Complementary Therapies in Clinical Practice 36 (2019) 1–6

Contents lists available at ScienceDirect

Complementary Therapies in Clinical Practice

journal homepage: www.elsevier.com/locate/ctcp

Integrated care for migraine and chronic tension-type headaches: A prospective observational study

Holger Cramer[a,b,*], Marie Hehlke[a], Jonas Vasmer[a], Thomas Rampp[a], Dennis Anheyer[a], Felix J. Saha[a], Anna Paul[a], Romy Lauche[b,c], Gustav Dobos[a]

[a] Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, Faculty of Medicine, University of Duisburg-Essen, Essen, Germany
[b] Australian Research Centre in Complementary and Integrative Medicine (ARCCIM), Faculty of Health, University of Technology Sydney, Sydney, Australia
[c] Department of Internal and Integrative Medicine, Sozialstiftung Bamberg, Chair of Integrative Medicine, Faculty of Medicine, University of Duisburg-Essen, Germany

ARTICLE INFO

Keywords:
Headache
Integrated care
Migraine

ABSTRACT

Background and purpose: This prospective observational study aimed to investigate the effects of an interdisciplinary multimodal integrated care program in patients with chronic migraine and/or tension-type headache.

Materials and methods: Patients (n = 158) underwent inpatient, outpatient and/or semi-stationary treatment including conventional as well as complementary headache treatment. Headache frequency was defined as the primary outcome; secondary outcomes included pain (VAS, PPS), medication use, quality of life (SF-36), function (HDI, PSFS), depression and anxiety (HADS), and pain self-efficacy (PSEQ).

Results: Headache frequency decreased from 17.0 ± 8.8 days/month at treatment start to 11.4 ± 9.2 at treatment end and to 10.6 ± 9.3 at 6-month follow-up ($p < 0.001$). All other outcome measures also improved across the course of the study (all $p < 0.001$).

Conclusions: An integrated care approach based on integrative medicine improved headache symptoms and functioning in patients with chronic migraine and/or tension-type headache. Interdisciplinary multimodal treatment approaches seem to adequately address the specific treatment needs of headache patients.

1. Introduction

Chronic headache is one of the most common disorders of the nervous system and is characterized by the presence of cephalic pain for at least fifteen days per month, over a period of more than 3 months [1]. The most common types within this collective are migraine (with or without aura) and tension-type headache (TTH). The global mean prevalence rates are reported to be 47% for all chronic headaches, 38% for TTH, 10% for migraine, and 3%–6% for chronic daily headache (CDH) [2–4]. However, prevalence strongly differs between countries ([4]). While migraine episodes are characterized by the appearance of moderate to severe unilateral pulsating headache, tension-type headache episodes are often stress related or associated with musculoskeletal problems in the neck. Severe headache attacks can be associated with several side effects, such as nausea, and can last from hours to days and often lead to reduced work quality or inability to work [5]. Medication-overuse headache affects 1% of the worldwide population [6].

Underestimated, underrecognized and undertreated headaches cause great individual suffering, impaired quality of life and socioeconomic impact. Headache disorders are currently the sixth leading cause of disability worldwide (based on years lived with disability) [7,8]. In the United States of America, migraine alone causes up to 86.5 million lost workdays annually, and related thereto an indirect annual cost of US$9.3 billion [9]. In addition to the physiological impairments, the psychological, social, and economic implications of headache are therefore substantial.

The common conventional therapy consists of a combination of nonsteroidal anti-inflammatory drugs and triptans; opioids, barbiturates, and ergots are also used [10,11]. A frequent use can induce medication-overuse headache, which is also a leading cause of disability worldwide [8]. So new and different therapy options are urgently needed. A medical prophylaxis such as propranolol, metoprolol, nadolol, amitriptyline, or nortriptyline is also available [10,12].

Besides the conventional medical care, our Department of Internal and Integrative Medicine offers several evidence-based therapy options for migraine and tension-type headaches. Traditional European and Chinese Medicine procedures (such as acupuncture or cupping) are combined with stress management approaches and lifestyle

* Corresponding author. Kliniken Essen-Mitte, Klinik für Naturheilkunde und Integrative Medizin, Am Deimelsberg 34a, 45276, Essen, Germany.
E-mail address: h.cramer@kem-med.com (H. Cramer).

https://doi.org/10.1016/j.ctcp.2019.04.001
Received 25 October 2018; Received in revised form 19 March 2019; Accepted 10 April 2019
1744-3881/

modification by means of mind-body medicine within the integrated care [13–18]. Offering integrated headache care in other settings has been shown to be an effective way to reduce the headache frequency [19]. Nevertheless complementary therapies are for the most part not taken into consideration for the treatment of patients with headache.

The aim of this prospective observational study was to investigate the effect of the integrated care regarding headache symptoms, quality of life, coping with the disease and self-efficacy of patients with migraine and chronic tension-type headaches.

2. Materials and methods

2.1. Design and patients

This prospective observational study was conducted at a Department for Internal and Integrative Medicine, established in 1999 to treat patients with chronic internal and pain diseases. Patients who were over 18 years old, insured with one of two large German statutory health insurances, and diagnosed with migraine and/or tension-type headaches for at least 6 months were eligible for integrated care. Diagnoses had to be made by a neurologist according to ICD-10 criteria; serious causes for headache had to have been excluded by medical imagining.

In addition to the ICD-10 diagnostic criteria, patients were required to suffer from headache requiring acute treatment at least five days per month. Additionally, patients were required to either take analgesic drugs that can themselves elicit headache (no specific dose or frequency defined) and/or to take at least 10 triptans per month. Patients with an additional diagnosis of medication overuse headache were eligible. Referred by specialists or general practitioners to the Department of Internal and Integrative Medicine, patients first had to keep a 30 days headache and medication diary, before running through detailed diagnostics, including medical history, circumstances and social sphere. A detailed consultation gave them an overview of available treatment options, including complementary therapies. Patients who expressed an interest to undergo integrative care and who were motivated to participate, were then enrolled into the program. Written informed consent was obtained. The individual treatments were based on the patients' special needs.

Outcome measures were gathered at admission, at discharge and six months after the end of the treatment. Collected data included headache frequency, drug use (in particular triptans), pain intensity, headache-related disability, quality of life, anxiety/depression and self-efficacy.

The study was approved by the ethics committee of the local University Hospital (approval number: 11–4749) prior to patient recruitment. All patient gave oral and written informed consent before being included. The study was registered retrospectively at clinicaltrials.gov (NCT03503734; registered 11 April 2018; first participant enrolled 18 August 2011).

2.2. Intervention

The treatment could be realized on an inpatient, outpatient and/or day care basis, according to the severity level of illness and comorbidities (Fig. 1). The integrated care model has been described in detail elsewhere [18]. Patients' treatment regimens were based on their individual needs. The course if the treatment was determined by the treating physician in consultation with the patient.

The inpatient treatment took place at the Department of Internal and Integrative Medicine. The stay was slated for 14 days. The treatment was geared on the patients' individual needs. First examination was for that reason a detailed collection of patients' history, obtained by different skilled medical staff (nurses, physicians, mind-body-medicine therapists). Conventional diagnostic of headaches was carried out, just as interventional medical approaches: physiotherapy and complementary techniques. Traditional medicine was used in the form of Traditional Chinese Medicine, acupuncture and many more. Classical naturopathy was realized as hydrotherapy, thermotherapy, manual therapy, massage, phytotherapy, exercise, nutritional therapy and fasting. Mind-body-medicine sessions were integrated into the inpatient stay. Patients learned to achieve a health promoting lifestyle by means of exercise, diet, stress-reduction and self-help. The active participation of patients in their care should be increased. Mind-body-medicine therapy sessions were based on Harvard Medical School's Benson-Henry Institute for Mind/Body Medicine Program [20] and the University of Massachusetts' Mindfulness-Based Stress Reduction Program [21]. Cognitive restructuring as element of cognitive behavioral therapy aimed to improve coping strategies and to maintain newly acquired skills and health promoting lifestyle.

Day care could follow the inpatient stay or could be applied as sole therapy. As part of the standard care provided at the Department for Internal and Integrative Medicine, it occurred at a semi-residential clinic for 6 h once a week over a total of 10 weeks. Aim of this 60 h program was to consolidate lifestyle changes and coping strategies [22]. Days started with a short program of activating exercises, extended by yoga, qigong or tai chi to help improving self-awareness and self-regulation. Medical rounds with a physician trained in integrative medicine were integral part of each session. Further agenda items were physical exercises, Mediterranean diet and relaxation training based on progressive muscle relaxation according to Jacobson [23], the body scan and mindfulness meditation [24]. Patients were encouraged to practice relaxation training at home with the use of manuals or CDs. An important element of the semi-stationary treatment was learning coping strategies. To improve the learning success background information about stress and stress-reactions were taught. Through the introduction to mindfulness, patients learned to act mindful during daily activities, especially when dealing with emotional distress or pain. Self-help strategies and self-treatments were introduced, including cataplasms, phytotherapy, cupping massage, acupressure and hydrotherapy. With the help of cognitive behavioral therapy approaches, irrational and maladaptive patterns of perception, communication, judgement and social interaction were identified to improve self-perceptive and self-responsible attitudes and behavior [25]. Follow-up meetings aimed to keep up the health-promoting lifestyle changes.

The outpatient treatment was delivered in the Department's outpatient ward. It consisted of acupuncture, cupping, hydrotherapy and massages as well as nutritional counseling. The patients could additionally be offered one-to-one mind-body-medicine interventions, where the focus especially was on improving the patients' knowledge of their disease, so that they could better handle the headaches and avoid triggers, improving stress management skills and encouraging reflection.

For patients with an additional diagnosis of medication overuse

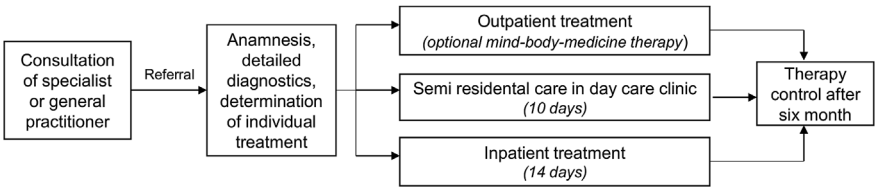

Fig. 1. Flowchart of the integrated headache care program.

headache, an inpatient medication withdrawal was a mandatory part of the integrated care. For patients without such a diagnosis, their medication as prescribed by their neurologist was not changed or was reduced during the course of treatment, when headache symptoms were reduced.

2.3. Outcome measures

Outcome measures were collected at treatment start, treatment end and at a 6-month after the end of treatment. At each assessment point, patients documented their headache frequency (days per month) and the use of analgetics and triptans per month in a 28-day headache diary. Analgesics' use was recalculated as defined daily doses [26]; triptans use as days/month. Diaries were completed the four weeks prior to the start of the treatment, the four weeks following the end of treatment and at weeks 19–22 after the end of treatment. Change in headache frequency during the study period was defined as the primary outcome.

During visits at the department, pain intensity and pain bothersomeness were assessed using visual analog scales (VAS) [27]. Further data were collected using standardized questionnaires. The Pain Perception Scale (PPS) assesses affective and sensory pain on 24 items [28]. The short form health survey (SF-12) measures the patients' health-related quality of life by two principle component scales (mental and physical); a high score indicates a high quality of life [29]. The Headache Disability Inventory (HDI) assessed how the headache influences patients' everyday life. Emotional and functional values are considered [30]. The Hospital Anxiety and Depression Scale (HADS) measures anxiety and depression and is specifically designed for patient populations with physical illness [31]. In the Patient-specific Functional Scale (PSFS) patients are requested to identify important daily life activities they are unable to perform because of their disease [32]. The Pain Self-Efficacy Questionnaire (FESS) assesses the confidence of chronic pain patients to be able to follow their daily activities while being in pain. A high score is in favor of a high self-efficacy [33].

2.4. Sample size calculation and statistical analysis

The required sample size was calculated a priori using G-Power software (Version 3.0.10); the study was powered to detect a clinical relevant reduction in headache frequency. A 50% reduction in headache frequency commonly is regarded as clinically relevant. Assuming a mean headache frequency of 12 days per month [34] and a standard deviation of 20 a two-sided, level 5% *t*-test requires a total of 119 patients to detect 6-day reduction with a statistical power of 90%. Accounting for a potential loss of power because of a maximum of 20% dropouts (estimated based on clinical experience), it was planned to include at least 150 patients in this trial.

Differences between patients completing the study and those dropping out early in sociodemographic and clinical characteristics at admission were analyzed using independent sample t-tests or Chi-squared tests as appropriate.

Outcomes were analyzed in the per-protocol analysis by univariate repeated-measures analyses of variance with 'time' (pre, post, follow-up) as within-group factor. The analysis including only patients that completed all 3 measurements. Patients who did not complete one or more of the three measurements were excluded from the statistical analysis. Changes from baseline to the end of treatment and to follow-up and from end of treatment to follow-up were analyzed by post hoc tests using Bonferroni corrections for multiple testing.

The proportion of patients with a clinically meaningful reduction of at least 50% in headache frequency was further compared between the different headache diagnoses (migraine, tension-type headache, both) by means of Chi-squared tests. The same analyses were done for patients reaching a reduction of at least 25% in headache frequency.

Independent predictors of reaching a clinically meaningful reduction of at least 50% or at least 25% in headache frequency were further identified using multiple logistic regression analyses. The following sociodemographic predictors were considered: age (categories: 18–29; 30–39; 40–49; 50–64, 65 years or older), gender (categories: female; male), migraine diagnosis (categories: yes; no) tension-type headache diagnosis (categories: yes; no), 'other' headache diagnosis (categories: yes; no), headache frequency (categories: 0–5, 6–10, 11–15, 16–20, 21–25, 26–31 days/month), outpatient treatment (categories: yes; no), inpatient treatment (categories: yes; no), and mind-body group treatment (categories: yes; no), mind-body individual treatment (categories: yes; no). A backward stepwise procedure with a logistic regression statistic p-value of ≤ 0.05 was chosen, and adjusted odds ratios with 95% confidence intervals were calculated. The same analyses were conducted for reaching an increase of at least 5 points in the SF12 subscales.

Statistical analyses were performed using the Statistical Package for Social Sciences software (IBM SPSS Statistics for Windows, release 22.0. Armonk, NY: IBM Corp).

3. Results

3.1. Patients

From August 18, 2011 to April 30, 2013, a total of 158 patients were included in the study. A total of 39 patients (24.7%) stopped treatment early and did not attend the second assessment; a further 12 (7.6%) were lost to follow-up at 6 months after the end of treatment. The majority of patients was female (86,7%); mean age was 41.8 ± 13.2 years (Table 1). Most patients had multiple headache diagnoses with migraine being the most commonly diagnosed headache type. Patients suffered from headache on average 17.0 ± 8.8 days per month and patients with migraine relied on the use of triptans on 4.4 ± 5.4 days per month. The majority of patients underwent outpatient treatment; a considerable proportion of patients additionally underwent inpatient or semi-stationary treatment (Table 1; Supplementary Table 1).

Patients who stopped the study early were younger ($p = 0.017$) and had a higher headache frequency ($p = 0.013$) than those who completed the study (Supplementary table 2).

Table 1
Sociodemographic and clinical characteristics at admission (n = 158).

Variable	Number (%)	Mean ± Standard Deviation
Sociodemographic characteristics		
Age, in years	–	41.8 ± 13.2
Gender		
Female	137 (86.7%)	–
Clinical characteristics		
Diagnosis[a]		
Migraine	127 (80.4%)	–
Tension type headache	78 (49.4%)	–
Other headache	18 (11.4%)	–
Headache days/month	–	17.0 ± 8.8
Triptane use in days/month	–	4.4 ± 5.4
Pain intensity	–	5.6 ± 1.8
Treatment[b]		
Inpatient treatment	66 (41.8%)	–
Outpatient treatment	135 (85.4%)	–
Mind-body-medicine group treatment (semi-stationary)	59 (37.3%)	–
Mind-body-medicine individual treatment	38 (24.1%)	–
Treatment expectancy[c]	–	8.5 ± 1.6

[a] More than one headache diagnosis per patient possible.
[b] More than one treatment per patient possible.
[c] Treatment expectancy was assessed on a 100 mm visual analog scale.

Table 2
Outcome measures (mean ± standard deviation) at treatment start, treatment end, and 6-month follow-up. F1- and p-values were derived from univariate repeated-measures analyses of variance including only patients that completed all 3 measurements. Patients who did not complete one or more of the three measurements were excluded from the statistical analysis. F1 and p1-values are given for main effects of time and indicate changes across the 3 time points treatment start, treatment end and follow-up. For analyses of variances, p-values < 0.05 were considered significant. T1-and p2-values are derived from post-hoc tests and indicate changes from treatment start to treatment end, T2-and p3-values changes from treatment start to follow-up; and T3-and p4-values changes from treatment end to follow-up. For post-hoc tests, p-values < 0.016 were considered significant.

	Treatment start (n = 158)	Treatment end (n = 119)	Follow-up (n = 107)	F; P1	T1; P2	T2; P3	T3; P4
Pain intensity	5.6 ± 1.8	4.6 ± 1.6	4.9 ± 2.0	24.6; < 0.001	6.2; < 0.001	5.2; < 0.001	−1.3; 0.208
Pain bothersomness	7.6 ± 1.8	5.3 ± 2.8	4.5 ± 2.6	86.7; < 0.001	9.6; < 0.001	11.2; < 0.001	3.2; 0.002
Triptane use in days/month[a]	4.4 ± 5.4	2.8 ± 4.0	2.7 ± 4.1	17.8; < 0.001	4.7; < 0.001	5.0; < 0.001	0.0; 0.994
Analgetics use DDD	0.9 ± 0.6	0.8 ± 0.5	0.8 ± 0.5	9.5; < 0.001	3.5; 0.001	3.4; 0.001	< 0.01; 0.987
PPS							
Affective pain	38.0 ± 10.8	30.9 ± 11.3	30.0 ± 12.4	43.8; < 0.001	7.5; < 0.001	7.7; < 0.001	1.1; 0.265
Sensory pain	21.0 ± 6.2	19.0 ± 6.6	19 ± 7.0	10.2; < 0.001	3.7; < 0.001	3.9; < 0.001	0.4; 0.677
SF-12							
Physical component score	33.4 ± 7.5	39.5 ± 9.2	40.6 ± 10.0	33.9; < 0.001	6.3; < 0.001	7.2; < 0.001	1.7; 0.100
Mental component score	40.3 ± 10.8	48.1 ± 10.2	48.0 ± 10.3	31.4; < 0.001	7.3; < 0.001	6.0; < 0.001	0.6; 0.538
HDI							
Emotional scale	31.5 ± 10.9	22.0 ± 12.3	19.3 ± 13.0	50.8; < 0.001	7.5; < 0.001	8.7; < 0.001	2.2; 0.027
Functional scale	30.8 ± 7.9	23.4 ± 10.1	21.4 ± 11.00	56.4; < 0.001	8.5; < 0.001	9.2; < 0.001	1.7; 0.099
Total score	62.3 ± 17.3	45.3 ± 21.6	40.7 ± 23.0	60.3; < 0.001	8.4; < 0.001	9.4; < 0.001	2.1; 0.036
HADS							
Anxiety	8.7 ± 3.8	6.6 ± 4.0	6.1 ± 3.8	42.8; < 0.001	7.6; < 0.001	7.6; < 0.001	1.4; 0.168
Depression	8.7 ± 3.5	6.9 ± 2.9	6.6 ± 3.0	21.9; < 0.001	5.3; < 0.001	5.2; < 0.001	0.9; 0.360
PSFS	3.4 ± 2.1	5.9 ± 2.5	6.1 ± 2.7	55.3; < 0.001	9.5; < 0.001	8.3; < 0.01	0.1; 0.890
FESS	27.7 ± 10.0	38.0 ± 12.0	40.6 ± 12.4	65.5; < 0.001	8.1; < 0.001	9.7; < 0.001	2.7; 0.008

DDD, defined daily dose; FESS, Pain-specific Self-efficacy Questionnaire; HADS, Hospital Anxiety and Depression Scale; HDI, Headache Disability Inventory; PSFS, Patient-specific Functional Scale; SES, Pain Perception Scale; SF-36, Short-Form 36.
[a] Only patients with a diagnose of migraine.

3.2. Outcome measures

All outcome measures improved across the course of the study (Table 2), regardless of the applied treatment (Supplementary Tables 3–6). Headache days per month decreased from 17.0 ± 8.8 at the treatment start to 11.4 ± 9.2 at the end of the treatment and to 10.6 ± 9.3 days per month at the 6-month follow-up ($p < 0.001$; Fig. 2). At the end of treatment, 42.9% and 28.1% had reached at least 25% and 50% reduction in headache frequency, respectively with no significant difference between headache types ($p = 0.831$ and $p = 0.737$; Fig. 3). At 6-month follow-up, 45.4% and 27.5% still had a 25% and a 50% reduction in headache frequency, respectively, compared to baseline, again without significant differences between diagnoses ($p = 0.105$ and $p = 0.192$; Fig. 3).

Comparable reductions were also seen for pain intensity, pain bothersomness, perceived sensory and affective pain, anxiety, depression, use of triptans and analgetics, and headache-specific disability (Table 2; Supplementary Tables 3–6). Bonferroni corrected post-hoc analyses revealed decreases from treatment start to treatment end and from treatment start to follow-up and no changes from treatment end to follow-up for all variables, except for pain bothersomeness and all scales of the Headache Disability Inventory that further decreased from treatment end to follow-up.

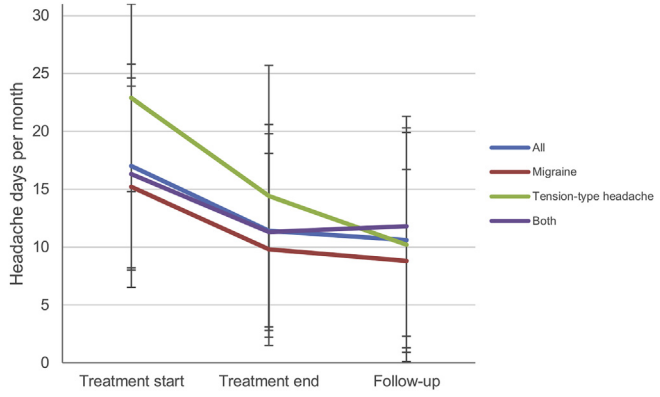

Fig. 2. Effects (mean ± standard deviation) of the integrated headache care program on headache frequency.

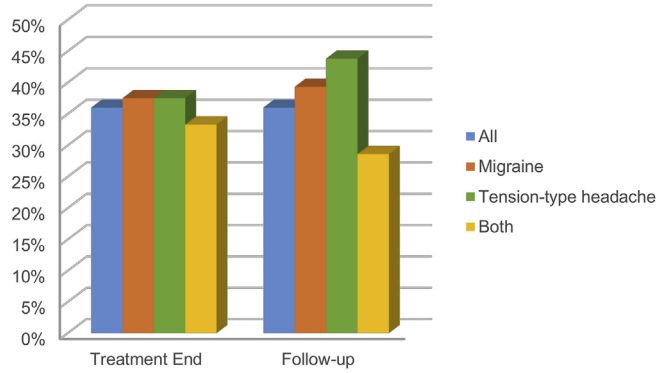

Fig. 3. Number of patients (in percentage) that reached at least 50% reduction in their headache frequency at treatment end or follow-up.

Comparable improvements occurred for quality of life, pain-specific self-efficacy, and patient-specific function (Table 2). Bonferroni corrected post-hoc analyses revealed increases from treatment start to treatment end and from treatment start to follow-up and no changes from treatment end to follow-up.

In logistic regression analysis, none of the independent variables predicted reaching a reduction of at least 50% in headache frequency at end of treatment or at follow-up. A 25% reduction in headache frequency at end of treatment was independently predicted by mind-body-medicine individual treatment (odds ration [OR] = 2.6; 95% confidence interval [CI] = 1.1–6.1; $p = 0.025$). At follow-up, a 25% reduction in headache frequency was independently predicted by female gender (OR = 4.0; 95% CI = 1.3–12.7; $p = 0.019$), and by not being diagnoses with 'other' types of headache (OR = 0.2; 95% CI = 0.05–0.8; $p = 0.022$). For the SF12, female gender significantly predicted an increase of at least 5 points in the physical component

score at follow up (OR = 4.8; 95% CI = 1.2–18.7; p = 0.023).

4. Discussion

4.1. Comparisons with the literature

The findings of this study are in line with prior studies on integrative medicine concerning treatment of painful conditions. A 2-week inpatient stay at the Department for Internal and Integrative Medicine [35] improved patients' quality of life and anxiety/depression. This led to reduced drug intake and lower work absenteeism, with potential positive socioeconomic impact. The treatment has also been shown to increase motivation for health behavioral changes [36]. These changes on the one hand depend on the motivation itself, but on the other hand also on the ability to initiate and maintain the acquired health behavior [37]. Mind-body-medicine introduces a health promoting lifestyle and teaches self-help and coping strategies for patients with pain syndromes [36]. Through increased disease acceptance a better treatment success and less pain and depression can be noticed [36,38].

Compared with other structured programs like mindfulness-based stress reduction (MBSR) or mindfulness-based cognitive therapy (MBCT) the results of these intervention programs in treating pain conditions are inconclusive. For chronic headaches (including migraine and TTH) no significant group differences in headache frequency, headache duration or pain intensity were found by a meta-analysis that compared MBSR/MBCT to usual care. However, due to the low number, small scale and often high or unclear risk of bias of the included randomized controlled trials, the results of this meta-analysis have to be judged as imprecise [39]. For low back pain a recent meta-analysis found small short-term improvements in pain intensity and physical functioning if MBSR was compared to usual care but not in comparison with active comparators. However, these effects failed to reach clinical meaningfulness. No effects were found for improving pain acceptance [40]. For the fibromyalgia syndrome a meta-analysis revealed statistical significant short-term improvements of quality of life and pain when compared to usual care and when compared to active control interventions. Quality of the included studies was mainly low [41]. For treating patients with chronic headaches existing studies on MBSR/MBCT interventions could not find positive effects on headache frequency and duration, while the effects on pain intensity are inconclusive [42–46].

4.2. Study limitations

The observational design of this study weakens its informative value. The lack of a control group could favor overestimation of the results due to unspecific effects. Therapist attention and care and other context factor showed in several studies effects similar to real treatments [47]. Moreover, effects cannot be assigned to single interventions. Most patients received multiple interventions (inpatient, outpatient, semistationary mind/body medicine group treatment). Therefore, differences in efficacy between different interventions could not be calculated. The choice of treatments were based on individual needs, which might reduce reproducibility and might have introduced bias. Finally, there is the possibility of selection bias because patients self-selected for the integrated care.

4.3. Implication for further research

In order to exclude non-specific effects clinical trials with distinct control conditions are urgently needed. Moreover, long-term effects are of particular importance in pain therapy. Therefore it is necessary to generate more definite ideas of the onset and duration of effects by choosing follow-up intervals of different lengths. In this context, patient compliance and adherence are of particular interest.

In addition to these aspects, the role of the individual components of multimodal approaches to patient recovery could also be of interest. So far, for example, it is completely unclear which kind of exercise therapy should be used in order to achieve a greatest possible effect.

5. Conclusion

The results of this study allow drawing the following conclusions: integrated care on an inpatient, outpatient and/or semi-stationary basis significantly decreased patients' headache frequency. Further positive effects were found on quality of life, depression, anxiety, self-efficacy and drug intake. While more research is needed to reach conclusive judgements, the integrated care model assessed here can be preliminarily considered an effective treatment for patients with migraine and/or tension-type headache.

Competing interests

The authors declare that they have no competing interests.

Funding

No specific funding was received for this study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctcp.2019.04.001.

References

[1] Headache Classification Committee of the International Headache Society (IHS), The international classification of headache disorders, 3rd edition (beta version), Cephalalgia 33 (9) (2013) 629–808.
[2] L. Stovner, K. Hagen, R. Jensen, Z. Katsarava, R. Lipton, A. Scher, T. Steiner, J.A. Zwart, The global burden of headache: a documentation of headache prevalence and disability worldwide, Cephalalgia 27 (3) (2007) 193–210.
[3] S.J. Cho, M.K. Chu, Risk factors of chronic daily headache or chronic migraine, Curr. Pain Headache Rep. 19 (1) (2015) 465.
[4] GBD 2017 Disease and Injury Incidence and Prevalence Collaborators, Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017, Lancet 392 (10159) (2018) 1789–1858.
[5] K.F. Masuhr, F. Masuhr, M. Neumann, Duale Reihe Neurologie, 7 ed., Thieme, Stuttgart, 2012.
[6] WHO, Lifting the Burden. Atlas of Headache Disorders and Resources in the World. Geneva, (2011).
[7] T.J. Steiner, L.J. Stovner, T. Vos, GBD 2015: migraine is the third cause of disability in under 50s, J. Headache Pain 17 (1) (2016) 104.
[8] GBD 2015 Disease and Injury Incidence and Prevalence Collaborators, Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015, Lancet 388 (10053) (2016) 1545–1602.
[9] R.C. Kessler, V. Shahly, P.E. Stang, M.C. Lane, The associations of migraines and other headaches with work performance: results from the National Comorbidity Survey Replication (NCS-R), Cephalalgia 30 (6) (2010) 722–734.
[10] H.C. Diener, Z. Katsarava, V. Limmroth, Aktuelle Diagnostik und Therapie der Migräne [Current diagnosis and treatment of migraine]. quiz 59-60, Schmerz 22 (Suppl) (2008) 51–58.
[11] National Guideline Clearinghouse, Diagnosis and treatment of headache, (1998) Available from: https://www.guideline.gov/summaries/summary/43791/diagnosis-and-treatment-of-headache.
[12] W.J. Becker, T. Findlay, C. Moga, N.A. Scott, C. Harstall, P. Taenzer, Guideline for primary care management of headache in adults, Can. Fam. Physician 61 (8) (2015) 670–679.
[13] K. Linde, G. Allais, B. Brinkhaus, Y. Fei, M. Mehring, B.C. Shin, A. Vickers, A.R. White, Acupuncture for the prevention of tension-type headache, Cochrane Database Syst. Rev. 4 (2016) CD007587.
[14] K. Linde, G. Allais, B. Brinkhaus, Y. Fei, M. Mehring, E.A. Vertosick, A. Vickers, A.R. White, Acupuncture for the prevention of episodic migraine, Cochrane Database Syst. Rev. (6) (2016) CD001218.
[15] A. Ahmadi, D.C. Schwebel, M. Rezaei, The efficacy of wet-cupping in the treatment of tension and migraine headache, Am. J. Chin. Med. 36 (1) (2008) 37–44.
[16] A. Sullivan, S. Cousins, L. Ridsdale, Psychological interventions for migraine: a systematic review, J. Neurol. 263 (12) (2016) 2369–2377.

[17] G. Dobos, The clinic for integrative medicine in essen. Germany, Eur J Integr Med 1 (4) (2009) 167.
[18] R. Lauche, H. Cramer, A. Paul, G.J. Dobos, T. Rampp, Introducing integrative integrated migraine care (IIMC): a model and case presentation, Eur J Integr Med 4 (2012) E37–E40.
[19] C. Gaul, J. Bromstrup, G. Fritsche, H.C. Diener, Z. Katsarava, Evaluating integrated headache care: a one-year follow-up observational study in patients treated at the Essen headache centre, BMC Neurol. 11 (2011) 124.
[20] H. Benson, E.M. Stuart, The Wellness Book: the Comprehensive Guide to Maintaining Health and Treating Stress-Related Illness, 1 ed., Simon & Schuster, New York, 1993.
[21] J. Kabat-Zinn, An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results, Gen. Hosp. Psychiatry 4 (1) (1982) 33–47.
[22] A. Paul, R. Lauche, H. Cramer, N. Altner, G.J. Dobos, An Integrative Day-Care Clinic for chronically ill patients: concept and case presentation, Eur J Integr Med 4 (2012) E455–E459.
[23] E. Jacobson, Progressive Relaxation. Chicago, (1938).
[24] J. Kabat-Zinn, Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness, Bantam Books trade paperback, New York, 2013.
[25] A.T. Beck, A.J. Rush, B.F. Shaw, G. Emery, Cognitive Therapy of Depression, The Guilford Press, NY, 1979.
[26] WHO Collaborating Centre for Drug Statistics Methodology, Definition and General Considerations, (2018) Available from: https://www.whocc.no/ddd/definition_and_general_considera/.
[27] M. Pfingsten, B. Nagel, O. Emrich, H. Seemann, G. Lindena, J. Korb, Deutscher Schmerzfragebogen, (2007) [May 11, 2016]. Available from: http://www.dgss.org/fileadmin/pdf/12_DSF_Manual_2012.2.pdf.
[28] E. Geissner, The Pain Perception Scale–a differentiated and change-sensitive scale for assessing chronic and acute pain, Rehabilitation (Stuttg) 34 (4) (1995) XXXV–XLIII.
[29] J. Ware Jr., M. Kosinski, S.D. Keller, A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity, Med Care 34 (3) (1996) 220–233.
[30] G.P. Jacobson, N.M. Ramadan, S.K. Aggarwal, C.W. Newman, The henry ford hospital headache disability inventory (HDI), Neurology 44 (5) (1994) 837–842.
[31] A.S. Zigmond, R.P. Snaith, The hospital anxiety and depression scale, Acta Psychiatr. Scand. 67 (6) (1983) 361–370.
[32] K.K. Horn, S. Jennings, G. Richardson, D. van Vliet, C. Hefford, J.H. Abbott, The patient-specific functional scale: psychometrics, clinimetrics, and application as a clinical outcome measure, J. Orthop. Sport. Phys. Ther. 42 (1) (2012) 30-D17.
[33] M. Mangels, S. Schwarz, G. Sohr, M. Holme, W. Rief, Der Fragebogen zur Erfassung der schmerzspezifischen Selbstwirksamkeit (FESS) Diagnostica, 55 (2009) 84–93.
[34] D. Melchart, W. Weidenhammer, A. Streng, A. Hoppe, V. Pfaffenrath, K. Linde, Acupuncture for chronic headaches–an epidemiological study, Headache 46 (4) (2006) 632–641.
[35] R. Lauche, H. Cramer, S. Moebus, G. Dobos, Results of a 2-week Inpatient Stay at the Department for Internal and Integrative Medicine: an Observational Study. Evidence-Based Complementary and Alternative Medicine eCAM, (2012).
[36] F.J. Saha, A. Bruning, C. Barcelona, A. Bussing, J. Langhorst, G. Dobos, R. Lauche, H. Cramer, Integrative medicine for chronic pain: a cohort study using a process-outcome design in the context of a department for internal and integrative medicine, Medicine (Baltim.) 95 (27) (2016) e4152.
[37] B.H. Marcus, L.R. Simkin, The transtheoretical model: applications to exercise behavior, Med. Sci. Sports Exerc. 26 (11) (1994) 1400–1404.
[38] Y. Tul, A. Unruh, B.D. Dick, Yoga for chronic pain management: a qualitative exploration, Scand. J. Caring Sci. 25 (3) (2011) 435–443.
[39] D. Anheyer, M.J. Leach, P. Klose, G. Dobos, H. Cramer, Mindfulness-based stress reduction for treating chronic headache: a systematic review and meta-analysis, Cephalalgia (2018) 333102418781795.
[40] D. Anheyer, H. Haller, J. Barth, R. Lauche, G. Dobos, H. Cramer, Mindfulness-based stress reduction for treating low back pain: a systematic review and meta-analysis, Ann. Intern. Med. 166 (11) (2017) 799–807.
[41] R. Lauche, H. Cramer, G. Dobos, J. Langhorst, S. Schmidt, A systematic review and meta-analysis of mindfulness-based stress reduction for the fibromyalgia syndrome, J. Psychosom. Res. 75 (6) (2013) 500–510.
[42] N.M. Bakhshani, A. Amirani, H. Amirifard, M. Shahrakipoor, The effectiveness of mindfulness-based stress reduction on perceived pain intensity and quality of life in patients with chronic headache, Glob. J. Health Sci. 8 (4) (2015) 142–151.
[43] A. Omidi, F. Zargar, Effect of mindfulness-based stress reduction on pain severity and mindful awareness in patients with tension headache: a randomized controlled clinical trial, Nurs Midwifery Stud 3 (3) (2014) e21136.
[44] R.E. Wells, T. Burch, R. Paulsen, P. Wayne, C. Aschenbrenner, T.T. Houle, E. Loder, Meditation for migraines: a pilot randomized controlled trial, Cephalalgia 33 (2013) 96–97.
[45] M.A. Day, B.E. Thorn, L.C. Ward, N. Rubin, S.D. Hickman, F. Scogin, G.R. Kilgo, Mindfulness-based cognitive therapy for the treatment of headache pain: a pilot study, Clin. J. Pain 30 (2) (2014) 152–161.
[46] S. Cathcart, N. Galatis, M. Immink, M. Proeve, J. Petkov, Brief mindfulness-based therapy for chronic tension-type headache: a randomized controlled pilot study, Behav. Cognit. Psychother. 42 (1) (2014) 1–15.
[47] J.B. Moseley, K. O'Malley, N.J. Petersen, T.J. Menke, B.A. Brody, D.H. Kuykendall, J.C. Hollingsworth, C.M. Ashton, N.P. Wray, A controlled trial of arthroscopic surgery for osteoarthritis of the knee, N. Engl. J. Med. 347 (2) (2002) 81–88.