, were collected at assessment and 3 and 6 months later together with secondary outcomes (e.g. depression, anxiety, stress, catastrophizing, health-related quality of life).

***Results*:** A total of 620 (68.4%) valid questionnaires were available at the 6-month follow-up. The mean reduction (numerical rating scale,

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0–10) in terms of improvement within both groups (IG/CG) was 1.6/1.7 points for PI and 1.9/1.8 points for DS. Most secondary outcomes improved as well. However, the differences between the two groups did not reach statistical significance, although there was a tendency for the IG to have a greater effect on some psychological outcomes. Regarding the recommended treatment approaches, the focus in the IG was more on physical activity and psychological and psychosomatic interventions, whereas in the CG there was also a preference for adjusting the medication.

Conclusions: Both early MPA and IMA seem to have a positive effect on outcomes such as pain intensity, functional limitations and psychological factors for patients at risk of developing chronic pain. We critically reflect on the results of the primary research question by discussing the limitations in detail and conclude that further research should ensure that the control conditions reflect standard care and that the follow-up period is long enough.

Trial registration: German Clinical Trials Register (DRKS-ID: DRKS00015443).

Keywords: Chronic pain; Healthcare delivery; Medical pain assessment; Mixed models for repeated measures; Multimodal interdisciplinary pain treatment; Pain and risk factors; Public health; Recurrent pain; Secondary prevention

Key Summary Points

Patients who report recurrent or persistent pain and are at risk of developing chronic pain are often underdiagnosed and therefore undertreated; 20% of those patients require multidisciplinary pain treatment to prevent further impairment

This multicentre randomised controlled trial (RCT) evaluated the effects of the earliest possible interdisciplinary multimodal pain assessment

Pain intensity and functional impairment were reduced after 6 months, but there was no relevant difference between the intervention and control group, which was unexpected

We take a critical look at the results and believe that the study thus helps to shed light on the complicated issue of interdisciplinary pain care

INTRODUCTION

The prevalence of chronic pain with moderate to severe intensity is approximately 15 to 25% in adults worldwide [1–5]. Chronic pain is often accompanied by significant impairment of the affected person's daily activities, social and working life. With an estimated prevalence of 17%, chronic pain is also a frequent cause of sick leave and early retirement in Germany [6, 7].

In line with international studies (e.g. [1, 8, 9]), German researchers report overuse, misuse and underuse of patient care [10]. While overuse can be characterised in particular by excessive use of instrumental diagnostics (multiple imaging for non-specific low back pain) or medication (primarily opiate prescriptions), misuse is due to a lack of patient-centred care options or non-compliance with guideline recommendations [11, 12]. Thus, patients with back pain often receive passive treatment regimens (e.g. massage, injections, tablets) [13]. Regarding underuse, there are reports of insufficient implementation of strongly recommended interventions, such as physical exercise or cognitive-behavioural and interdisciplinary multimodal interventions when psychosocial risk factors (e.g. depression or distress in daily work and private life) are present [11, 14].

Identifying risk factors as early as possible could help to prevent future impairments caused by chronic pain. Following German guidelines, the concept of interdisciplinary multimodal assessment (IMA) includes medical, psychosocial and functional diagnostics by

an interdisciplinary team consisting of a physician, a psychologist and a physiotherapist [15]. The common goal is to achieve a holistic understanding of the patient's current situation, which results in an individualised diagnosis and treatment recommendation. Considering the findings of all professions, the patient and the team develop a joint treatment plan.

For patients with chronic pain, there is clinical experience and some evidence that an IMA can improve outcomes in terms of quality of life, perceived impairment and treatment satisfaction [16]. It seems to be a suitable instrument for directing patients into tailored treatment paths [17, 18]. However, there is an overall lack of sufficient data for health care approaches targeting pain in transition, including for the use of IMA in patients with recurrent or persisting pain and at risk for developing chronic pain [10, 15]. Implementing early diagnostic and treatment strategies tailored to the specifics of pain and its accelerating mechanisms would prevent people from developing chronic, disabling pain conditions [19, 20].

The aim of this study was to introduce an early IMA for patients with recurrent (or persistent) pain who are at risk of developing chronic pain. We assumed that by steering these patients into cross-sectoral, needs-based treatment services, chronic pain could be prevented through improved healthcare delivery. The primary question was whether participants receiving IMA would show greater improvement in pain intensity and functional impairment over a 6-month follow-up period compared to patients receiving a unimodal (physician-only) medical pain assessment (MPA).

METHODS

Study Design

The present study, funded by the Federal Joint Committee under the acronym PAIN2020 ("patient-oriented.graduated.interdisciplinary.network") (Innovation Fund 01NVF17049), is a nationwide multicentre randomised controlled trial (RCT). The evaluation design envisaged 6000 patients at baseline (t1) and a calculated drop-out rate of 20% at each of the two follow-ups after 3 and 6 months (t2 and t3). Participants were included in 28 pain centres across Germany between February 2019 and August 2021. After inclusion, participants were assigned to the intervention group (IG) or the control group (CG) with a probability of 70% (IG) and 30% (CG), respectively. The unequal assignment to the two groups was based on the ethical consideration that study participants should have a higher probability of being assigned to the intervention group. Computer-generated block randomization with variable block length was used. The IG received an IMA; the CG was assigned to a unimodal (physician-only) MPA. Participants were informed about the treatment they received in the two groups. Blinding was therefore not possible.

PAIN2020 is registered at the German Clinical Trials Register, which contains the most important key points of the study [21]. A published study protocol for detailed information is available [22]. The study was conducted in accordance with the 1964 Declaration of Helsinki and its subsequent amendments. It was approved by all participating institutions, including the Ethics Committee of the University Hospital Carl Gustav Carus in Dresden (EK 216062018) as the main ethics committee. Written informed consent was obtained from all participants.

Participants

The study included people in the region of one of the participating centres, aged ≥ 18 years, who were insured by BARMER statutory health insurance (the second largest in the German health insurance system with around 8.7 million insured persons). The project was later opened up to the Kaufmännische Krankenkasse (KKH) and finally patients insured by all statutory health insurance funds to facilitate recruitment.

BARMER played a key role in patient recruitment. In all regions with participating centres, insured persons were informed by post about the PAIN2020 project if the care data showed a continuous intensive use of

services in association with pain diagnoses [e.g. visits to general practitioners (GP) and specialists in several consecutive quarters]. Interested insured persons could contact BARMER's telemedical advisory service, which, after a preliminary check of the inclusion and exclusion criteria, referred the insured persons to the participating centres for an information appointment. Further recruitment paths were based on informing GP practices and medical specialists. These efforts were supplemented by contacting specialist associations, selective press releases and social media activities. Each interested person who attended the information appointment and met the inclusion criteria was consecutively included in the study.

The inclusion criteria for the study were:

- Persistent pain for at least 6 weeks and/or recurrent pain during the last 2 years,
- Pain-related limitations relevant to the patient (e.g. ≥ 4 weeks of previous sick leave or cumulative sick leave of ≥ 6 weeks in the past year, interference with daily activities, family, leisure, work and homework);
- Risk factors for chronic pain [including spreading pain, signs of stress in family/partnership/working life, depressive symptoms in experience and/or behaviour, feelings of frustration/anger, maladaptive behaviour (fear avoidance, task persistence or endurance), signs of somatisation, high health care utilisation including seeking further diagnostics].

Patients had to be ≥ 18 years old, have sufficient written and spoken German language skills, live in the vicinity of the participating healthcare facility and give verbal and written consent to participate.

The following criteria led to exclusion:

- Clinical signs of a serious illness requiring urgent acute therapy or other serious illnesses (red flags, e.g. severe cardiac insufficiency, tumour disease) that make activation treatment impossible,
- A manifest chronic pain condition that had already occurred (e.g. sick leave due to pain for > 6 months, pain-relevant diagnosis for > 4 quarters, previous treatment with strong opioids for > 3 months, previous interdisciplinary multimodal pain therapy in the last 2 years),
- A severe and active psychiatric disorder (personality disorder, severe depression or anxiety disorder, signs of suicidal tendencies),
- An ongoing application for retirement or a rehabilitation programme planned for the near future,
- Linguistic and/or cognitive impairments.

The listed inclusion and exclusion criteria were checked by the physician as part of the anamnesis during the information appointment. For this purpose, the physician also had the information provided by the patient in the German Pain Questionnaire ("Deutscher Schmerzfragebogen", DSF) [23, 24].

Participating Centres

Healthcare institutions ($n = 28$) specialised in pain care from all over Germany (11 out of 16 federal states) were involved in the implementation of the new healthcare diagnostic procedure IMA.

20 centres were located in large cities, four centres in mid-sized cities and four centres in a rural region. Six centres could be classified as outpatient pain practices, 15 were located at smaller or larger hospitals with pain units and seven were located at university pain clinics. The study centres already offered interdisciplinary multimodal pain therapy (IMPT) or had the prerequisites for cooperation between the professions required for IMPT according to the consensus recommendations of the German pain societies [25, 26]. They received information about the study from the project team, including data management, obligations related to study procedures and training of professionals and teams to implement a standardised framework for the IMA. The centres were monitored and supervised by the project team during the complete course of the study.

Interventions

The centres implemented the IMA based on Casser et al. [15] and adapted the procedures according to the study protocol and the target patients with risk factors for chronic pain. Each discipline carried out the anamnesis and diagnostics and documented the respective results of the patient examination and evaluation (60 min allocated per profession) as well as potential treatment options. In a team session (20 min), the findings were discussed and the joint evaluation and treatment recommendation were formulated. Recommendations included the entire spectrum of established treatment options within the German healthcare system. In addition, two special multimodal treatment group programmes were offered for IG patients that were not part of standard care. Finally, these interdisciplinary findings were explained to the patient (including diagnosis, disease model and potential treatment options) followed by a mutual decision on the final treatment recommendation with the patient (20 min). All steps of the IMA were documented in standardised form.

The MPA in the CG consisted of a visit to a specialist pain physician, located in either a centre providing IMA or an external practice setting. As with the IMA, the MPA was fundamentally open-ended regarding treatment recommendations. This MPA was not a standard treatment within the German healthcare system but rather an early referral to a specialist. The physicians who conducted the MPA were only trained in the required documentation; the MPA itself was carried out in the respective clinical routine.

For both MPA and IMA, the medical documentation was based on the standard pain quality assurance protocol of the German Pain Association [27], including the Mainz Pain Staging System (MPSS) [28].

Power Calculations

The original case number planning with 6000 patients and three primary outcome measures had to be revised, especially because of the COVID-19 pandemic and its impact on patient recruitment. The revised sample size calculation performed with MLPowSim [29] was based on two primary outcome variables (treatment satisfaction was excluded but remained as a secondary outcome measure for analysis) and two measurement time points, each with a dropout rate of 30%. Based on a probability of error for the first type of error in a two-tailed test with a significance level of $\alpha = 0.05$, the α error was adjusted to $\alpha = 0.05/4 = 0.0125$ according to Bonferroni because of the correction for multiple testing. A total sample size of 4500 participants at baseline (net sample 2175 at 6-month follow-up) was sufficient to detect small intervention effects with a power of 0.80.

Outcome Variables

Outcome variables and additional patient data were collected using the German Pain Questionnaire ("Deutscher Schmerzfragebogen", DSF) and its follow-up version ("Schmerz-Verlaufsfragebogen", VFB) via paper and pencil [23, 24]. At a later stage of the survey, study participants were also given the opportunity to use an electronic version of the VFB.

DSF and VFB comprise the two primary outcome measures Characteristic Pain Intensity (PI) and Disability Score (DS), which are also components of the Graded Chronic Pain Scale (GCPS) [30, 31] (Table 1). Mean scores were calculated for each of the three numeric rating scales belonging to PI (pain right now/average pain/worst pain) and DS (pain interference in daily activities/recreational, social and family activities/ability to work). The endpoints of these rating scales were labelled "no pain" or "no interference" (0) and "pain as bad could be" or "unable to carry on any activities" (10).

Additionally, DSF and VFB also regularly include the Depression Anxiety Stress Scale (DASS) [32, 33], the Veterans Rand 12 Item Health Survey (VR-12) [34, 35], the Pain Description List (PDL) [24] and the Marburg Questionnaire for Habitual Well-Being (MFHW) [36], assessing the secondary outcome measures. The Pain Catastrophizing Scale (PCS) [37, 38], not integrated as standard in the DSF or VFB,

Table 1 Schedule of enrolment, interventions and assessments

	Study period			
	Enrolment and allocation	Post-allocation		
Timepoint	t_0	Baseline (assessment) t_1	Follow-up (3 months) t_2	Follow-up (6 months) t_3
Enrolment				
Eligibility screen	X			
Informed consent	X			
Allocation	X			
Interventions				
IMA IG		X		
MPA CG		X		
Assessments				
Primary outcome				
Characteristic Pain Intensity (PI)		X	X	X
Disability Score (DS)		X	X	X
Secondary outcome				
Depression Anxiety Stress Scale (DASS)		X	X	X
Veterans Rand 12 Item Health Survey (VR-12)		X	X	X
Pain Catastrophizing Scale (PCS)		X	X	X
Pain Description List (PDL)		X	X	X
Habitual well-being (MFHW)		X	X	X
Treatment satisfaction (CSQ-8/ZUF-8) and global change item			X	X

CG control group, *IG* intervention group

was added. At both follow-ups, to assess treatment satisfaction from the patient's perspective, participants were additionally surveyed with a global change item ("When you look at it all together, how would you rate the success of your treatment so far?"; 1 = very good, 5 = very poor) and the Client Satisfaction Questionnaire (CSQ-8/ZUF-8) [39, 40]. DSF and PCS were assessed at baseline (assessment, t1), the VFB and PCS as well as CSQ-8/ZUF-8 at the two follow-ups after 3 (t2) and 6 months (t3).

Data Management

All data were entered into a study database. The principles of data management and data protection were described in a comprehensive

data management plan and approved by the responsible supervisory authorities.

Monitoring

A extensive monitoring concept was developed to ensure that the intervention was carried out as well as possible in accordance with the study protocol. This included two personal on-site visits to the centres. Among other things, the project team checked whether the medical documentation was correct and whether the practitioners had received sufficient training. A weekly telephone conference was offered by the project team for any questions from the centres. Furthermore, the data in the study database were continuously monitored by the evaluator to provide ongoing feedback on data quality and the development of case numbers.

Statistical Analysis

For the statistical analysis, the intention-to-treat principle (ITT) was applied: All participants with valid consent who had been randomised and who had received an assessment were included in the analysis.

The comparison of the outcome measures of IG and CG over time was based on a mixed model for repeated measures (MMRM) [41]. The value expressions of the primary and secondary outcome measures at t2 and t3 were predicted from (1) the baseline values of the outcome measures at t1 (yt1), (2) the factors of group membership (group) and the relevant time point (time) and (3) the interaction effect of group membership and time point. A random effect was included in the model for the regression constant.

$$yt = a + b1 * yt1 + b2 * group + b3 * time + b4 * group \times time$$

The regression models were parameterised so that the baseline values (t1) were centered and the CG and t3 were defined as the reference category. The regression constant therefore describes the value expected under the model for the respective dependent variable in the CG at t3.

The time effect defines to what extent the value at t2 deviates from that at t3. The group effect describes the extent to which the value of the IG deviates from that of the CG. The same applies to the interaction effect. The analysis model thus corresponds to an analysis of covariance as recommended for the analysis of controlled studies with longitudinal data as an alternative to using difference values to control for baseline values [42]. Missing values at measurement time points were not imputed. Analyses were performed using IBM SPSS Statistics 28.

To investigate possible centre effects, the sample composition of the respective patient collective was analysed in more detail, including characteristics such as age, sex, education, pain diagnoses or other structural parameters at the centre level (e.g. case numbers, response rates, patient satisfaction or whether standard care was provided in-house or externally in a specialist practice).

RESULTS

Sample

Overall, 1233 individuals attended a screening visit at one of the 28 participating centres between February 2019 and August 2021 (Fig. 1). Of those invited for the screening visit, 223 (18.1%) did not meet the inclusion criteria or did not give consent to the PAIN2020 study, so 1010 individuals were randomised. An assessment appointment was scheduled with all study participants. Baseline data (t1) were collected for 906 (89.7%) subjects. From this baseline sample, 696 (76.8%) valid follow-up questionnaires were returned by study participants at 3-month follow-up (t2) and 620 (68.4%) at 6-month follow-up (t3).

For quality assurance reasons (uncertain data quality), all cases of one participating centre had to be excluded from data analysis. This concerned 18 (2.0%) study participants from the baseline sample. In addition, four further (0.4%)

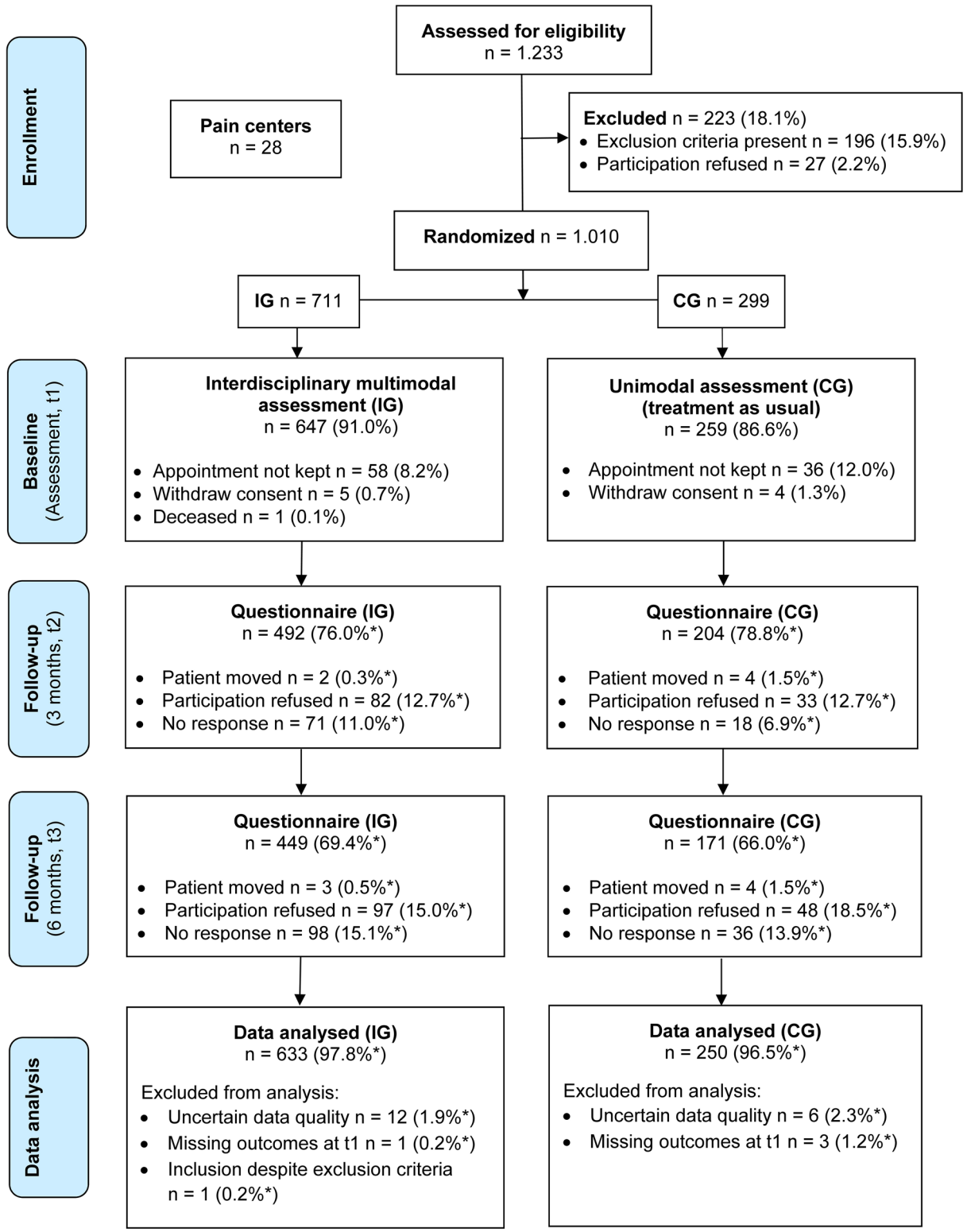


Fig. 1 CONSORT flow chart. *CG* control group, *IG* intervention group, *related to t1

Table 2 Sample characteristics (baseline, t1)

		IG		CG		p
		n	%	n	%	
		633	(100)	250	(100)	
Sex	Female	421	(66.5)	162	(64.8)	0.629[e]
	Male	212	(33.5)	88	(35.2)	
	Missing	0	(0.0)	0	(0.0)	
Age	Mean ± SD (in years)	55.0 ± 12.7		55.5 ± 13.4		0.589[d]
	Min–max (in years)	20–87		22–89		
	Missing	1	(0.2)	0	(0.0)	
Educational level	No graduation	3	(0.5)	1	(0.4)	0.960[e]
	Basic education (≤ 9 years)	74	(11.8)	31	(12.6)	
	Secondary education (10–11 years)	253	(40.2)	97	(39.3)	
	Higher education (≥ 12 years)	299	(47.6)	118	(47.8)	
	Missing	4	(0.6)	3	(1.2)	
Persons in household (multiple answers possible)	Single	123	(20.2)	49	(19.6)	0.997[e]
	Spouse/partner	456	(74.9)	179	(71.6)	
	Children	174	(28.6)	65	(26.0)	
	(In-)law parents	25	(4.1)	10	(4.0)	
	Missing	24	(3.8)	12	(4.8)	
Employed	Yes	427	(67.6)	180	(72.0)	0.200[e]
	No	205	(32.4)	70	(28.0)	
	Missing	1	(0.2)	0	(0.0)	
If employed then currently unfit for work	Yes	43	(10.1)	16	(9.0)	0.664[e]
	No	381	(89.9)	162	(91.0)	
	Missing	3	(0.7)	2	(1.1)	
If employed then days of incapacity last 3 months	Mean ± SD	10.9 ± 22.0		9.1 ± 20.4		0.372[d]
	Missing	13	(3.0)	10	(5.6)	

Table 2 continued

		IG		CG		p
		n	%	n	%	
		633	(100)	250	(100)	
Intention to apply for a pension	Yes	22	(3.6)	7	(2.9)	0.630[e]
	No	595	(96.4)	234	(97.1)	
	Missing	16	(2.5)	9	(3.6)	
Receiving a pension	Yes	145	(27.0)	53	(24.9)	0.553[e]
	No	392	(73.0)	160	(75.1)	
	Missing	96	(15.2)	37	(14.8)	
Pain for…	< 1 month	2	(0.3)	0	(0.0)	0.554[e]
	1 month–1/2 year	77	(12.2)	39	(15.7)	
	1/2 year–1 year	180	(28.4)	72	(29.0)	
	1–2 years	160	(25.3)	52	(21.0)	
	2–5 years	105	(16.6)	43	(17.3)	
	> 5 years	109	(17.2)	42	(16.9)	
	Missing	0	(0.0)	2	(0.8)	
Main medical pain diagnoses (Only information that contained a conclusive diagnosis was used. Missing information and multiple answers, e.g. in the free text, were categorized as missing value)	Headache and orofacial pain	40	(6.3)	7	(2.8)	0.352[e]
	Neck and back pain[a]	271	(42.8)	124	(49.6)	
	Joint pain	105	(16.6)	36	(14.4)	
	Localised musculoskeletal pain[b]	88	(13.9)	32	(12.8)	
	Multi-localised pain/ fibromyalgia	3	(0.5)	2	(0.8)	
	Neuropathic pain	14	(2.2)	5	(2.0)	
	Chronic pain without closer specification	11	(1.7)	2	(0.8)	
	Chronic pain disorder with somatic and psychological factors (F45.41)	33	(5.2)	15	(6.0)	
	Other medical pain diagnoses[c]	12	(1.9)	2	(0.8)	
	Missing	56	(8.8)	25	(10.0)	
Characteristic Pain Intensity (PI)	Mean ± SD (0–10)	5.8 ± 1.2		5.9 ± 1.6		0.374[d]

Table 2 continued

		IG		CG		p
		n	%	n	%	
		633	(100)	250	(100)	
	Missing	0	(0.0)	0	(0.0)	
Disability Score (DS)	Mean ± SD (0–10)	4.9 ± 2.3		4.8 ± 2.3		0.626[d]
	Missing	0	(0.0)	1	(0.4)	
Graded Chronic Pain Scale (GCPS)	0	3	(0.5)	0	(0.0)	0.234[e]
	1	126	(20.1)	49	(19.9)	
	2	148	(23.6)	73	(29.7)	
	3	164	(26.1)	52	(21.1)	
	4	187	(29.8)	72	(29.3)	
	Missing	5	(0.8)	4	(1.6)	
Mainz Pain Staging System (MPSS)	1	248	(39.3)	92	(37.4)	0.086[e]
	2	317	(50.2)	115	(46.7)	
	3	66	(10.5)	39	(15.9)	
	Missing	2	(0.3)	4	(1.6)	
Pain Description List (PDL)	Mean ± SD (sum, 0–12)	4.1 ± 3.4		4.1 ± 3.3		0.851[d]
	Missing	32	(5.1)	14	(5.6)	
Habitual well-being (MFHW)	Mean ± SD (sum, 0–35)	17.1 ± 8.3		17.0 ± 8.1		0.913[d]
	Missing	2	(0.3)	0	(0.0)	
Depression Anxiety	Mean ± SD (Depression, 0–21)	5.4 ± 4.5		5.5 ± 4.4		0.922[d]
Stress Scale (DASS)	Mean ± SD (Anxiety, 0–21)	3.1 ± 3.2		2.9 ± 3.0		0.395[d]
	Mean ± SD (Stress, 0–21)	7.5 ± 4.6		7.9 ± 4.4		0.343[d]
	Missing	1	(0.2)	0	(0.0)	
Pain Catastrophizing	Mean ± SD (Helplessness, 0—20)	7.9 ± 4.7		8.0 ± 4.5		0.658[d]
Scale (PCS)	Missing	2	(0.3)	6	(2.4)	
	Mean ± SD (Magnification, 0–12)	4.1 ± 2.7		4.2 ± 2.6		0.720[d]
	Missing	3	(0.5)	7	(2.8)	
	Mean ± SD (Rumination, 0–20)	8.6 ± 4.9		8.5 ± 4.6		0.874[d]
	Missing	5	(0.8)	8	(3.2)	

Table 2 continued

		IG		CG		p
		n	%	n	%	
		633	(100)	250	(100)	
	Mean ± SD (total, 0–52)	20.6 ± 11.0		20.7 ± 10.4		0.859[d]
	Missing	2	(0.3)	6	(2.4)	
Health-related quality of life (VR-12)	Mean ± SD (PCS, standard: 50)	35.9 ± 9.1		35.4 ± 9.5		0.498[d]
	Mean ± SD (MCS, standard: 50)	44.8 ± 11.5		44.8 ± 10.5		0.958[d]
	Missing	7	(1.1)	2	(0.8)	
Medication before starting therapy	Yes	467	(75.5)	200	(81.3)	0.025[e]
	No	163	(24.5)	46	(18.7)	
	Missing	3	(0.5)	4	(1.6)	
Waiting time for the assessment	Mean ± SD (in weeks)	3.4 ± 3.3		3.5 ± 3.8		0.527[d]
	0–3 weeks	402	(63.5)	155	(62.0)	
	4–6 weeks	163	(25.8)	60	(24.0)	
	> 6 weeks	68	(10.7)	35	(14.0)	
	Missing	0	(0.0)	0	(0.0)	

CG control group, *IG* intervention group, *SD* standard deviation, *Min* minimum, *Max* maximum, *NRS* numeric rating scale, *PCS* Physical Component Summary, *MCS* Mental Component Summary. Note: Percentages for "Missing" refer to the entire group sample; all other percentages reflect the valid percentages of the distribution of the respective characteristic. *P*-values refer to baseline differences. [a]Includes back, thoracic spine, lower back and lower back/leg. [b]Including localised rheumatic diseases. [c]For example, abdomen, urogenital, chest thorax. [d] t-test; [e] chi-square test

cases were excluded from data analysis because both primary outcome measures were missing at t1. One case (0.1%), also not considered for analysis, was enrolled in the study despite meeting exclusion criteria. Thus, 883 data sets were available for analysis.

The baseline sample showed no statistically significant differences between the IG and the CG. It consisted of two-thirds women with a mean age of 55.1 years (Table 2). The main pain diagnosis was related to the spine and back in about half. The sample was almost evenly distributed among the GCPS I–IV. According to the MPSS, most participants were classified into stage I and II, corresponding to mild to moderate pain chronicity. Regarding the outcome measures, the study participants reported an average PI of 5.8 and a DS of 4.9 on the numerical rating scale (0–10).

Primary Outcomes

The predicted values of the primary outcome measures under the analysis of covariance model are shown in Fig. 2. For both PI and DS, the predicted values for t2 adjusted for baseline differences are almost identical in the IG and the CG. There was a significant time effect ($p < 0.001$) for both outcome measures. For t3,

only insignificantly lower values were expected in the IG. The differences between the groups and the interaction effect did not reach statistical significance for either primary outcome measure. These results were also seen when the analyses were conducted separately for both sexes.

Descriptively, the mean reduction in PI after 6 months *within* the two groups was 1.6 (IG) and 1.7 points (CG) (approximately 28% and 29% respectively), corresponding to a Cohen's d of 0.66 and 0.69 respectively ($p<0.001$ in each case). The second primary outcome measure, DS, decreased by 1.9 and 1.8 points (39% and 38%). Here, Cohen's d was 0.72 and 0.70 (both $p<0.001$). There were also no statistically relevant reductions between the groups in favour of IG or CG for either primary outcome and only marginal effect sizes of $|d| < 0.10$ in each case.

Secondary Outcomes

The results for the secondary outcome measures are presented in Fig. 2. Descriptive differences between the groups in favour of the IG were found, with only a few exceptions (including VR-12 PCS). These differences were more pronounced for predicted values at t3 than at t2 in some cases. However, according to the inferential statistical results for the secondary outcome measures, no differences could be statistically validated here either, although some of the *p*-values approached the 0.05 threshold (e.g. Pain Description List PDL). Moreover, when considering the practical significance of the descriptive differences between the groups, the effect sizes were mainly < 0.10. Some scales, particularly the psychological constructs (including the Pain Catastrophizing Scales, VR-12 MCS) and the PDL, had effect sizes slightly > 0.10.

Treatment Satisfaction from the Patient's Perspective

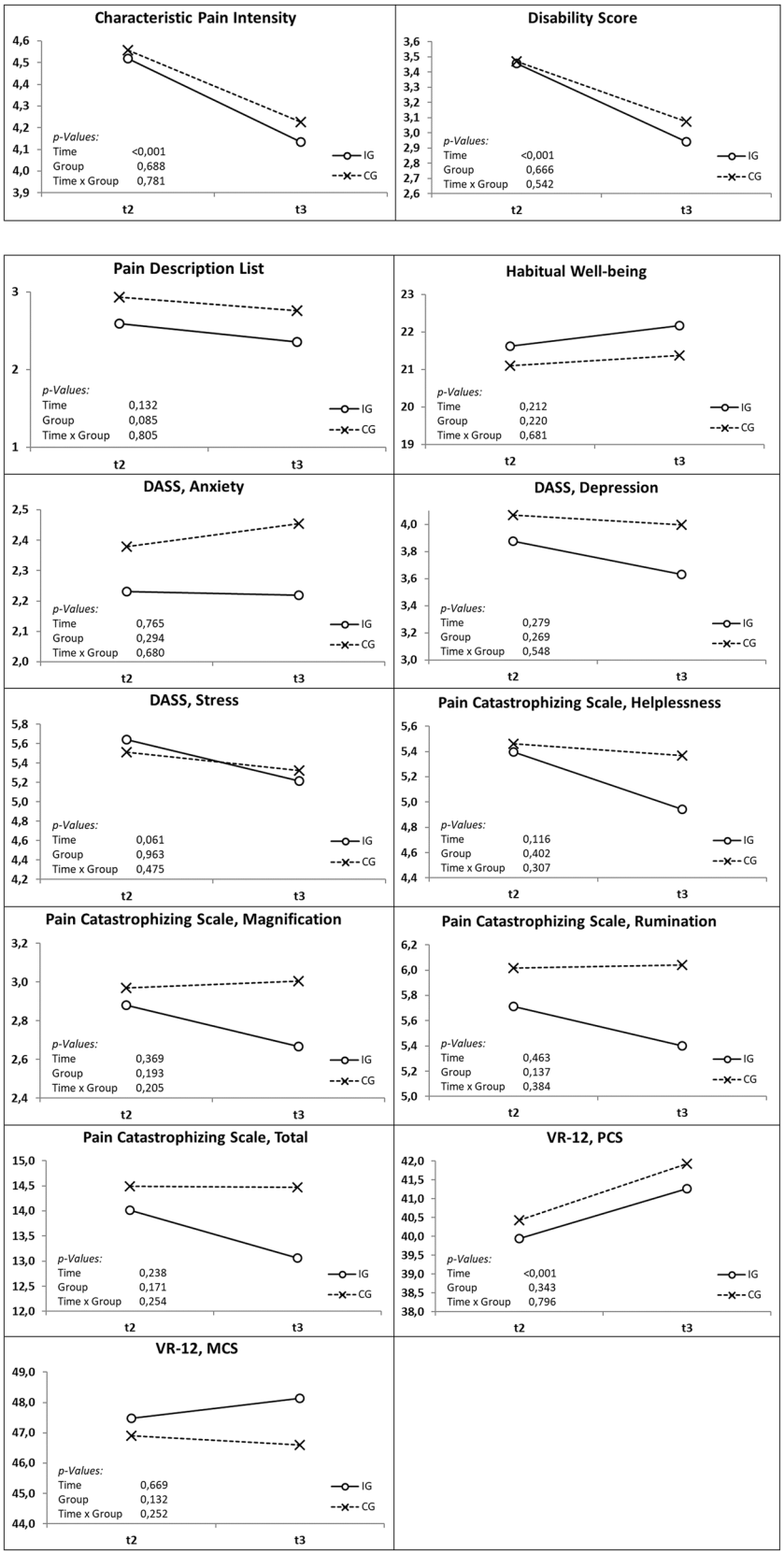
The values for treatment satisfaction from the patient's perspective were practically unchanged at both follow-ups in both groups. At 6-month follow-up, the ZUF-8 score (whose range of values is 8–32, with high values indicating high satisfaction) reached a mean of 23.8 ± 6.0 in the IG and 23.4 ± 6.1 in the CG ($p=0.552$). The mean score of the global change item was 2.9 ± 1.1 in the IG and 3.0 ± 1.2 in the CG ($p=0.357$). The ZUF-8 correlated with a reduction in PI at 6 months with $r=0.23$ ($r_{IG}=0.23$; $r_{CG}=0.25$) and the global change item with $r=0.52$ ($r_{IG}=0.51$; $r_{CG}=0.54$). A reduction in DS was also associated with high treatment satisfaction: the ZUF-8 correlated with $r=0.24$ ($r_{IG}=0.23$; $r_{CG}=0.25$) and the global change item correlated with $r=0.41$ ($r_{IG}=0.42$; $r_{CG}=0.39$) (for all reported correlation coefficients: $p<0.01$).

Pain Centres Involved

Figure 3 shows centre-specific effect sizes for PI (Fig. 3a) and DS (Fig. 3b). All 13 centres that had at least five cases in each of the two groups at t3 were included in this analysis. Due to the small number of cases per centre and group, the 95% confidence intervals were sometimes very wide. Descriptively, a rather heterogeneous picture emerged for both primary outcome measures, with some centres achieving effect sizes of > 1.0 in favour of IG as well as CG. Supplementary explorative analyses at the centre level described above (potential influence of characteristics such as age, sex, education, pain diagnoses or structural parameters such as case numbers, response rates, patient satisfaction, etc.) did not provide any systematic insights which could explain the observed heterogeneity of effect sizes.

Treatment Recommendations

IG participants received an average of 2.9 different treatment recommendations. In the CG, an average of 2.5 options was indicated in the assessment. Table 3 shows the treatment recommendations given. In both groups, about half of the patients were recommended physiotherapy or occupational therapy (IG: 51.8%, CG: 49.8%). The second most frequently mentioned recommendation with 44.1% in the IG was to continue or increase everyday physical activity. With 34.8%, this recommendation was also


Characteristic Pain Intensity
p-Values:
Time <0,001
Group 0,688
Time x Group 0,781
IG
CG
t2
t3
Disability Score
p-Values:
Time <0,001
Group 0,666
Time x Group 0,542
Pain Description List
p-Values:
Time 0,132
Group 0,085
Time x Group 0,805
Habitual Well-being
p-Values:
Time 0,212
Group 0,220
Time x Group 0,681
DASS, Anxiety
p-Values:
Time 0,765
Group 0,294
Time x Group 0,680
DASS, Depression
p-Values:
Time 0,279
Group 0,269
Time x Group 0,548
DASS, Stress
p-Values:
Time 0,061
Group 0,963
Time x Group 0,475
Pain Catastrophizing Scale, Helplessness
p-Values:
Time 0,116
Group 0,402
Time x Group 0,307
Pain Catastrophizing Scale, Magnification
p-Values:
Time 0,369
Group 0,193
Time x Group 0,205
Pain Catastrophizing Scale, Rumination
p-Values:
Time 0,463
Group 0,137
Time x Group 0,384
Pain Catastrophizing Scale, Total
p-Values:
Time 0,238
Group 0,171
Time x Group 0,254
VR-12, PCS
p-Values:
Time <0,001
Group 0,343
Time x Group 0,796
VR-12, MCS
p-Values:
Time 0,669
Group 0,132
Time x Group 0,252

◂**Fig. 2** Change in primary and secondary outcomes over time (MMRM). **MMRM* mixed effects model for repeated measures. When interpreting the results, note that for most scales high values represent an unfavourable expression of the characteristic. In these cases, a curve for the intervention group lying below the curve for the control group implies a descriptive difference in favour of the intervention group. For the following characteristics, however, high values correspond to favourable expressions, so exactly the opposite case exists here: Habitual Well-Being, VR-12 PCS (Physical Component Summary), VR-12 MCS (Mental Component Summary)

frequently made in the CG, but here medication adjustment played an even greater role with 39.3%. Psychological or psychosomatic interventions were recommended twice as often in the IMA (IG: 21.9%, CG: 10.9%). In both groups, around 20% received a recommendation for (partial) inpatient interdisciplinary multimodal pain therapy (as part of standard care).

DISCUSSION

The PAIN2020 study is a multicentre, randomised, controlled trial aiming to examine the effects of an IMA to prevent chronic pain and improve care.

In general, the study was conducted without relevant deviations from the original evaluation concept [21, 22]. This applies in particular to using all planned measurement instruments, the planned scheme of measurement time points for the collection of primary data and the basic concept of data analysis. However, due to recruitment problems during the COVID pandemic, the number of primary outcomes had to be reduced. A revised sample size calculation resulted in a total sample size of 4500 participants, which was also not achieved.

Considering the two primary outcomes over time within the two groups, large effects, according to Cohen [43], were observed for the reductions in Characteristic Pain Intensity and Disability Score after 6 months. With the study design described here, it is difficult to estimate what proportion of these improvements can be attributed to the early assessment as either interdisciplinary multimodal assessment or unimodal medical pain assessment by a physician specialised in pain therapy and what proportion is due to other factors. It is known that regardless of the therapeutic approach, significant improvement in pain and health-related parameters is often seen within the first 6 weeks followed by only rather small reductions in the subsequent period [44].

Regarding the primary questions of the RCT, no practically relevant and statistically significant differences between the IG and the CG were observed over time for either outcome measure, PI or DS. Thus, the results did not correspond to the hypothesis (an effect size of 0.10 in favour of the IG was postulated). Among the secondary outcomes, at least descriptively, there was a trend in favour of the IG, particularly in the field of mental and cognitive outcomes such as anxiety, depression, catastrophising and the mental component summary (MCS) of the VR-12. Effect sizes for differences between IG and CG reached values > 0.10 in some of these cases.

In our opinion, this study has largely succeeded in reaching the target population. In a reference sample of $N = 4082$ pain patients from outpatient care in Germany, 49.3% were classified as stage 3 on the MPSS (high level of pain chronification) [45]. This is a rather high proportion of patients with severe chronic pain. In contrast, there were significantly fewer patients in this stage in PAIN2020 (IG: 10.5%, CG: 15.9%). This indicates that patients at risk of developing chronic pain could be reached with early specific diagnostic and therapeutic services. However, it should be noted that our sample also included a small proportion of chronic MPSS stage 3 patients. They had not yet received any pain therapy. Even PAIN2020 patients with low MPSS predominantly showed relevant pain intensities and pain-related impairments, which indicates the need for treatment of the patients recruited. This is also reflected in the treatment recommendation of IMPT as part of standard care in about 20% of patients.

Another important goal of PAIN2020 was to offer participants an assessment early after enrolment. In two thirds of all cases, this was achieved within 3 weeks. Unlike the very

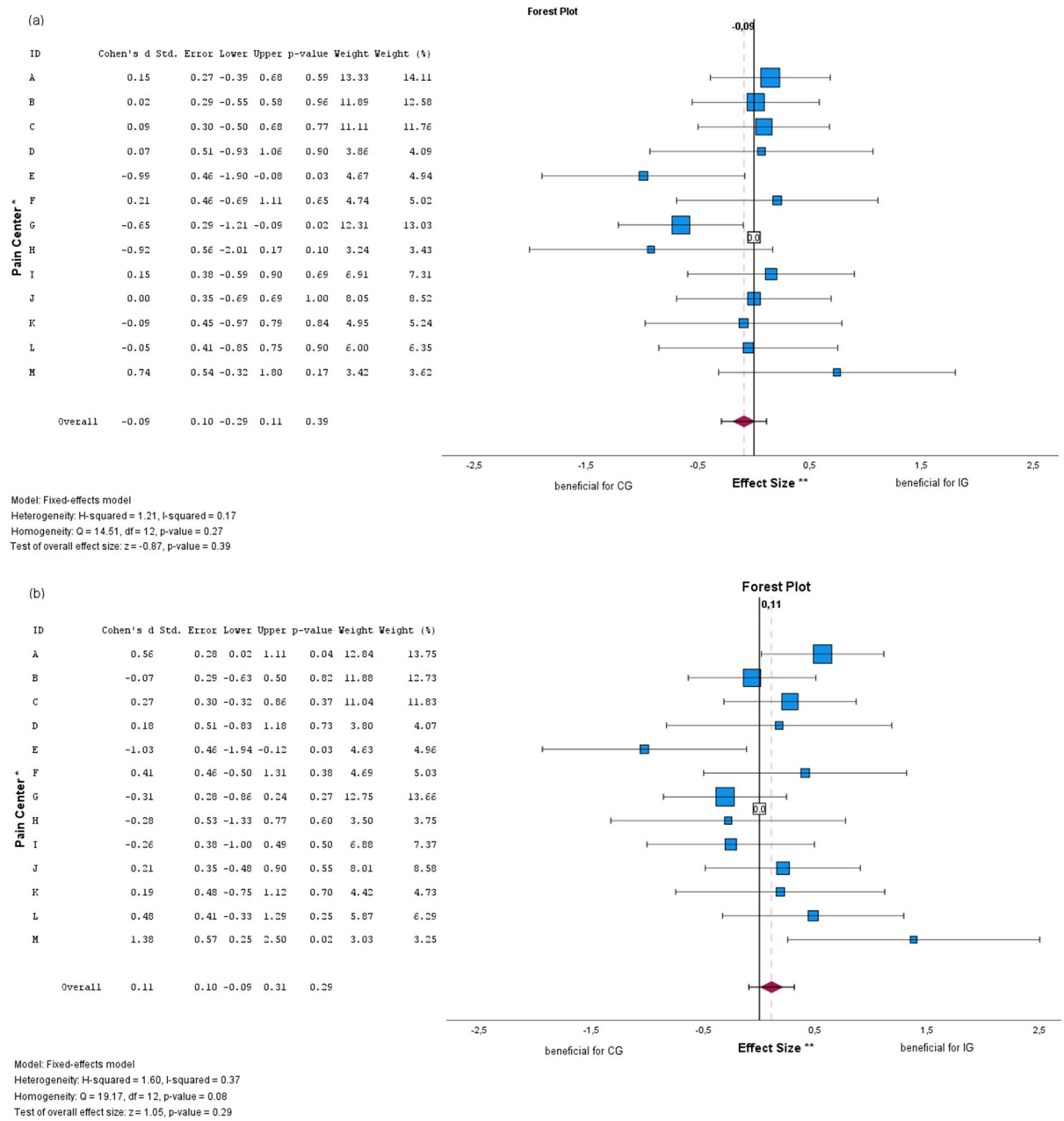


Fig. 3 Change in PI (**a**) and DS (**b**) after 6 months depending on the centre. **a** Change in Characteristic Pain Intensity (PI) after 6 months, **b** change in Disability Score (DS) after 6 months. *Included centres with at least five responses in IG and CG each, **Cohen's d of mean differences between IG and CG (for the period between t1 and t3)

low 2% in the Europe-wide study by Breivik et al. [1], all patients here were treated by a pain specialist. As a result of the assessment, PAIN2020 participants were offered two to three treatment options. Unfortunately, how often these recommendations were subsequently followed by the patients is not known.

The conclusions of Casser et al. [15] confirmed that the decision to offer interdisciplinary multimodal pain therapy should be open-ended. In

Table 3 Treatment recommendations given in the assessment

	IG ($n = 633$) %	CG ($n = 247$*) %	p (Chi-square test)
Continuation of existing primary care treatment	13.0	10.5	0.324
Continuation of existing specialised treatment	13.7	8.5	0.033
Acute inpatient care (examination of surgery indication)	1.6	1.2	0.687
New outpatient specialised treatment	14.4	10.5	0.131
Medication adjustment	22.7	39.3	< 0.001
Continuation or expansion of everyday physical activity	44.1	34.8	0.012
Functional training/rehabilitation exercises	25.0	20.2	0.139
Physiotherapy or occupational therapy	51.8	49.8	0.590
Psychological or psychosomatic interventions	21.9	10.9	< 0.001
Outpatient or inpatient rehabilitation treatment	6.2	2.4	0.024
(Partial) inpatient IMPT (as part of standard care)	22.3	21.1	0.694
Educational IMPT (1 session) [a]	31.8	–	
Outpatient IMPT (10 sessions) [a]	19.0	–	

Multiple recommendations possible. *CG* control group, *IG* intervention group, *IMPT* interdisciplinary multimodal pain therapy. [a]These two therapy modules were only offered within the framework of the PAIN2020 study for IG patients and are not part of standard care. *Documentation of the treatment recommendation was missing for three cases in the control group

PAIN2020, it was interesting to observe that the treatment approaches recommended in the IG focused more on physical activity and psychological or psychosomatic interventions, whereas in the CG there was a preference for adjusting the medication.

The fact that the IMA did not show an advantage over the control condition in terms of the primary outcome measures was contrary to our hypothesis and will be discussed in more detail below.

A first explanation is that the effect of a 1-day assessment on outcome measures might simply be too small and be overshadowed by the impact of subsequent treatment. It is important to remember that the aim was to measure the isolated effect of assignment to the different treatment pathways. There is sufficient reason to assume that the treatment itself will also have an effect on the outcome and that this effect will probably exceed an effect size of $d = 0.1$. Furthermore, a wide spectrum of treatment options could be recommended after the assessment, making it difficult to measure the effect of each individual treatment option (which would also require a much larger case number). Moreover, it is also possible that the patient-specific recommendations from the IMA were not implemented by the primary healthcare providers (e.g. physiotherapy). Unfortunately, there is a lack of valid data on the implementation of the various treatment recommendations. Monitoring treatment adherence was not within the scope of the study. In practice, this can only be implemented in close cooperation with various healthcare providers (e.g. GP, physiotherapist) and requires clarifying many conceptual questions (e.g. can adherence still be ensured if individual sessions of multimodal group pain therapy are missed by the patients or staff because of illness or vacation? If so, how many sessions and which modules can be missed, and which

practitioners can be absent, etc.?). The fact that we have no data on this limits the conclusions on effectiveness.

Second, the 6-month follow-up period could simply be too short. Rothman et al., for example, observed their study participants with chronic movement-related pain for up to 15 months [16]. In this context, waiting times could also be an important aspect. In PAIN2020, the average waiting period between enrolment and assessment was relatively short (3–4 weeks) in both groups. It can be assumed that this does not reflect real-world and standard care conditions. Group-based treatment services, for instance, require a minimum number of participants and more intensive planning for content-related, organizational and economic reasons, which may be associated with longer waiting times. Free-text data and increased missing rates regarding the assessment of treatment success and satisfaction from the patient's view indicated that some patients had not yet received treatment after 3 months and did not feel able to give a relevant evaluation. Different waiting periods could therefore have influenced the results.

A third explanation is the striking heterogeneity of the effect sizes between the participating centres. This strong centre effect could not be explained by the examined structural characteristics, so the observed heterogeneity seems to be caused by one or more unknown parameters. The internal organization, personnel resources and qualifications could play an important role here, despite a standardised training for all participating centres. As mentioned above, most of the patients were offered an assessment as early as possible within the first 3 weeks after enrolment in the study. This was a short time period, presenting an organizational challenge for some centres in practice.

The fourth point is that standard care in the control condition was provided in-house in most centres. Therefore, the physician who did the assessment for the CG patients was also a specialised pain therapist (or at least in training to be one). Physicians familiar with the concept of interdisciplinary treatment who regularly perform diagnostics together with psychologists and physiotherapists will also bring their experience from these disciplines to a unimodal assessment. This could dilute the effect of an IMA. However, we conducted an unblinded study in which knowledge of group membership may have influenced the patients' experience of pain. It may be speculated that such a bias would tend to result in a greater difference between the two groups.

Finally, there is another study limitation. Due to various problems that arose specifically in the context of the COVID-19 pandemic, only 22.4% of cases in the revised sample size calculation could be included in the study. Although BARMER is one of the largest statutory health insurers in Germany, not all regions had the same number of potential participants. The drop-out rate across the measurement time points was considerably lower than expected. As the MMRM, unlike a complete case approach, makes maximum use of available data, imputation of missing data did not appear to be a useful option. Nevertheless, it can be assumed that there was a critical loss of power in the data finally available for the analysis. A post hoc power analysis revealed that only effect sizes (Cohen's d) > 0.30 could be detected for the primary endpoints with sufficient power of 0.80. This limited the analysis options, even though the randomization avoided significant baseline differences between the groups and no selection effects were found in the further course of the study.

CONCLUSIONS

Patients with recurrent and persistent pain at risk of developing chronic pain could be identified from the general population and participated in this study. This potentially underserved group may benefit from interventions based on a biopsychic understanding of the development and maintenance of chronic pain.

Both early unimodal and interdisciplinary multimodal assessments seem to have a positive effect on outcomes such as pain intensity, functional limitation, health-related

quality of life, and emotional and cognitive factors in patients at risk of developing chronic pain. Measurement of the isolated effect of the treatment recommendation by an interdisciplinary assessment, detached from other potentially relevant factors, proved to be difficult. Therefore, contrary to expectations, the additional benefits of this diagnostic approach could not be demonstrated or could have led to contradictory results that strongly depended on the participating pain centres, at least in the context of the RCT presented here. Nevertheless, early diagnostic strategies focussed on pain and related specialties, either unimodal with pain specialists or interdisciplinary, should be considered before treatment is planned. This would avoid overuse of (more somatically oriented) diagnostics and underuse of common psychosocial interventions. It can be assumed that resources can be reduced and patients can be supported much earlier in maintaining (or restoring) their physical and mental functioning, thus retaining their ability to work and participate in society.

Based on the limitations discussed, we recommend further research on implementing IMAs in the healthcare system. The IMA presented in this study implements the recommendations of the German National Health Care Guideline for non-specific back pain. To resolve the unanswered questions, studies should include a longer follow-up period of at least 1, preferably 2 years and attempt to monitor treatment after the assessment despite practical challenges.

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Author Contributions. Daniel Szczotkowski, Thomas Kohlmann, Ulrike Kaiser, Gabriele Lindena, Frank Petzke, Bernd Nagel, Thomas Isenberg and Ursula Marschall designed the trial. Gabriele Lindena, Frank Petzke, Bernd Nagel and Anke Preisler were responsible for the design and supervision of the medical part. Ulrike Kaiser, Anne Gärtner, Beatrice Metz-Oster, Katja Schwenk and Lena Milch were responsible for the design and supervision of the psychological part, and Leonie Schouten, Frank Petzke, Karin Deppe, Greta Hoffmann and Ulrike Kaiser were responsible for the design and supervision of the physiotherapeutic part of the intervention. André Möller, Gabriele Lindena, Daniel Szczotkowski, Thomas Kohlmann, Ursula Marschall, Catharina Schumacher and Julia Pritzke-Michael supervised the database, data collection and data quality. Ulrike Kaiser, Gabriele Lindena, Thomas Isenberg, Carolin Martin and Anja Waidner administered and supervised the study. All authors were involved in conducting the study and in regular discussion meetings. Daniel Szczotkowski, Sandra Meyer-Moock and Thomas Kohlmann conducted the statistical analysis, interpreted findings and produced the final draft of the manuscript. All authors were involved in the discussion of the final draft of the manuscript.

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Data Availability. The datasets generated and analysed in the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Daniel Szczotkowski, Sandra Meyer-Moock, Thomas Kohlmann, Karin Deppe, Anne Gärtner, Greta Hoffmann, Thomas Isenberg, Gabriele Lindena, Ursula Marschall, Carolin Martin, Beatrice Metz-Oster, Lena Milch, André Möller, Bernd Nagel, Frank Petzke, Anke Preissler, Julia Pritzke-Michael, Leonie Schouten, Katja Schwenk, Catharina Schumacher, Anja Waidner, Ulrike Kaiser declare that they have no competing interests.

Ethical Approval. The study was conducted in accordance with the 1964 Declaration of Helsinki and its subsequent amendments. It was approved by all participating institutions, including the Ethics Committee of the University Hospital Carl Gustav Carus in Dresden (EK 216062018) as the main ethics committee. Written informed consent was obtained from all participants.

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