Pain Medicine, 00(0), 2021, 1–12
doi: 10.1093/pm/pnab321
Advance Access Publication Date: 3 November 2021
Original Research Article

A Randomized Controlled Trial of the Sources of Meaning Card Method: A New Meaning-Oriented Approach Predicts Depression, Anxiety, Pain Acceptance, and Crisis of Meaning in Patients with Chronic Pain

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Funding sources: The authors have no funding sources to report.

Conflicts of interest: The authors have no conflicts of interest to report.

Received on 13 February 2021; revised on 25 July 2021; Accepted on 24 August 2021

Abstract

Objective. Although considered the first-line psychological treatment for chronic pain, cognitive behavioral therapy has recently been criticized as being too limited, insufficient, and sometimes ineffective in the treatment of patients with chronic pain. Moreover, important existential perspectives are sparsely or not at all integrated into cognitive behavioral therapy. We therefore propose to complement chronic pain treatment with a meaning-based intervention, the Sources of Meaning Card Method (SoMeCaM). This study tested its efficacy. **Design**. A randomized controlled trial was conducted with 42 patients with chronic pain. The trial compared an intervention group (standard care and participation in the SoMeCaM, a meaning-oriented approach) with a control group (standard care). We evaluated both groups at baseline and at 1 (t1) and 2 months (t2) after the intervention. The primary outcome assessed was pain acceptance, while depression, anxiety, pain intensity, pain medication, satisfaction with life, meaningfulness, and crisis of meaning were examined as secondary outcomes. **Results**. Comparisons within and between groups showed significant treatment effects at t1. Higher increases in pain acceptance and decreases in anxiety, depression, and crisis of meaning were observed in the intervention group. Improvements in pain acceptance and anxiety persisted until t2, when pain intensity was also lower. Effect sizes at t2 were medium to large. **Conclusion**. Our preliminary work demonstrates the importance of the existential perspective in chronic pain therapy.

Key Words: Chronic Pain; Meaning; Crisis of Meaning; Existential Psychology; Pain Acceptance; Psychological Intervention

Introduction

Chronic pain is a widespread problem in the Western world [1, 2]. The current version of the *International Classification of Diseases* of the World Health Organization recognizes pain as chronic if it lasts or recurs for more than 6 months [3]. Chronic pain is a challenging and stressful condition that includes more aspects than the perception of pain. It is often life changing for patients and their families, too; their life worlds are forced to transform. In almost every case, chronic pain is accompanied by problems and consequences on the physical, mental, and social levels [4]. This can manifest in social withdrawal, isolation, depressiveness, aggressiveness, suicidality, family conflicts, problems at work, or the

appearance of the question of meaning [5, 6]. All of that may lead to serious restrictions of the patients' life perspectives, especially when previously important sources of meaning in life are given up [5]. In many cases, chronic pain threatens patients' perceptions about what gives them meaning and diminishes the assumption that they can find meaning in their daily lives [7]. The impact of a chronic pain condition is thus not limited to patients' biopsychosocial functioning but also affects the existential domain [8–10]. Because of its multifaceted etiology and symptomatology, chronic pain requires a multidisciplinary team, with treatment guidelines recommending multidisciplinary pain management programs for the primary management of chronic pain [11]. The multidisciplinary approach consists of physical exercises, a behavioral-psychological principle, and a medical treatment provided by a physician specializing in pain management. A systematic review showed moderate-quality evidence that multidisciplinary treatment reduced pain and disability compared with usual care. Other trials provided only low-quality evidence [12]. Nevertheless, existential concerns are sparsely integrated into therapy.

Cognitive behavioral therapy (CBT) is considered the first-line psychological treatment for chronic pain [13, 14]. Here, the primary purpose is pain control and the reduction or elimination of thoughts and feelings that cause distress [15]. This approach has been criticized as being too limited [16]. Several authors have indicated that problem-oriented strategies are insufficient for dealing with chronic pain [14, 17, 18] and that focusing on pain might even aggravate the problem [19–22]. Overall, only small to moderate effect sizes on a variety of variables have been reported for CBT treatments in patients with chronic pain [14, 23–25]. In addition, a significant proportion of patients do not benefit from CBT at all [26–28].

Meaning in life has been shown to be related to many resources, both among healthy and ill persons [29–32]. Meaningfulness predicts objective as well as subjective physical health [33] and risk of death [e.g., 34, 35]. A lack of meaning, on the other hand, is experienced as highly distressing [36–44]. Gale (2011) [45] reported that chronic pain patients with higher meaningfulness had a lower suicide risk, and the availability of reasons for living was negatively associated with suicidality. In a longitudinal study, patients with pain showed that high values of meaningfulness predicted fewer depressive symptoms and higher level of satisfaction with life 2 years later. Furthermore, patients who had a higher presence of meaning adapted better to their pain [46]. Another study investigated how satisfied patients were with the attention of their practitioners to the consequences of pain on their biological, psychosocial, and existential life domains and how the satisfaction was related to patient functioning. They observed that satisfaction with each domain correlated negatively with pain intensity, pain disability, and depressive symptoms and positively with life satisfaction. Therefore, attention to the existential domain in the treatment of chronic pain seems extremely important for patient functioning [47].

Although these studies show promising associations of meaningfulness, there is little quantitative research on existential approaches to the treatment of chronic pain. Among the studies that have addressed existential approaches, a recent study examined the efficacy of a standard cognitive behavioral group program for patients with chronic pain in comparison with the same group program but including an existential perspective [48]. Results indicated that the integration of an existential approach led to a significantly lower level of pain-related disability than did the classic cognitive behavioral group program. A retrospective cohort study with a multidisciplinary group pain management program that also contained a meaning-based element showed significant improvements in pain intensity and physical and psychological function. Also, a strong association between aspects of spiritual well-being and pain reduction, as well as other measures of psychological well-being, has been observed [49].

Several qualitative studies and case reports also support the relevance of existential matters in the treatment of chronic pain and other chronic illnesses [50–52].

Acceptance and Commitment Therapy (ACT; third-wave CBT) is increasingly viewed as an alternative standard therapy for chronic pain. ACT focuses on the acceptance of the given life conditions and the ability to commit oneself to valued action in spite of pain [53–55]. The method intends to support the patient in living a more fulfilling life [16]. Greater acceptance of pain has shown associations with lower pain intensity, less pain-related anxiety and avoidance, fewer depressive symptoms, fewer physical and psychosocial restrictions, more daily uptime, and better work status. Pain acceptance predicted better adjustment on all measures of patient functioning, independent of the perceived pain intensity [17]. Another study showed acceptance of pain to predict mental well-being beyond pain severity and pain catastrophizing. It was found that pain acceptance was related to engagement in daily life activities and to the acknowledgment that the pain might not change [56]. Working with values, ACT has some similarities to existential approaches. However, the background theories, as well as the practical application, differ. ACT is based on Skinner's radical behaviorism [57], whereas existential approaches usually are grounded in phenomenological traditions. The main focus of ACT is acceptance and committed action. In practice, ACT asks people to accept their conditions, choose values, and take action. Existential traditions, on the other hand, usually consider working on the topic of meaning and purpose as a goal in itself. Here, practical implications are left to the individual. Whereas the ACT approach is rather directive, probably because of its grounding in radical behaviorism, the phenomenological approach is open to the patient's input but is unstructured. With the aim of cutting out a path

between top-down directivity and bottom-up openness, the Sources of Meaning Card Method (SoMeCaM) [41, 42] was developed. It is rooted in existential theory, as well as in contemporary empirical psychology of life meaning. The instrument systematically explores sources of personal meaning in a short-term ambulatory setting. It has been used for patients with chronic pain, hospital staff, clergy, volunteers, students, and primary school pupils, with promising feedback [29, 58].

The aim of the present study was to test the efficacy of the SoMeCaM, as compared with normal treatment, in patients with chronic pain. To that end, a randomized controlled trial was conducted, with an expectation of short- and medium-term effects of the SoMeCaM intervention in contrast to normal treatment. On the basis of previous findings on existential matters and pain, it was believed that effects would probably manifest as lower pain-related disability after changes in life orientations. The primary outcome was set to be greater pain acceptance, and secondary outcomes were expected to be changes in levels of anxiety and depression, pain intensity, and pain medication. Furthermore, we assumed that meaning in life and satisfaction with life might be affected by the treatment, though not necessarily in an immediately positive way. The process of reflection on existential issues is often followed by a phase of confusion and insecurity [e.g., 59, 60], thus lowering a potential sense of meaningfulness or satisfaction with life. After the individual has rebuilt a reliable existential foundation, life meaning and satisfaction may return or even increase beyond the previous state [29, 61]. On the basis of this rationale, the following hypotheses were tested: We expected that, compared with the control group (CG), pain acceptance would change significantly in the experimental group (EG) from baseline to the 1-month follow-up (t1) and that this change would still be statistically and clinically significant at the 2-month follow-up (t2). Apart from these between-group effects, we expected that within the EG, clinically and statistically significant differences in pain acceptance would be seen between baseline and t1 and between baseline and t2. The above-specified effects were also expected with regard to the secondary outcomes: depression, anxiety, pain intensity, and pain medication. Moreover, because of the assumed dynamics of disturbance and reorganization, we expected between- and within-group changes for satisfaction with life, crisis of meaning, and meaningfulness at t2.

The study was approved by the ethics committee of the University of Innsbruck.

Methods

Design

A parallel-group randomized controlled trial was conducted with baseline, 1-month, and 2-month follow-up assessments. The EG received usual care (medical treatment, physiotherapy, therapist massage) plus one session with the SoMeCaM, whereas the CG received usual care alone. To ensure that data was collected at approximately equivalent intervals after randomization for both groups, every patient in the EG was matched with one patient in the CG, and both filled out the questionnaires on the same date. The period for the collection of baseline data for the full sample was 1 month. The study design and report follow the Consolidated Standards of Reporting Trials (CONSORT).

Participants and Recruitment

All participants were patients diagnosed with chronic pain by specialist physicians. Inclusion criteria were age $\geq$18 years, the ability to speak and read German, and a minimum duration of pain $\geq$6 months. Patients with mental disabilities like severe cognitive problems or emotional turmoil were excluded. Participants were recruited through a general surgery unit in Bavaria, Germany. All had been offered at least one consultation with the doctor before the intervention. No changes in medication took place during the intervention. All participants had also received a prescription for massage and physiotherapy, which included physical treatment as well as advice for training at home. The participants' flow through the study is depicted in Figure 1. The final sample size was 42 patients (n = 21 per group).

Randomization

Simple randomization procedures and IBM SPSS Statistics (SPSS, Inc., Chicago, IL, USA) were used to randomly assign 21 subjects to the EG and 21 to the CG. The blinded random allocation sequence was generated by the first author. The participants were enrolled by a general practitioner and the first author. The first author carried out the assignment of the participants to the EG and CG in a blinded mode 1 month before the baseline measurement.

Data Collection

Most of the questionnaires were distributed by e-mail and completed online. Fifteen participants had no e-mail account, had no Internet at their home, or preferred the paper-and-pencil format for the questionnaires. Those participants therefore received the questionnaires in closed envelopes 1 day before the first measurement. All questionnaires were completed at the patients' homes.

Intervention Method

The intervention method, the SoMeCaM [62, 63], consists of three different stages: 1) From a total of 26 cards with printed statements relating to the 26 sources of meaning, patients are asked to select three to five that are highly important to them. Several rounds of sorting are usually necessary, leading from perceived "flooding" via "structuring" to "prioritizing." 2) A semistructured

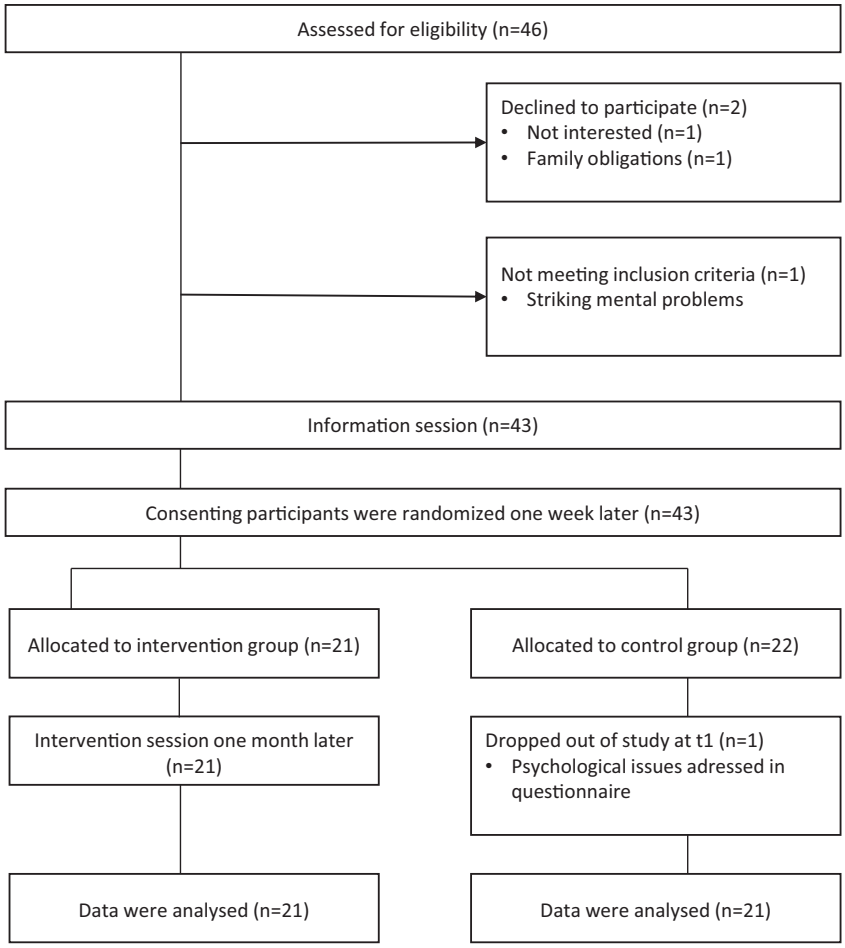

Figure 1. Study flow diagram: enrollment to analysis.

conversation follows, with a view to the statements' meaning, personal significance, actual importance, threats, and possibilities for personal change for each of the chosen cards. 3) The patients' priorities, decisions, and essential parts of the conversation are summarized on a prepared sheet of paper and handed out at the end of the session. Sessions take approximately 1 hour. However, their duration may vary depending on the patients' pain and need for short breaks. For further information, see www.somecam.org. The intervention was conducted by the first author and performed 1 day after the baseline measurement. There was 1 month between the randomization and the intervention.

Measurements

Baseline Measurements

Baseline demographic and health data were collected, including age, sex, nationality, work and relationship status, formal education, duration of pain, and pain location(s).

Outcome Measurements and Time Schedule

The questionnaire comprised the six instruments listed below, distributed at three time points: 1 day before the intervention (baseline data), 4 weeks after the intervention (1-month follow-up data), and 2 months after the intervention (2-month follow-up data). Reliability was assessed with Cronbach's alpha. Open questions on the usefulness and acceptability of the intervention and integration into everyday life were posed at four time points in the questionnaire to motivate patients to reflect on the intervention session on their own at home, directly after the intervention (e.g., "How did you like the intervention? Is there anything you would like to mention with regard to the intervention?"), 2 weeks after the intervention (e.g., "What do you remember from the intervention? Would you choose different cards today? If yes, why?"), 4 weeks after the intervention, and 2 months after the intervention (e.g., "How do you organize your life since our session? Did anything change? If yes, what?").

Outcome Variables

The primary outcome was *pain acceptance,* assessed with the German version of the Chronic Pain Acceptance Questionnaire (CPAQ-D) [64]. Three scores can be calculated: engagement in activity, pain willingness, and the total pain acceptance score. The total score ranges from 0 to 120, and the range for the subscores is 0–60. A

higher score indicates greater pain acceptance. For engagement in activity, $\alpha = 0.89$, 0.80, and 0.87 at baseline, 1 month, and 2 months, respectively; for pain willingness, $\alpha = 0.88$, 0.91, and 0.90; and for the total pain acceptance score, $\alpha = 0.93$, 0.90, and 0.92.

Secondary outcomes included the following: 1) *Depression and anxiety* was measured by the Hospital Anxiety and Depression Scale (HADS) [65], which has been validated and found reliable for patients with chronic pain [66–68]. Scores range from 0 to 21 for both anxiety and depression, with higher scores indicating more anxiety and depression. For anxiety, $\alpha = 0.71$, 0.74, and 0.79 at baseline, 1 month, and 2 months, respectively; for depression, $\alpha = 0.74$, 0.76, and 0.80. 2) *Pain intensity* was assessed by three questions ("What is the level of pain at this moment?," "What was the highest pain level last week?," and "What was the lowest pain level last week?") on a 10-point scale (1 = no pain at all, 10 = very high levels of pain) [69, 70]. In line with Bush et al. (1999), a composite pain index was obtained through the mean of these items, with $\alpha = 0.71$, 0.82, and 0.85 at the baseline, 1-month, and 2-month assessments. 3) *Pain medication* was measured by a single item: "How often do you currently have the feeling that you need the support of your pain reliever?" A five-point Likert scale was used. 4) The *Sources of Meaning and Meaning in Life questionnaire (SoMe)* [71] measures degrees of meaningfulness, crisis of meaning, and 26 sources of meaning. Meaningfulness is defined as a fundamental sense of purpose, orientation, coherence, and belonging. A crisis of meaning is present when life is evaluated as frustratingly empty, pointless, and lacking meaning. For meaningfulness, $\alpha = 0.69$, 0.81, and 0.78 at the baseline, 1-month, and 2-month assessments; for crisis of meaning, $\alpha = 0.81$, 0.84, and 0.88 at the three time points. 5) *Satisfaction with life* was assessed with the Satisfaction with Life Scale [72]. In this sample, $\alpha = 0.90$ at the baseline and 1-month assessments, and $\alpha = 0.88$ at the 2-month follow-up measurement.

La Cour and Schnell (2016) [73] developed several questions to evaluate the SoMeCaM. Questions are answered on a six-point Likert scale. Open questions tapped into feelings, thoughts, and deliberations prompted by the intervention.

Sample Size—Data Analysis

All collected data were analyzed with SPSS for Windows 21.0 (SPSS, Inc., Chicago, IL, USA). Descriptive statistics are presented as means (M) and standard deviations (SD) for continuous variables and absolute numbers (n) for categorical variables. Independent *t* tests were used for the comparison of between-group differences for continuous variables, and chi-squared tests were used for between-group comparisons of categorical data (baseline data). Matched *t* tests were used for the comparison of within-group differences for continuous variables. We used the analysis of variance (ANOVA) to test group-× time interaction effects. Because of the differences at baseline, we used difference scores instead of absolute values [74, 75]. For the primary and secondary outcomes, preliminary effect sizes and their 95% confidence intervals (CIs) were calculated with Cohen's *d* for continuous variables.

Power analysis for sample size estimation was performed. On the basis of a meta-analysis of existential therapies that found a mean effect size of $d = 0.65$ for changes in life meaning [76], a total sample size of n = 22 would have been adequate (G*Power 3.1.9.2, University of Düsseldorf, Germany). Because those therapies were of much longer duration, however, we expected a smaller effect for the SoMe Card Method and thus targeted a sample size of 20 to 25 patients per group. The final total sample size after attrition (n = 42) resulted in a power of 0.98 for an alpha error probability of 0.05.

Results

Statistical comparisons between the EG (n = 21) and the CG (n = 21) at baseline revealed some significant differences. Despite randomization, anxiety and depression were higher ($P = 0.001$ and 0.004) and engagement in activity was close to being lower ($P = 0.05$) in the EG. However, neither group deviated substantially from the levels of anxiety, depression, and pain acceptance found in other studies of patients with chronic pain [e.g., 17, 56, 77–79]. Both groups were comparable with regard to all other variables (see Table 1).

Primary Hypotheses

Within-Group Effects

Results support our first hypotheses (see Tables 2 and 3). At the 1-month follow-up, a significant treatment effect was observed for pain acceptance in the EG. The intervention resulted in greater pain willingness and readiness to engage in activities despite pain. At the 2-month follow-up, the effects of pain willingness and readiness to engage in activities despite pain remained significant. The effect size for engagement in activity was larger at the 2-month follow-up than at the 1-month follow-up assessment, $t(20) = -3.73$, $P < 0.001$, $d = 0.76$. Participants in the CG did not show any significant improvements over time (see Table 3).

Between-Group Effects

Changes from baseline to 1-month follow-up assessment differed significantly between the EG and the CG in engagement in activity (pain acceptance) (see Table 4). The test revealed a large estimated effect size ($d = 0.87$; 95% CI : –1.51 to 0.24). According to recommendations, improvements of at least 0.5 standard deviations can be considered clinically relevant changes [80]. Hence, 10 patients (48%) in the intervention group reported

Table 1. Comparison of demographic, psychological, and pain-related characteristics of two groups (N = 42), baseline assessment

Measure	Experimental (n = 21)	Control (n = 21)	t or χ^2	P
Age, years mean (SD)	57.29 (13.83)	60.62 (13.27)	–0.80*	0.43
Sex	8 (M), 13 (F)	7 (M), 14 (F)	0.10†	0.78
Marital status				
Single	2	2		
Living in partnership	3	0		
Married	13	14		
Divorced	1	2		
Widowed	2	3		
			3.57†	0.47
Educational level				
No educational qualification	2	3		
Middle school or lower	16	12		
High school	2	5		
College or above	1	1		
			2.15†	0.83
Employment status				
Full-time job	6	2		
Part-time job	2	3		
Under 15 hours	0	3		
Unemployed	13	13		
			5.20†	0.16
Duration of pain				
6 months to 1 year	1	0		
1–5 years	5	5		
5–10 years	5	2		
>10 years	10	14		
			2.95†	0.40
Pain acceptance				
Pain willingness, mean (SD)	20.95 (11.15)	23.67 (7.53)	–0.93*	0.36
Engagement in activity, mean (SD)	32.00 (11.40)	39.19 (11.72)	–2.02*	0.05
HADS, anxiety, mean (SD)	11.10 (3.70)	7.48 (3.01)	3.48*	0.001
HADS, depression, mean (SD)	9.24 (3.19)	6.38 (2.78)	3.09*	0.004
Pain intensity, mean (SD)	5.63 (1.32)	4.94 (1.69)	1.50*	0.14
Pain medication, mean (SD)	5.38 (1.36)	5.05 (1.40)	0.78*	0.44
Satisfaction with life, mean (SD)	19.24 (7.60)	22.76 (7.11)	–1.55*	0.13
Meaningfulness, mean (SD)	2.86 (0.94)	3.14 (0.92)	–1.0*	0.33
Crisis of meaning, mean (SD)	1.73 (1.24)	1.29 (1.0)	1.29*	0.20

*t test;
†chi-squared test.

clinically relevant changes. Of these, five showed a small improvement (improvement ≥0.5 SD), and five showed a moderate improvement (improvement ≥1 SD). Both groups also differed in engagement in activity (pain acceptance) from baseline to 2-month follow-up assessment. The test for group differences showed a large estimated effect size ($d = 0.92$, 95% CI: –1.56 to –0.29). Twelve patients (57%) in the intervention group reported clinically relevant changes. Of these, three (14%) showed a small improvement (≥0.5 SD), three (14%) showed a moderate improvement (≥1 SD), and five (24%) showed a substantial improvement (≥1.5 SD). The effect size for the difference between the two groups in engagement in activity was larger at the 2-month follow-up assessment than at the 1-month follow-up assessment, $t(40) = 3.0$, $P < 0.01$, $d = 0.93$.

Group × Time Interaction

Significant within- and between-group effects from baseline to 2-month follow-up were observed for engagement in activity. There was a group × time interaction ($F(2,80) = 5.69$, $P = 0.01$, $\eta^2 = 0.13$), indicating that engagement in activity increased for the EG but not the CG.

Secondary Hypotheses

Within-Group Effects

The results partially confirm our secondary hypotheses. At the 1-month follow-up, a significant treatment effect was observed for anxiety, depression, and crisis of meaning in the EG. The intervention resulted in lower levels of anxiety, depression, and crisis of meaning, but these effects did not persist to the 2-month follow-up. At the 2-month follow-up, only anxiety remained significant. Additionally, a significant treatment effect could be identified in a lower level of pain medication. The CG did not show any significant improvements over time but did show increases in perceived pain intensity and depression (see Table 3).

Table 2. Within-group effects in the EG

	EG				
	Baseline Mean (SD)	1 Month Mean (SD)	2 Months Mean (SD)	*P* Value Baseline to 1 Month	*P* Value Baseline to 2 Months
Pain acceptance					
Engagement activity	32.00 (11.40)	36.86 (8.02)	38.38 (8.83)	0.005	< 0.001
Pain willingness	20.95 (11.15)	24.38 (10.34)	23.86 (10.0)	0.01	0.025
Pain acceptance, total score	52.95 (20.20)	61.24 (16.32)	62.24 (16.88)	0.002	< 0.001
Pain intensity	5.63 (1.32)	5.25 (1.62)	5.41 (1.66)	0.06	0.14
Pain medication	5.38 (1.36)	5.14 (1.56)	4.95 (1.72)	0.13	0.04
HADS, anxiety	11.10 (3.70)	9.48 (3.30)	9.95 (3.57)	0.001	0.04
HADS, depression	9.24 (3.19)	7.71 (2.90)	8.48 (3.39)	0.005	0.11
Satisfaction with life	19.24 (7.60)	20.95 (6.49)	19.71 (7.04)	0.06	0.33
Meaningfulness	2.86 (0.94)	2.84 (1.02)	2.65 (0.94)	0.45	0.07
Crisis of meaning	1.73 (1.24)	1.35 (0.97)	1.42 (1.12)	0.05	0.14

Table 3. Within-group effects in the CG

	CG				
	Baseline Mean (SD)	1 Month Mean (SD)	2 Months Mean (SD)	*P* Value Baseline to 1 Month	*P* Value Baseline to 2 Months
Pain acceptance					
Engagement activity	39.19 (11.72)	38.14(10.48)	39.10 (11.11)	0.21	0.47
Pain willingness	23.67 (7.53)	24.43 (8.93)	24.90 (9.18)	0.28	0.24
Pain acceptance, total score	62.86 (17.61)	62.57 (16.85)	64.0 (18.07)	0.45	0.33
Pain intensity	4.94 (1.69)	5.21 (1.97)	5.67 (2.13)	0.20	0.02
Pain medication	5.05 (1.40)	4.90 (1.48)	4.81 (1.63)	0.26	0.18
HADS, anxiety	7.48 (3.01)	7.67 (4.00)	7.57 (3.85)	0.34	0.45
HADS, depression	6.38 (2.78)	6.19 (2.87)	7.14 (3.48)	0.32	0.04
Satisfaction with life	22.76 (7.11)	22.29 (7.13)	22.14 (6.44)	0.30	0.15
Meaningfulness	3.14 (0.92)	3.12 (0.98)	3.04 (1.13)	0.43	0.20
Crisis of meaning	1.29 (1.0)	1.38 (1.22)	1.50 (1.27)	0.29	0.12

Between-Group Effects

Changes from baseline to 1-month follow-up assessment differed significantly between the EG and the CG. EG participants reported larger decreases in anxiety, depression, and crisis of meaning (see Table 4). A large estimated effect size ($d = 0.86$, 95% CI: 0.22 to 1.49) was observed for anxiety. Puhan et al. [81] recommended a minimal important difference of 1.5. Therefore, patients with a reduction of 1.5 were ascribed a clinically relevant change. Twelve patients (57%) in the intervention group reported clinically relevant changes in anxiety. Of these, six showed a small reduction (≥1.5), five showed a moderate reduction (≥3), and one showed a substantial reduction (≥4.5).

With regard to depression, the test for group differences at the 1-month follow-up revealed a medium estimated effect size ($d = 0.66$, 95% CI: 0.03 to 1.28). Nine patients (43%) in the intervention group reported clinically relevant changes. Of these, three (14%) showed a small reduction (≥1.5), three (14%) showed a moderate reduction (≥3), and three (14%) showed a substantial reduction (≥4.5) in depressive symptoms. Additionally, we observed a larger decrease in crisis of meaning for the EG than for the CG at the 1-month follow-up assessment ($t(40) = -1.7$, $P = 0.05$, $d = 0.53$). Here, we also used the recommendation that improvements of at least 0.5 standard deviations can be considered clinically relevant changes [80]. Five patients from the EG reported clinically relevant changes (improvement ≥0.5 SD). Of these, four were slightly better (improvement ≥0.5 SD), and one was much better (improvement ≥1 SD).

Both groups also differed with regard to changes from baseline to the 2-month follow-up assessment; the EG reported larger decreases in pain intensity and depression (see Table 4). The test for group differences revealed a medium estimated effect size ($d = 0.65$, 95% CI: 0.03 to 1.2) with regard to depression. Ten patients (48%) in the intervention group reported clinically relevant changes. Of these, six showed a small reduction (≥1.5), two showed a moderate reduction (≥3), and two showed a substantial reduction (≥4.5). With a view to pain intensity, the test for group differences showed a medium estimated effect size ($d = 0.75$, 95% CI: 0.13 to 1.38). According to the recommendations of Dworkin et al. [82], four patients (20%) reported clinically relevant changes. Of these, three were slightly better (≥15%), and one was much better (≥33%).

Table 4. Between-group effects

Measure and Group*	1 Month Mean Difference† (SD)	2 Months Mean Difference† (SD)	1 Month Effect Size (Cohen's *d*)‡95% CI	*P* Value 1 Month Between Groups	2 Months Effect Size (Cohen's *d*)‡ 95% CI	*P* Value 2 Months Between Groups
Pain acceptance						
Pain willingness			0.44 (–1.05 to 0.17)	0.08	0.23 (–0.84 to 0.38)	0.23
Experimental	3.43 ± 6.24	2.90 ± 6.51				
Control	0.76 ± 5.86	1.24 ± 7.79				
Engagement activity			0.87 (–1.51 to 0.24)	0.004	0.93 (–1.56 to –0.29)	0.003
Experimental	4.86 ± 7.60	6.38 ± 7.83				
Control	–1.05 ± 5.84	–0.10 ± 6.05				
Pain intensity			0.52 (–0.10 to 1.13)	0.05	0.75 (0.13 to 1.38)	0.01
Experimental	–0.38 ± 1.07	–0.22 ± 0.90				
Control	0.27 ± 1.41	0.73 ± 1.54				
Pain medication			0.11 (–0.50 to 0.71)	0.37	0.18 (–0.43 to 0.78)	0.29
Experimental	–0.24 ± 0.94	–0.43 ± 1.03				
Control	–0.14 ± 0.96	–0.24 ± 1.14				
HADS, anxiety			0.86 (0.22 to 1.49)	0.004	0.43 (–0.19 to 1.04)	0.09
Experimental	–1.62 ± 2.12	–1.14 ± 2.78				
Control	0.19 ± 2.11	0.10 ± 3.02				
HADS, depression			0.66 (0.03 to 1.28)	0.02	0.65 (0.03 to 1.2)	0.02
Experimental	–1.52 ± 2.23	–0.76 ± 2.68				
Control	–0.19 ± 1.81	0.76 ± 1.92				
Satisfaction with life			0.50 (–1.11 to 0.12)	0.06	0.28 (–0.42 to 0.79)	0.19
Experimental	1.71 ± 4.82	0.48 ± 4.93				
Control	–0.48 ± 3.97	–0.62 ± 2.62				
Meaningfulness			0.00 (–0.61 to 0.61)	0.50	0.19 (–0.12 to 1.11)	0.28
Experimental	–0.02 ± 0.62	–0.21 ± 0.62				
Control	–0.02 ± 0.47	–0.10 ± 0.56				
Crisis of meaning			0.53 (–0.08 to 1.15)	0.05	0.49 (–0.12 to 1.11)	0.06
Experimental	–0.38 ± 1.01	–0.31 ± 1.26				
Control	0.10 ± 0.78	0.21 ± 0.80				

*Group sizes: EG, n = 21; CG, n = 21.

†Mean differences between assessments: 1-month mean difference= 1-month follow-up assessment minus baseline assessment; 2-month mean difference= 2-month follow-up assessment minus baseline assessment.

‡Effect size $d = Mt - Mc/\sigma pooled$. Mt= mean change in the score of the treatment group; Mc= mean change in the score of the CG; $\sigma pooled = \sqrt{(\sigma t2 + \sigma c2/2)}$; σt = standard deviation of the change in the score of the treatment group; σc = standard deviation of the change in the score of the CG.

Quantitative Evaluation of the Intervention

Table 5 displays the results of the quantitative evaluation of the SoMe Card Method, as given by members of the EG. The mean score of 3.89 and a median of 4.0 (range from 1.2 to 5.0; Cronbach's alpha = 0.90) indicates a positive evaluation.

Discussion

The SoMeCaM is a short intervention, to be completed in a single session of approximately 1 hour. Nevertheless, it showed various substantial effects in the present study, and participants evaluated it as helpful and inspiring.

In a comparison of pretreatment and t1 posttreatment scores, anxiety, depression, and crisis of meaning had decreased in the EG, whereas pain acceptance had risen. This attitude toward pain, as well as lower anxiety, remained stable until t2. At this point, pain medication had also decreased significantly. No changes for the better were noted in the CG. This was not surprising, as other randomized controlled intervention studies of patients with chronic pain who received an intervention or treatment as usual showed mixed results in terms of improvements in outcome measures in the CG [83–85]. Direct comparisons between the EG and CG established a larger increase in engagement in activity and larger decreases in anxiety and depression in the EG at t1. Ten patients (48%) in the EG showed clinically relevant changes in engagement in activity, 11 (52%) in anxiety, and 9 (43%) in depression. At t2, EG members reported a significantly stronger increase in engagement in activity and greater changes in depression and pain intensity. Effect sizes were medium to large, highlighting substantial differences between the two groups. More than 50% of the EG showed clinically relevant changes in engagement in activity. Nearly half of the EG experienced a reduction of depressive symptoms. Of these, two even reported a substantial reduction. We further observed that three of the 21 patients in the EG showed a slight improvement in pain intensity, and there was one substantial improvement. Given the chronic pain condition that most patients had had for more than 5 years, this is a strong indication of the efficacy of the intervention.

Table 5. Posttreatment quantitative evaluation of the SoMeCaM (n = 21)

The Card Method . . .	Mean (SD)	Median
1. . . . helped me reflect about the things that I am not necessarily thinking about.	4.00 (0.83)	4.00
2. . . . was a rewarding experience.	4.48 (0.81)	5.00
3. . . . gave me the feeling that I was learning more about my "real" self.	3.90 (1.26)	4.00
4. . . . sensitized my awareness of my personal sources of meaning.	3.76 (1.38)	4.00
5. . . . gave me ideas about how I can live more authentically.	3.62 (1.32)	4.00
6. . . . provided insights that can inspire me.	3.57 (1.25)	4.00

Possible range: 0–5.

The SoMeCaM intervention was shown to be most effective with respect to attitude toward pain. This might be due to a realignment of personal orientation, as suggested by the hierarchic model of meaning [86]. According to the model, perception, action, and goals are experienced as meaningful when they are motivated by personal sources of meaning. These might have been lost or forgotten during the patient's struggle with pain [7]. An exploration of sources of meaning during the SoMeCaM intervention probably inspired a change of perspective and reinstalled personally relevant life goals. Respective perception, action, and goal pursuit would thus be reinvigorated, while a preoccupation with pain issues would be deflected. The decrease in depression after intervention is consistent with other studies that found positive effects of behavioral activation on depressive symptoms [87, 88]. The simultaneous decrease in crisis of meaning in the EG is in line with empirical results that found a positive association between depressive symptoms and crisis of meaning [41, 89].

EG members also reported lower levels of anxiety after the intervention. More than 50% of the EG showed clinically relevant changes. The SoMeCaM may have allowed for identifying new ways and possibilities of living a good and meaningful life, despite the chronic illness. As a consequence, participants might have experienced renewed confidence and a sense of hope and orientation, which led to fewer catastrophizing thoughts and less rumination and could have changed the patients' focus in their daily life [90, 91]. Meaning in life and life satisfaction were not affected by the treatment in an immediately positive way, as had been expected. Representing an evaluation of life from a meta-perspective, these characteristics are known to be rather stable [86, 92] and thus not easily changed [29]. Longer-term studies would be necessary to investigate these processes.

The SoMeCaM could easily be integrated into a multimodal clinical treatment program or into psychotherapy in an ambulatory setting. The multimodal treatment is often conceptualized as a group setting with CBT sessions in a day clinic or in an inpatient setting. The cards enable easy access to reflections on the influence of pain on patients' life and can also support health care personnel by addressing existential issues, as talking about death or meaning in life is often found to be a challenge [93, 94]. The intervention has already been systematically and successfully used in a training program in Denmark for hospital staff called "existential laboratory." Hospital personnel were trained in incorporating existential topics into patient communication. The intervention is also regularly used in courses for pastors in Denmark. This can be a chance for patients to reflect on their situation and to search for new ways of living previously valued sources of meaning or to let go of them—or even to reflect on different paths.

In the ambulatory setting, 1–2 therapy sessions might be used for the SoMeCaM intervention, with the aim of integrating it into the whole therapeutic process. The SoMeCaM might be of particular value in the early rehabilitation of chronic illnesses. However, these settings have not yet been researched systematically.

Compared with the ACT approach to personal values, the SoMeCaM suggests a more thorough and unfolded way of exploring subjective meaning. The method adds time and structure to the important topic.

Some study limitations should be noted. First, this study tested the impact of the SoMeCaM intervention vs treatment as usual. Resulting differences between the CG and EG attest to an effect of the intervention, which is a promising finding, given its brevity. However, it is not yet possible to determine the exact source of these effects, as the SoMeCaM could not be compared with an alternative intervention. It might be possible that the change in distress about pain after receiving the SoMeCaM intervention is related to the therapeutic effect of talking to someone else. A meta-analysis by Hoffman et al. (2007) [23] showed that only self-regulatory therapy (biofeedback, relaxation, hypnosis) had an impact on depression in patients with chronic low back pain. Other psychological interventions (CBT, supportive counseling, psychoanalytics) did not have an effect. In particular, supportive counseling (nondirective or professional) can be compared with "simply talking to someone," and it did not have any effect on depression. In contrast, the SoMeCaM showed medium effect sizes in the reduction of depression. Having shown its general efficacy, further studies are necessary to test unique effects of the SoMeCaM.

Second, despite randomization, the EG had higher depression and anxiety scores and a lower engagement in activity to start with. This made it a more burdened sample to work with; on the other hand, it implied more

leeway for a change for the better. Moreover, the occurrence of such group differences is not overly surprising, as patients with chronic pain are a very heterogeneous group. Their mental, social, and somatic limitations can vary depending on many factors (e.g., pain location, age, gender, pain duration, pain severity) [77, 79, 95–97]. A follow-up study should control for these criteria. However, other variables also changed in the same direction, suggesting that improvements in depression, anxiety, and engagement in activity were not a statistical artifact. Also, the number of visits and further details about physiotherapy were not assessed. We also did not assess how often participants went to the doctor or to the massage. Because participants were randomly assigned to the EG and CG, no systematic differences with regard to the frequency of visits to doctors or physiotherapists can be expected.

As this was the first randomized controlled trial with the SoMeCaM, we tried to assess the potential effects of the method in combination with treatment as usual, i.e., medication, physiotherapy, and massage. The present study cannot provide any information on how the SoMeCaM compares with other psychotherapy approaches, either alone or in combination. The results of this study need replication in larger and more stringent study designs.

Conclusion

This randomized controlled small-sample trial study presented the first positive results for the efficacy of a new existential intervention in the treatment of chronic pain. The SoMeCaM was shown to be a promising additional tool for the treatment of chronic pain. The findings underline the relevance of acknowledging existential issues in the treatment of people confronted with adverse circumstances.

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