Complementary Medicine Research

Research Article / Originalarbeit

Complement Med Res 2022;29:453–464
DOI: 10.1159/000526757

Received: October 25, 2021
Accepted: August 23, 2022
Published online: September 1, 2022

Effects of an Impulse on the Sterno-Cleido-Mastoid Muscle on Back Pain, Discomfort, and Well-Being: A Randomized Controlled Trial in People with Low Back Pain

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Keywords
Back pain · Stress · Sterno-cleido-mastoid muscle · Vitametik

Abstract

Introduction: In the treatment of low back pain (LBP), passive regimens (e.g., relaxation) as opposed to active regimens (e.g., muscle training) may be a useful adjunct or, in certain cases, the only possible approach. Passive relaxation may be particularly useful for individuals who have lost the ability to adequately perceive relaxed muscles. The aim of the randomized controlled trial presented here was to investigate a specific and novel treatment for passive relaxation, namely, the Vitametik impulse (VI). ***Methods:*** Participants ($n = 135$; 73.3% women; 26.7% men) were individuals with mild to moderate LBP aged from 19 to 76 years ($M = 48.8$). The participants were randomly assigned to one of four different groups (three different 8-week interventions, one control group). Pain, discomfort, and well-being were measured before and after the intervention period and at an 8-week follow-up. ***Results:*** In the VI group, the decrease in various pain variables and discomfort was higher compared to the control group and compared to an education program (EP). There were no differences between the VI group and a combined VI/EP group. The effects remained stable until follow-up. ***Conclusion:*** VI appears to be an effective approach in the treatment of LBP, although the underlying mechanism remains unproven. Future studies should compare VI treatment with specific relaxation techniques or active muscle training. In addition, the results of the study need to be replicated.

Trial registry ID: DRKS00026270 (German Clinical Trials Registry).

Auswirkungen eines Impulses auf den Musculus sterno-cleido-mastoideus auf Rückenschmerzen, Beschwerden und Wohlbefinden: Eine randomisierte kontrollierte Studie bei Menschen mit Kreuzschmerzen

Schlüsselwörter
Rückenschmerzen · Stress · Musculus sterno-cleido-mastoideus · Vitametik

Zusammenfassung

Einleitung: Bei der Behandlung von Schmerzen im unteren Rückenbereich können passive Maßnahmen (z. B. Entspannung) im Gegensatz zu aktiven Maßnahmen (z. B. Muskeltraining) eine sinnvolle Ergänzung oder in bestimmten Fällen sogar der einzig mögliche Ansatz sein. Passive Entspannung kann besonders für Personen nützlich sein, die die Fähigkeit verloren haben, entspannte Muskeln angemessen wahrzunehmen. Ziel der hier vorgestellten randomisierten kontrollierten Studie war es, eine spezifische und neuartige Behandlung zur passiven

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Entspannung zu untersuchen, nämlich den Vitametik Impuls (VI). ***Methoden:*** Bei den Teilnehmenden (n = 135; 73.3 % Frauen; 26.7 % Männer) handelte es sich um Personen mit leichten bis mittelschweren Kreuzschmerzen im Alter von 19 bis 76 Jahren (M = 48.8). Die Teilnehmenden wurden nach dem Zufallsprinzip einer von vier verschiedenen Gruppen zugewiesen (drei verschiedene 8-wöchige Interventionen, eine Kontrollgruppe). Schmerzen, Beschwerden und Wohlbefinden wurden vor und nach der Interventionsphase sowie bei einer 8-wöchigen Nachuntersuchung gemessen. ***Ergebnisse:*** In der VI-Gruppe war der Rückgang der verschiedenen Schmerzvariablen und der Beschwerden höher als in der Kontrollgruppe und im Vergleich zu einem Schulungsprogramm (EP). Es gab keine Unterschiede zwischen der VI-Gruppe und einer kombinierten VI/EP-Gruppe. Die Effekte blieben bis zur Nachuntersuchung stabil. ***Schlussfolgerung:*** VI scheint ein wirksamer Ansatz für die Behandlung von LBP zu sein, obwohl der zugrunde liegende Mechanismus noch nicht bewiesen ist. In künftigen Studien sollte die VI-Behandlung mit spezifischen Entspannungstechniken oder aktivem Muskeltraining verglichen werden. Darüber hinaus sollten die Ergebnisse der Studie repliziert werden.

Introduction

Globally, every month, one in three people experiences back pain [1]. This highlights that back pain is a serious and common problem in modern society, with extreme economic costs [2]. Therapies for back pain and their effectiveness are described in a large number of systematic reviews and meta-analyses [3, 4]. Nonsurgical approaches seem to be the best decision in most cases of low back pain (LBP). These nonsurgical approaches can be divided into active and passive regimens, with active regimens (e.g., muscle training) being the regimen of choice whenever the clinical condition allows [5–7]. However, passive regimens may be a useful adjunct to active therapies or may be the only possible approach in certain cases (e.g., activity prohibitions or restrictions). This paper presents a study in the form of a randomized controlled trial of a specific passive treatment for back pain that has not been scientifically studied before.

Passive treatments for back pain are typically psychobehavioral approaches (especially cognitive behavioral therapy) or physical approaches (see review in [2]). Many of these passive approaches aim to change the tone of the muscle. This change in muscle tone is initiated through a variety of techniques, including pressure techniques (e.g., manual therapy), manipulation of specific body points (e.g., acupressure), or various forms of relaxation (e.g., progressive muscle relaxation, autogenic training). All aforementioned techniques aim to restore an individual's tension-relaxation balance, which is an important and general goal in the treatment of back pain.

With regard to the tension-relaxation balance of individuals with LBP, a major assumption is that many of these individuals have lost the ability to adequately perceive relaxed muscles [8]. This assumption is supported by research showing differences in interoceptive competence in chronic pain patients compared to healthy individuals [8, 9]. One possible explanation for this loss of competence is that there is an unconscious deficit in retrieving or remembering relaxation states, which may also be due to the pain-tension-pain cycle [10, 11]. The pain-tension-pain cycle does not allow for recovery periods and thus diminishes the experience of relaxation and relief. Various therapeutic concepts therefore aim to return the feeling of relaxation to the person through the use of relaxation techniques (e.g., PMR, autogenic training). The positive effects (e.g., reduction of pain and mood disturbance) of these techniques in back pain patients are supported by a large number of studies [12]. However, these approaches depend on the ability to consciously and adequately relax, which is a problem for many back pain patients [8].

In cases where the ability to relax consciously and adequately is limited, externally induced relaxation is required. Such externally induced relaxation techniques can be divided into those with a more muscular approach (e.g., massage, heat treatments) and those with a more nervous approach. Nerval processes seem to be particularly important in patients with idiopathic (i.e., nonspecific) chronic back pain [13]. These processes can be influenced by direct treatment of the brain (e.g., relaxation by brain stimulation) [14] or by indirect treatment (e.g., relaxation by transcutaneous electrical neuromuscular stimulation) [15]. An indirect nervous approach is also the treatment investigated in the present study (i.e., the Vitametik® impulse [VI]). Specifically, the VI combines an external relaxation impulse in the area of the sterno-cleido-mastoid muscle with a subsequent cognitive phase involving concentration on the relaxation state thus induced (see the Methods section).

The exact mechanism behind this process is largely unclear. However, the sterno-cleido-mastoid muscle is strongly connected and innovated with parts of the accessorius nerve and the spinal nerves C1–C4. This connection is thought to be responsible for the effect of VI on muscle relaxation, both at the local and central nervous level [16]. This connection of this upper cervical region with central nervous system function is therefore also used in many chiropractic techniques [17]. Moreover, this link between the external relaxing impulse (i.e., VI), central nervous system function, and the cognitive focus on relaxation aims to improve the individual's ability to

consciously and adequately relax [18]. VI however has not yet been investigated in any scientific study.

Given the lack of research on VI, the present study aims to provide initial results regarding the possible effect of VI in a randomized controlled design. Based on the aforementioned relaxing mechanism of VI, it can be assumed that there are not only positive effects of VI on back pain but also indirectly on well-being. Therefore, the assumptions of our study are (1) individuals with LBP treated with the VI (VI group) over an 8-week period will experience higher decreases in pain, higher decreases in general discomfort, and higher increases in general well-being compared to individuals within an education program (EP group) or compared to individuals in a non-treatment control group (CG). (2) Individuals who receive the VI treatment plus an EP (VI/EP group) will experience stronger changes in pain, discomfort, and well-being compared with individuals who receive VI treatment alone. (3) The effects of assumptions (1) and (2) will still be present at follow-up 8 weeks after the end of treatment.

Methods

Eligibility Criteria and Sample Size

Eligibility Criteria

Inclusion criteria for participation in the current study were defined as age between 18 and 80 years and current tension-related pain (neck, head, and shoulder). Defined exclusion criteria were current therapeutic or medical treatment based on the pain in the back, diagnosis of a degenerative disease in the region of the back, general inflammatory disease in the region of the back (e.g., rheumatic disease or arthrosis in the region of the back).

Calculation of Sample Size

In order to determine the necessary number of participants, first, a power analysis using the software G*Power 3.1 [19] for chronic back pain (as the central dependent variable) was carried out. The sample size was computed as a function of the significance level ($\alpha = 0.05$), the desired statistical power ($1 - \beta = 0.95$), and the effect size ($\eta^2 = 0.02$). For the whole sample (i.e., four groups), an optimal sample size of $N = 176$ participants (i.e., 44 per treatment) was identified.

Design and Treatment

The study was a randomized controlled trial using a 4 (between-subject treatment: VI, EP, combined VI/EP, CG) by 3 (within-subject repeated measurement points: t0 [pretest], t1 [posttest], t2 [follow-up]) design. Subjects were randomly assigned to one of the treatment groups (1:1:1:1; concealed randomization via Microsoft Excel©). The concealed allocation was not possible in single cases because some participants were married or living in a partnership and therefore should be placed in the same group. In these cases, these participants were randomly allocated as pairs. Each group except for CG underwent an 8-week intervention from the first measurement (t0) to the second measurement (t1). The third measurement (t2) was organized as a follow-up 8 weeks after t1 (see Fig. 1).

VI: Participants in this group received a specific treatment including the VI. This treatment took place once a week for 8 weeks and lasted approximately 30 min per session. The treatment followed the standardized Vitametik procedure [18]. The instructor, a trained Vitametist, first determined which side of the body to administer the VI based on the leg length difference of the participants. The leg length difference was assessed by visually inspecting participants in the prone position. In addition, specific head movements in this position help to detect leg length differences. During the treatment, the treated person was required to lie in a lateral position on a sofa specially designed for the VI. The couch has a special head section that helps transmit the VI to the neck muscles. Using their thumb, the Vitametist applies a fast impulse (lasting about 40 ms) in the area of the muscle insertion of the sterno-cleido-mastoid muscle. After a 5-min rest phase, the leg length difference was measured again. This was followed by a 20-min rest phase for relaxation and self-regulation of the body. In this phase, participants were instructed to perceive the state of their muscles with a particular focus on their neck and back muscles.

EP: Participants in this group received an EP regarding the connection of stress, stressors, and physical reactions or complaints in daily life. This intervention took place once a week for 8 weeks, with each session lasting approximately 60 min and included additional homework. Each intervention unit was organized in a course. Each course consisted of twelve participants and was conducted by a course instructor, a trained Vitametist. Each unit had a different focus. The focus of each intervention unit (including materials) and the order of the intervention units were determined by the prevention concept of the Professional Association for Vitametik (i.e., the Berufsverband für Vitametik e.V.) [18]: (1) muscle tension along the spine (e.g., explanation of how muscle tension along the spine can have an effect), (2) sensomotoric amnesia (e.g., explanation of the effects of chronic muscle tension), (3) stress and stress reactions of the body (e.g., information about stressors in daily life and stress reactions), (4) tense muscles press on the nerves (e.g., explanation of the relationship between muscle relaxation and nerves), (5) movement supports relaxation (e.g., positive health effects of physical activity), (6) tension-related complaints in the cervical vertebra region (e.g., explanation about origins, background, and consequences), (7) tension-related complaints in the breast and lumbar vertebral region (e.g., explanation about origins, background, and consequences), (8) balance between tension and relaxation (e.g., information about the importance of balancing stress).

Following each of the eight units, participants received tasks on the respective topics. These tasks aimed to promote self-management and were to be carried out independently at home. Participants were asked to integrate what they had learned into everyday life. At the beginning of the each subsequent course unit, participants gave feedback on the implementation of the self-management tasks to the course instructors [18].

VI/EP: Participants in this group received an intervention comprising both the VI and EP. This intervention took place once a week for 8 weeks and lasted approximately 120 min per session. Each intervention unit was organized in a course. Each course consisted of 12 participants and was conducted by a trained Vitametist (course instructor). This intervention consisted of the theoretical contents described above (EP) and practical component (VI). In comparison to the VI group, the Vitametik treatment in this group was carried out on all participants successively in the presence of the others. The 20-min rest phase took place together in the group in a quiet room.

CG: Within the CG, participants received neither a practical nor a theoretical intervention during the course of the study. Participants were informed at the beginning of the study that VI was

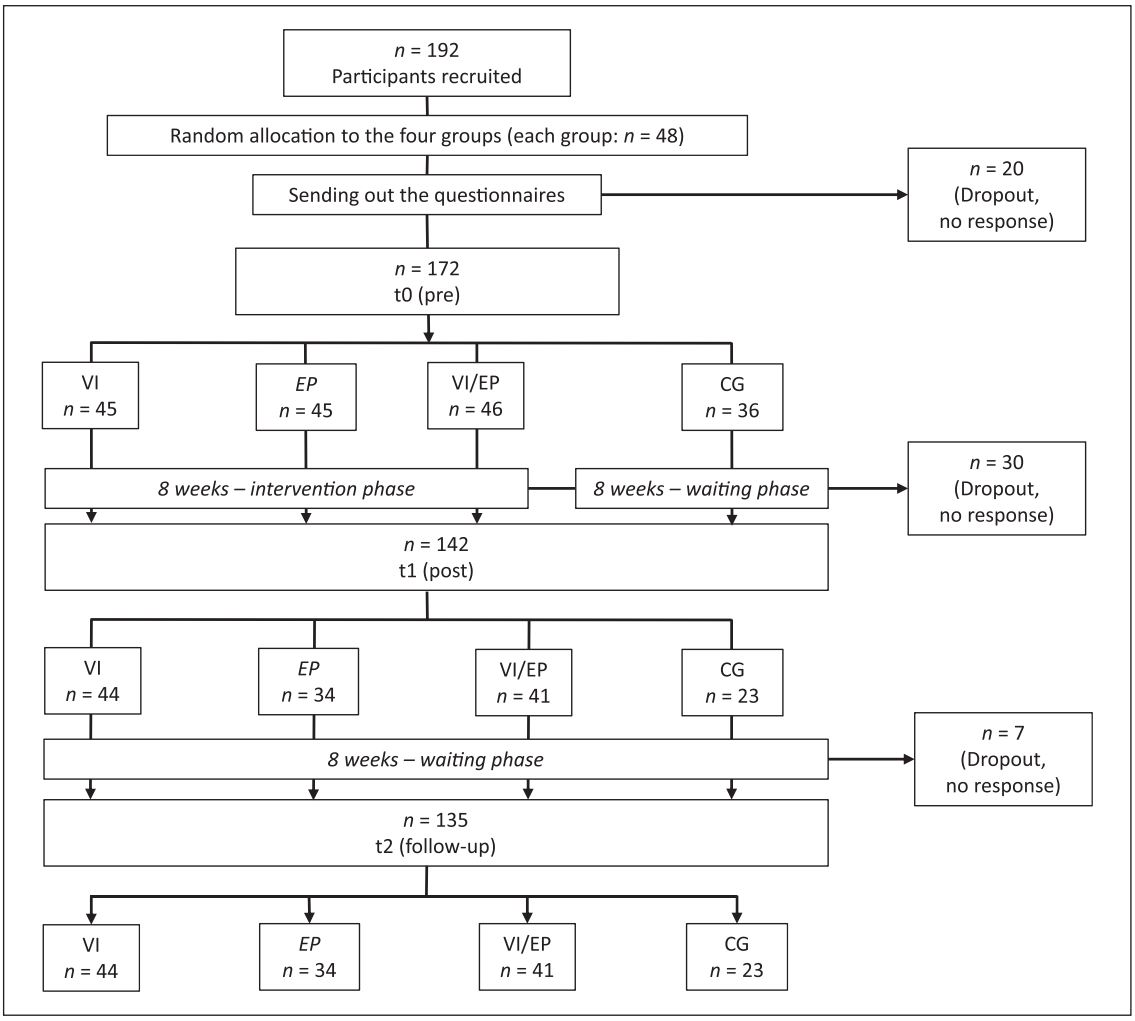

Fig. 1. Flowchart explaining participant dropout and study design. VI, Vitametik® impulse group; EP, education program group; VI/EP, combined Vitametik® impulse and education program group; CG, control group.

booked out and that they were therefore on the waiting list. In the cover letters for participation in the study, participants were asked to answer three questionnaires over the entire study period and to return them to the study management. As compensation, participants in the waiting group received two free VI treatment sessions from the Professional Association for Vitametik after completion of the study.

Measures

Pain

Chronic Back Pain. Chronic back pain was measured using the German version [20] of the Chronic Pain Grade Questionnaire (CPGQ) [21]. The CPGQ assesses back pain with three items asking for pain: current back pain ("How would you rate your pain on a 0–10 scale at the present time, that is right now, where 0 is "no pain" and 10 is "pain as bad as could be"?"), worst back pain during the past 3 months ("In the past 3 months, how intense was your worst pain rated on a 0–10 scale where 0 is 'no pain,' and 10 is 'pain as bad as could be'?"), and average back pain during the past 3 months ("In the past 3 months, on the average, how intense was your pain rated on a 0–10 scale where 0 is 'no pain,' and 10 is 'pain as bad as could be'? [i.e., your usual pain at times you were experiencing pain]") on an 11-point scale 0 ("no pain") to 10 ("pain as bad as could be"). The CPGQ has been shown to be a valid instrument to assess the chronic back pain [20].

General Pain. General pain was measured using a subscale of the German-language questionnaire "Freiburger-List of complaints" (Freiburger-Beschwerdenliste, FBL) [22]. The FBL is an instrument to assess frequencies and dimensions of physical complaints. In this study, only the subscale "general pain" was used (α_{t0} = 0.71, α_{t1} = 0.81, α_{t2} = 0.79). This subscale consists of eight items (e.g., "Do you have neck pain?") on a 5-point scale ranging from 1 ("almost daily") to 5 ("practically never"). The FBL has been shown to be a valid instrument to assess physical complaints [22].

Discomfort

Depressed Mood. Depressed mood was measured using the German version of the Patient Health Questionnaire (PHQ-2) [23]. The PHQ-2 is a screening tool to assess the frequency of depressed mood over the past 2 weeks with two items ("little interest or pleasure in doing things" and "feeling down, depressed, and hopeless"; α_{t0} = 0.75, α_{t1} = 0.72, α_{t2} = 0.75) on a 4-point scale from 0 ("not at all") to 3 ("nearly every day"). The PHQ-2 is a valid screening instrument [24].

Perceived Stress. Perceived stress was measured using the German version [25] of the Perceived Stress Questionnaire (PSQ-20)

[26]. The PSQ-20 is an instrument to assess subjectively experienced stress during the past 4 weeks. The PSQ consists of 20 items (e.g., "You are afraid of the future" or "You feel that too many demands are being made on you."). The PSQ has a 4-point response scale (1: "almost never," 2: "sometimes," 3: "often," 4: "usually"). It is a reliable ($\alpha_{t0} = 0.94$, $\alpha_{t1} = 0.94$, $\alpha_{t2} = 0.95$) and valid instrument [27] that enables the assessment of perceived stress.

Well-Being

Well-being was measured using the German version [28] of the well-being index (WHO-5) [29]. The WHO-5 is a screening tool to assess psychological well-being during the past 2 weeks with five items (e.g., "Over the past 2 weeks I have felt calm and relaxed"; $\alpha_{t0} = 0.86$, $\alpha_{t1} = 0.89$, $\alpha_{t2} = 0.91$) on a six-point scale from 0 ("at no time") to 5 ("all of the time"). The WHO-5 is a valid instrument to assess subjective psychological well-being [28].

Procedure

After approval of the study by the Ethics Committee of the conducting university, participants were recruited in three different cities in Germany. Four course instructors of the Professional Association for Vitametik carried out recruitment (via flyers, notices, and postings) and treatments in their respective city. Interested persons were asked to contact the course instructors to arrange an appointment for an initial telephone interview. This telephone interview was conducted in order to determine which persons were suitable for participation in the study according to the inclusion and exclusion criteria. Information from the initial telephone interviews were also checked by the study management with regard to the inclusion criteria.

When 192 participants had registered for the study (for each group: $n = 48$), the acquisition was considered completed. Some dropouts were expected, so more participants were recruited than the power analysis ($n = 180$) indicated. Subsequently, lists with all interested participants were compiled for the individual study locations. For all three locations, a randomized assignment of the participants was carried out (with the use of a software generator integrated in Microsoft Excel©). The software generator allocated participants to the four different groups. An ANOVA for t0 shows that the randomization worked. The groups did not differ at the beginning of the study regarding back pain (present time: $F(3, 165) = 6.55$, $p = 0.29$, $\eta^2 = 0.02$; past 3 months: $F(3, 165) = 2.25$, $p = 0.084$, $\eta^2 = 0.04$; average pain: $F(3, 166) = 2.21$, $p = 0.089$, $\eta^2 = 0.04$), general pain ($F(3, 168) = 1.67$, $p = 0.175$, $\eta^2 = 0.03$), perceived stress ($F(3, 166) = 1.07$, $p = 0.36$, $\eta^2 = 0.02$), and well-being (WHO-5: $F(3, 168) = 1.98$, $p = 0.09$, $\eta^2 = 0.04$; PHQ-2: $F(3, 168) = 2.19$, $p = 0.09$, $\eta^2 = 0.04$) at t0. This indicates that there were similar starting values before the intervention program commenced. Thus, there were no floor or ceiling effects that differed between groups.

After assignment to the treatment groups, the included participants were informed about the exact course of the study by mail from the study management and were asked to submit a declaration of consent before the start of the study. The interventions/treatments took place as described above. To reduce the risk of a Rosenthal effect (also known as Pygmalion effect), which can occur in hierarchical relationships (e.g., caregiver – patient), the course instructors were trained to adhere to a standardized procedure [18].

Data collection was carried out with a paper-pencil questionnaire that was sent to the participants at each measurement point by mail (including return envelope). After completing the questionnaire, the participants sent it back to the study organization. The data from the questionnaires were then transferred into IBM SPSS Statistics 26.

Data Analysis

The statistical analysis was limited to data from those subjects who returned questionnaires at all three measurement points (i.e., final sample, see Eligibility Criteria and Sample Size). Using the four groups (VI, EP, VI/EP, and CG) and three measurement points (t0, t1, and t2), mixed group by time repeated measures (i.e., 4×3) ANOVAs were calculated for each dependent variable. In cases where significant interactions were found, subsequent sequentially reduced ANOVAs were run. This process involved removing groups one at a time from successive ANOVAs until it was possible to pinpoint between which groups and measurement points interaction effects existed (i.e., 3 groups × 3 measurement points, 2 groups × 3 measurement points, and finally 2×2). All analyses were run with IBM SPSS Statistics 26.

Results

Sample

In order to achieve the desired sample size, an acquisition of more than 180 participants was aimed at. Of 192 participants who registered their interest in the study, 172 participants completed the first measurement point (t0; VI: $n = 45$, EP: $n = 45$, VI/EP: $n = 46$, CG: $n = 36$; see Fig. 1); thus, the optimal number of 45 participants in the subsamples was reached with the exception of the CG. Over the course of the study, 142 participants took part in the second measurement point (t1; 17.4% dropout from t0). 135 participants took part in follow-up (t2; 21.5% dropout from t0, 4.9% dropout from t1; nonresponders with unknown reasons). The reasons for dropout were personal (e.g., vacation, job-related) or physical (e.g., illness unrelated to back pain), but in most cases, reasons for the dropouts are unknown.

Baseline Sample (t0)

The baseline sample of 172 participants consisted of 123 (71.5%) women and 49 men (28.5%) aged from 19 to 76 years ($M = 46.7$, SD = 19.27). Most participants were married or in a stable partnership (68.6%); 15.7% were single, 12.8% divorced, and 2.3% widowed. The overall health status at t0 ($n = 172$) was rated as "excellent" by 2.9% of the participants, 10.5% rated their status as "very good," 67.3% as "good," 18.7% as "less good," and 0.6% as "bad."

Final Sample (t2)

The sample at t2 ($n = 135$) consisted of 96 women (73.3%) and 35 men (26.7%; no response: $n = 4$) aged from 19 to 76 years ($M = 48.4$, SD = 10.88). Most participants were married or in a stable partnership (71.5%), 14.6% were single, 12.3% divorced, and 1.5% widowed. The overall health status at t2 ($n = 135$) was rated as "excellent" by 1.2% of the participants, 19.2% rated their status as "very good," 47.7% as "good," and 10.5% as "less good." All participants were experiencing current ten-

Table 1. Descriptive statistics of dependent variables

Group	t0			t1			t2		
	N/n	*M*	SD	*N/n*	*M*	SD	*N/n*	*M*	SD
Current back pain									
VI	41	3.30	2.19	41	1.45	1.34	41	1.70	2.15
EP	32	2.91	1.75	32	2.41	2.01	32	2.78	2.27
VI/EP	38	3.55	2.45	38	1.82	1.78	38	2.24	1.94
CG	23	3.29	2.72	23	3.19	2.32	23	3.10	2.49
Total	134	3.27	2.25	134	2.07	1.90	134	2.34	2.21
Worst back pain									
VI	41	5.33	2.08	41	3.65	2.26	41	3.20	2.44
EP	31	5.68	1.85	31	4.41	2.11	31	5.00	2.54
VI/EP	38	6.03	2.21	38	4.37	2.50	38	4.05	2.63
CG	23	5.67	2.33	23	5.29	2.51	23	5.67	2.31
Total	133	5.67	2.10	133	4.31	2.37	133	4.28	2.63
Average back pain									
VI	41	4.00	2.01	41	2.60	1.92	41	2.58	2.24
EP	23	3.94	1.70	23	3.00	1.67	23	3.63	2.24
VI/EP	38	4.47	2.29	38	3.42	2.14	38	3.08	2.11
CG	23	4.10	1.89	23	4.00	2.17	23	4.19	2.27
Total	134	4.14	2.00	134	3.16	2.01	134	3.24	2.26
General pain									
VI	42	2.89	0.65	42	2.17	0.61	42	2.21	0.70
EP	32	2.91	0.66	32	2.51	0.68	32	2.55	0.72
VI/EP	38	3.06	0.77	38	2.41	0.79	38	2.46	0.67
CG	23	3.00	0.66	23	2.97	0.79	23	2.84	0.72
Total	135	2.96	0.69	135	2.45	0.75	135	2.47	0.72
Depressed mood									
VI	42	0.81	0.68	42	0.35	0.41	42	0.46	0.50
EP	32	0.75	0.55	32	0.73	0.52	32	0.95	0.64
VI/EP	38	1.07	0.77	38	0.49	0.44	38	0.57	0.56
CG	23	0.81	0.54	23	0.86	0.76	23	0.95	0.72
Total	135	0.87	0.66	135	0.56	0.55	135	0.69	0.62
Perceived stress									
VI	42	2.38	0.60	42	1.96	0.51	42	1.95	0.47
EP	32	2.54	0.61	32	2.27	0.60	32	2.37	0.68
VI/EP	38	2.52	0.62	38	2.01	0.46	38	2.07	0.54
CG	22	2.65	0.61	22	2.46	0.56	22	2.57	0.58
Total	134	2.50	0.61	134	2.13	0.56	134	2.18	0.60
Well-being									
VI	42	2.56	1.02	42	3.59	0.68	42	3.52	0.80
EP	32	2.36	1.11	32	2.88	0.97	32	2.73	1.20
VI/EP	38	2.36	0.99	38	3.49	0.69	38	3.30	0.81
CG	23	2.39	0.95	23	2.39	1.05	23	2.63	1.14
Total	135	2.43	1.01	135	3.19	0.93	135	3.12	1.03

VI, Vitametik® impulse group; EP, education program group; VI/EP, combined Vitametik® impulse and education program group; CG, control group.

Table 2. Results of 4 ×3 mixed measures ANOVAs for pain (current back pain, worst back pain, average back pain, general pain)

	df[1]	df[2]	*F*	*p value*	η^2
Current back pain					
Time	1	127	16.15	<0.001	0.11
Group	3	127	1.83	0.145	0.041
Group × time	6	254	3.12	0.006	0.07
VI versus CG					
t0–t1	1	64	9.70	0.003	0.13
t0–t2	1	61	5.62	0.021	0.08
VI versus EP					
t0–t1	1	74	7.75	0.007	0.095
t0–t2	1	70	8.43	0.005	0.11
VI/EP versus CG					
t0–t1	1	62	7.96	0.006	0.11
VI/EP versus EP					
t0–t1	1	72	6.40	0.14	0.08
t0–t2	1	68	4.71	0.034	0.07
Worst pain (past 3 months)					
Time	1	125	29.52	<0.001	0.19
Group	3	125	3.17	0.027	0.07
Group × time	6	250	3.97	0.008	0.07
VI versus CG					
t0–t1	1	64	5.25	0.025	0.08
t0–t2	1	61	9.48	0.003	0.14
VI versus EP					
t0–t2	1	68	5.43	0.023	0.07
t1–t2	1	69	4.02	0.049	0.05
VI/EP versus CG					
t0–t1	1	62	5.81	0.019	0.08
t0–t2	1	59	6.84	0.011	0.10
Average back pain (past 3 months)					
Time	1	127	16.31	<0.001	0.11
Group	3	127	1.74	0.163	0.04
Group × time	6	254	2.97	0.008	0.07
VI versus CG					
t0–t1	1	64	10.63	0.002	0.14
t0–t2	1	61	8.07	0.006	0.12
VI versus EP					
t0–t2	1	70	6.51	0.013	0.09
VI/EP versus CG					
t0–t1	1	62	5.38	0.024	0.08
t0–t2	1	59	4.76	0.033	0.08
General pain					
Time	1	129	60.27	<0.001	0.32
Group	3	129	3.65	0.014	0.08
Group × time	6	258	4.06	0.001	0.09
VI versus CG					
t0–t1	1	65	16.73	<0.001	0.21
t0–t2	1	63	11.32	0.001	0.15
VI versus EP					
t0–t1	1	76	4.97	0.029	0.19
t0–t2	1	59	7.69	0.007	0.12
VI/EP versus CG					
t0–t1	1	62	14.88	<0.001	0.19
t0–t2	1	59	7.69	0.007	0.12

The group named first in a row has more beneficial effect over time than the respective comparison group (i.e., a [stronger] decrease in pain). VI, Vitametik® impulse group; EP, education program group; VI/EP, combined Vitametik® impulse and education program group; CG, control group. [1] Degrees of freedom of effect. [2] Degrees of freedom of error.

Table 3. Results of 4 × 3 mixed measures ANOVAs for discomfort

	df[1]	df[2]	*F*	*p value*	η^2
Depressed mood					
Time	1	129	4.61	0.034	0.04
Group	3	129	3.26	0.024	0.07
Group × time	6	258	6.58	<0.001	0.13
VI versus CG					
t0–t1	1	65	7.62	<0.001	0.11
t0–t2	1	63	12.55	0.001	0.17
VI versus EP					
t0–t1	1	76	12.20	0.001	0.14
t0–t2	1	72	19.03	<0.001	0.21
VI/EP versus CG					
t0–t1	1	62	14.01	<0.001	0.18
t0–t2	1	59	10.21	0.002	0.15
VI/EP versus EP					
t0–t1	1	73	23.01	<0.001	0.24
t0–t2	1	68	15.60	<0.001	0.19
Stress					
Time	1	126	42.84	<0.001	0.25
Group	3	126	4.65	0.004	0.10
Group × time	6	252	3.44	0.003	0.08
VI versus CG					
t0–t1	1	64	7.93	0.006	0.11
t0–t2	1	61	11.8	0.001	0.16
VI versus EP					
t0–t1	1	75	5.13	0.026	0.06
t0–t2	1	71	8.12	0.006	0.10
VI/EP versus CG					
t0–t1	1	62	14.88	<0.001	0.19
t0–t2	1	59	7.69	0.007	0.12
VI/EP versus EP					
t0–t1	1	72	7	0.010	0.09
t0–t2	1	67	4.9	0.031	0.07

The group named first in a row has more beneficial effect over time than the respective comparison group (i.e., a [stronger] decrease in discomfort). VI, Vitametik® impulse group; EP, education program group; VI/EP, combined Vitametik® impulse and education program group; CG, control group. [1] Degrees of freedom of effect. [2] Ddegrees of freedom of error.

sion-related head, neck, and/or shoulder issues/pain but not receiving therapeutic or medical treatment.

Descriptive Statistics

Table 1 shows descriptive statistics for the three parameters pain, discomfort, well-being, and their respective factors. The results of the 4 × 3 repeated measures ANOVAs for these parameters are displayed in Table 2 (pain), Table 3 (discomfort), and Table 4 (well-being). Due to the hypothesis, the results section focuses only on interaction effects.

Treatment Effects

Pain

Results showed significant interaction effects for all aspects of pain, namely, *current back pain* ($F(6, 254) = 3.12$, $p = 0.006$, $\eta^2 = 0.07$), *worst back pain during the past 3 months* ($F(6, 250) = 3.97$, $p = 0.008$, $\eta^2 = 0.07$), *average back pain during the past 3 months* ($F(6, 254) = 2.97$, $p = 0.008$, $\eta^2 = 0.07$), and *general pain* ($F(6, 258) = 4.05$, $p = 0.001$, $\eta^2 = 0.09$). Post hoc analyses of significant interactions using sequentially reduced ANOVAs revealed that only specific combinations of groups (VI-CG, VI/EP-CG, VI/EP-EP, and VI-EP) were involved in the significant interactions (statistics of significant post hoc interactions are displayed in Table 2). In more detail, results showed a (stronger) decrease in all factors of pain in VI compared to CG and EP and in VI/EP compared to CG (see Fig. 2). Moreover, for the factor current back pain, there was a stronger decrease in VI/EP compared to EP (see also Fig. 2).

Discomfort

Results showed significant interaction effects for both aspects of discomfort, namely, *depressed mood* ($F(6, 258) = 6.58$, $p < 0.001$, $\eta^2 = 0.13$) and *stress* ($F(6, 252) = 3.44$, p

Table 4. Results of 4 × 3 mixed measures ANOVAs for well-being

Well-being	df[1]	df[2]	*F*	*p value*	η^2
Time	1	129	43.38	<0.001	0.25
Group	3	129	6.35	<0.001	0.13
Group × time	6	258	4.61	<0.001	0.10
VI versus CG					
t0–t1	1	65	17.37	<0.001	0.21
t0–t2	1	63	7.24	0.009	0.10
VI versus EP					
t0–t1	1	76	5.95	0.017	0.07
t0–t2	1	72	5.27	0.023	0.07
VI/EP versus CG					
t0–t1	1	62	29.34	<0.001	0.32
t0–t2	1	59	5.62	0.021	0.09
VI/EP versus EP					
t0–t1	1	73	5.9	0.002	0.13
t0–t2	1	68	2.9	0.041	0.06

The group named first in a row has more beneficial effect over time than the respective comparison group (i.e., a [stronger] increase in well-being). VI, Vitametik® impulse group; EP, education program group; VI/EP, combined Vitametik® impulse and education program group; CG, control group. [1] Degrees of freedom of effect. [2] Degrees of freedom of error.

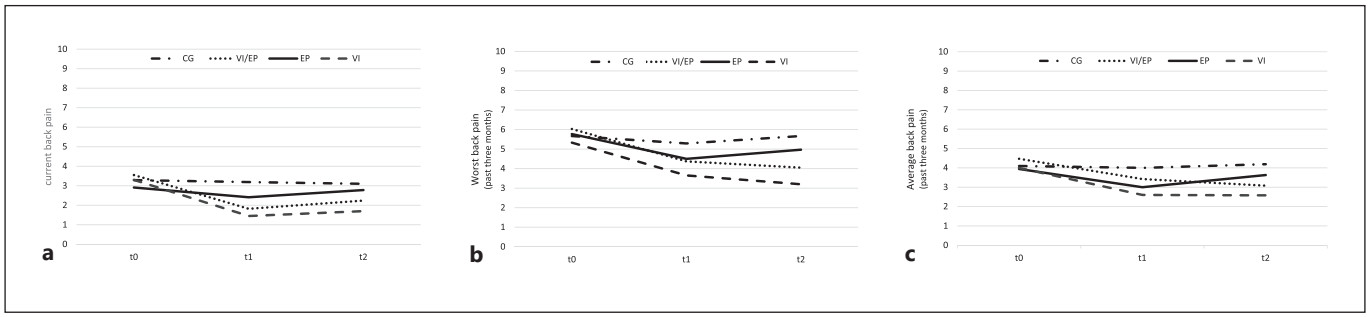

Fig. 2. Interaction of time × treatment groups in regard to current back pain (**a**), worst back pain in the past 3 months (**b**), and average back pain in the past 3 months (**c**). *Notes*: All values range from 0 (no pain) through 10 (strongest pain). **a** *Current back pain.* Significant interactions: VI and CG (t0–t1: $p = 0.003$ and t0–t2: $p = 0.021$); VI/EP and CG (t0–t1: $p = 0.006$); VI and EP (t0–t1: $p = 0.007$ and t0–t2: $p = 0.005$). **b** *Worst back pain past 3 months.* Significant interactions: VI and CG (t0–t1: $p = 0.025$ and t0–t2: $p = 0.003$); VI/EP and CG (t0–t1: $p = 0.019$ and t0–t2: $p = 0.011$); VI and EP (t0–t1: $p = 0.023$ and t1–t2: $p = 0.049$). **c** *Average back pain past 3 months.* Significant interactions: VI and CG (t0–t1: $p = 0.002$ and t0–t2: $p = 0.006$); VI/EP and CG (t0–t1: $p = 0.024$ and t0–t2: $p = 0.033$); VI and TGEP (t0–t2: $p = 0.013$).

= 0.003, $\eta^2 = 0.07$). Identical to the findings for pain, post hoc analyses of significant interactions using sequentially reduced ANOVAs revealed that only specific combinations of groups (VI-CG, VI/EP-CG, VI/EP-EP, and VI-EP) were involved in the significant interactions (statistics of significant post hoc interactions are displayed in Table 3). In more detail, similar to the results for pain, results showed a (stronger) decrease in both aspects of discomfort in VI compared to CG and EP and in VI/EP compared to CG and EP.

Well-Being

Results showed significant interaction effects for *well-being* ($F(6, 258) = 4.61$, $p < 0.001$, $\eta^2 = 0.10$). Identical to the findings for pain and discomfort, post hoc analyses of the significant interaction using sequentially reduced ANOVAs revealed that only specific combinations of groups (VI-CG, VI/EP-CG, VI/EP-EP, and VI-EP) were involved in the interaction (statistics of significant post hoc interactions are displayed in Table 4). In more detail, similar to the results for pain and identical to those for discomfort, results showed a (stronger) increase in well-being in VI compared to CG and EP and in VI/EP compared to CG and EP.

Discussion

The randomized controlled trial presented here investigated a specific and novel treatment for passive relaxation, namely, VI. Participants with LBP (n = 172) were randomly assigned to one of four different groups (three different 8-week interventions, one CG). Pain, discomfort, and well-being were measured before and after the interventions and at an 8-week follow-up. The results show that (1) the decrease in various pain variables and discomfort was higher in the VI group compared to the CG and compared to the EP group. (2) There were no differences between the VI group and a combined VI/EP group. (3) In addition, the effects remained stable until follow-up.

1. Individuals with LBP treated with VI over an 8-week period experience higher decreases in pain (i.e., current back pain, worst/average back pain in the past 3 months, general pain), higher decreases in general discomfort (i.e., depressed mood, perceived stress), and higher increases in general well-being compared to individuals with an EP or compared to individuals in a CG (i.e., no treatment). In terms of the pain variables measured, these results indicate that VI is an effective treatment in patients with LBP. The advantage of VI compared to the CG can be discussed in terms of assumed mechanisms of VI and in terms of the Hawthorne effect. With regard to the mechanisms of VI, the measured effect is based on the Vitametik treatment as a whole (see the Methods section), which includes the VI and the subsequent relaxation phase. Both components together should improve an individuals' ability to adequately perceive muscle relaxation, which is impaired through interoceptive problems in chronic pain patients [8, 9]. However, it is possible that the measured effects are the result of the single relaxation phase. Future studies of VI should therefore test whether VI has better effects than a single relaxation technique, given the same organizational structure (i.e., single patient, same treatment duration). In terms of the Hawthorne effect, clients' experience of care and observation and their subsequent change in perception, attitude, or behavior could be an explanation for the given effects. Therefore, placebo studies could be a possible design to distinguish between physiological effects of VI treatment and the Hawthorne effect. In addition, it would be of interest to measure the effect of VI physiologically (e.g., change in muscle tone or relaxation during treatment).

The superiority of VI over the EP applied here for stress management provides important clues. Previous studies have shown that stress management programs can have beneficial effects on psychosocial variables associated with back pain [12]. In contrast, in our study, VI had better results compared to EP in almost all variables. This indicates that EP was not as effective in the present study as VI, which may be due to the organization of EP. Specifically, EP was conducted as a course program in which a single therapist supervised up to 12 patients. In contrast, VI took place as a single session, in which a single therapist attended to one patient. Thus, patients in the VI condition may feel more respected and counseled, which could lead to higher compliance and greater changes in attitude, behavior, and ultimately pain and discomfort.

2. We found no differences between the VI group and a combined VI/EP group. This result shows that the EP has no additional effects on pain and mental health, which is consistent with the advantage of VI compared with EP. Obviously, the EP was not effective in our study. Explanations for this lie in the psychological and educational qualifications of the course instructors (i.e., trained Vitametists) and the Rosenthal effect. Regarding the qualifications of the course instructors, one might assume that the effects of EP would be enhanced when qualified psychologists or pedagogues lead the courses. However, the course program itself was state of the art and comparable to other pain and stress management courses. Nevertheless, studies comparing the Vitametik intervention with EPs led by specially qualified individuals seem to be needed. This requirement also arises from a possible Rosenthal effect. This effect states that the experimental condition (VI) has an advantage over the control condition (EP) if the therapist is convinced of the advantage of the experimental condition over the control condition and is aware of both conditions. Therefore, in future studies, the alternative treatment (i.e., EP) should be led by individuals who are convinced of the effectiveness of EP.
3. The effects of VI on pain and mental health remained stable until follow-up. With respect to pain, the benefits of VI compared to EP and the CG on the variables current pain, average/worst pain, and general pain in the past months persisted until the follow-up 8 weeks after the intervention. This very positive result is consistent with the assumption that VI is ability-oriented and thus more likely to be stable. Specifically, VI aims to improve patients' ability to adequately perceive relaxed muscles, which is limited in chronic pain patients [8]. Moreover, this improved ability to perceive relaxation could have improved VI participants' overall self-concept or self-efficacy, which in turn would explain the positive and stable effects on mental health variables (i.e., lower risk of depression, lower perceived stress, and higher overall well-being).

With regard to the clinical relevance of the given results, the minimum clinically important difference (MCID) can be considered. The MCID represents the

smallest improvement in a given area that is considered beneficial by a patient [30]. Besides the positive idea behind the MCID, the calculation methods of MCID differ, and in relation to chronic pain, there is currently no definitive agreement [30, 31]. However, some studies on the MCID of different pain scales define changes between 10 and 14% of the scale range as clinically relevant [32]. Given these recommendations, many of the changes in the treatment groups in this study are clinically relevant. For example, there are differences of 1.42 (VI group) and 1.39 (VI/EP group) in average back pain on the 11-point pain scale between t0 and t2 (follow-up).

Strengths and Limitations of the Study

The strengths of the present study are the experimental design (i.e., RCT), the inclusion of a follow-up, and the validity of the assessed questionnaires. In addition to these strengths, some limitations regarding the sample size, the included participants, and treatments of the study should be discussed. In terms of the sample size, we reached the calculated optimal sample size at t0 for the three intervention groups. However, due to dropouts, we missed this size at t1 and t2. Consequently, the power of the overall tests comparing the four groups across the period from t0 to t2 decreased slightly and concurrently; higher effect sizes were necessary to reach the required level of significance size. However, this was not problematic because instead of the expected small effects (η^2 = 0.02), we even found medium effects (η^2 = 0.07 to η^2 = 0.13). Regarding the participants, the specified exclusion criteria resulted in a group of individuals with rather mild to moderate pain (average pain in the last 3 months 4.3 on a 10-point scale). Moreover, the maintainers of the current study showed significantly lower back pain (M = 3.27; scale 0–10) compared to the dropouts (M = 4.24). Consequently, the effects of VI should not be generalized to patients with moderate to severe LBP. Furthermore, also risk for depression (PHQ-2) was significantly lower in maintainers (M = 0.87; scale 0–6) than in dropouts (M = 1.15), which could mean that patients with mild depressive symptoms are less able to persist throughout the treatment than patients without symptoms. In terms of the treatments, the limitations of both the experimental condition (VI) and the alternative condition (EP) should be discussed. Regarding VI, the effects of the VI and the subsequent relaxation phase cannot be distinguished. Future studies should therefore compare VI with other relaxation techniques that have been shown to be effective for low-pack pain. In addition, experimental studies on the physiological and psychological mechanisms of VI are needed. Such studies should also consider the placebo effect by using a physiologically inefficient VI for example. Regarding EP, course instructors were not qualified as psychologists or educators, which limits the strength of the EP, the content of which was however state of the art. In future studies, the alternative treatment (i.e., EP) should be led by different specialists, which would also reduce the Rosenthal effect (see discussion above).

Conclusion and Perspectives

The present study was the first RCT to investigate effects of the Vitametik treatment (including the VI) on back pain, discomfort, and well-being. Compared to an untreated CG, effects were demonstrated in almost all measured variables both at the end of the intervention and at follow-up. The benefits of VI compared to the EP should be evaluated with caution as the Vitametik experts did not have specific psychological or pedagogical qualifications. Further studies should therefore compare the Vitametik intervention with stronger educational approaches. In addition, further research should consider comparisons to other active relaxation techniques (e.g., biofeedback, PMR) or passive relaxation (e.g., massage, acupressure). Finally, replication studies are needed. Also, unproven to date are the assumed mechanisms of VI. Accordingly, effects of VI on patients' ability to relax should be investigated in experimental studies. In such studies, the inclusion of placebo conditions (e.g., ineffective VI that are too weak or too long) also seems reasonable.

Aside from the need for future research, VI has been shown to have positive potential in treating people with mild to moderate LBP. Furthermore, it is important to mention that so far no negative effects of VI, and thus, no harm to patients are known, which is why the use of VI in practice can be recommended in principle and according to the current state of research. However, not only replication studies but also larger scale studies to record conceivable side effects are missing for a conclusive evaluation. Finally, comparative studies with other forms of therapy should also help to evaluate the costs and benefits of VI in the future.

Statement of Ethics

Participants of the study provided their written informed consent, and the study protocol was reviewed and approved by the Ethics Committee of the German Sport University, Cologne, approval number 011/2017. This study was officially registered at the German Clinical Trials Registry (https://www.drks.de/) and is also visible in the WHO search portal (http://apps.who.int/trialsearch/); ID: DRKS00026270.

Conflict of Interest Statement

The authors have no personal conflicts of interest to declare.

Funding Sources

This work was supported by the Professional Association for Vitametik (Berufsverband für Vitametik e.V.).

Author Contributions

Jens Kleinert has substantial contributions to the conception and design of the work, to the analysis and interpretation of the data for the work, and to drafting the work and revising it. Carolin Bastemeyer has substantial contributions to the design of the work, to the acquisition, analysis, and interpretation of data for the work, and to drafting the work and revising it.

Matthew Watson and Fabian Pels have substantial contributions to the analysis and interpretation of the data for the work, and to drafting the work and revising it.

Data Availability Statement

Anonymized data from the present study are available upon request from the corresponding author and may be viewed for the purpose of replicating the results.

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