ORIGINAL ARTICLE

An Internet-Based Intervention for Chronic Pain

A Three-Arm Randomized Controlled Study of the Effectiveness of Guided and Unguided Acceptance and Commitment Therapy

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SUMMARY

Background: Persons with chronic pain can be treated effectively with acceptance and commitment therapy (ACT). In this trial, we examined the effectiveness of guided and unguided ACT-based online treatment (ACTonPain) for chronic pain patients.

Methods: 302 individuals were randomly assigned to ACTonPain with or without guidance ($n = 100/101$) or to a waiting-list control group ($n=101$). The primary outcome was pain interference as measured by the Multidimensional Pain Inventory. The secondary outcomes were physical and emotional functioning, pain intensity, ACT process variables, quality of life, satisfaction with the intervention, adherence, and participants' rating of overall improvement. The online measurements were carried out before randomization (T0) and 9 weeks and 6 months after randomization (T1 and T2, respectively). Intention-to-treat (ITT) data analysis was supplemented with additional per-protocol analyses.

Results: The guided ACTonPain group showed significantly less pain interference than the control group in the ITT analysis ($p = 0.01$), with a moderate effect size at T1 and T2 ($d = 0.58$ respectively), corresponding to a number needed to treat (NNT) of 3.14 for both time points. Participants in the guided ACTonPain group also indicated higher pain acceptance (T1: $d = 0.59$; T2: $d = 0.76$). The unguided ACTonPain group showed to be significantly less depressed in comparison to the control group at time T2 ($d = 0.50$). No significant differences with respect to effectiveness were found between the two ACTonPain groups ($p>0.05$).

Conclusion: The online intervention ACTonPain is effective for persons with chronic pain when the program is guided. Further research in a variety of settings of health care is needed in order to determine whether and how ACTonPain can be implemented.

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Chronic pain is widespread (1–3) and is associated with direct and indirect costs as well as adverse social, physical, and mental effects (2–5). In a cross-sectional survey conducted in Germany, 28.3 % of the respondents stated that they had chronic pain and 7.3 % fulfilled the criteria for chronic, non-tumor-related debilitating pain (6). Multimodal interdisciplinary therapy is acknowledged as the gold standard for evidence-based treatment of chronic pain (7). Psychological interventions such as acceptance and commitment therapy (ACT), a recent development in the field of cognitive behavioral therapy (CBT), represent a key element of such treatment (8).

The goal of ACT is for the affected person to accept unpleasant, unalterable experiences such as pain and lead a value-oriented life in open contact with their thoughts and feelings; this is summarized as “psychological flexibility” (9, 10). ACT represents an alternative to CBT, showing equivalent efficacy (small to moderate effects). People with chronic pain are, however, often confronted with limited accessibility and availability of established treatments (3, 13, 14), and according to a large European survey almost half of those affected are treated inadequately, e.g., only by medication (3).

Against this backdrop, Internet- and mobile-based interventions (IMIs) (15) for chronic pain could be an effective and cost-effective way of overcoming the above-mentioned barriers of face-to-face psychotherapy. Furthermore, IMIs may offer additional advantages over face-to-face treatments, e.g., shorter waiting times, anonymity, and flexibility of time and place (15–17).

A recent meta-analysis of 19 randomized controlled trials (RCTs) on the efficacy of IMIs in various groups of people with pain found an effect size of Hedge's $g = 0.41$ for pain interference, comparable to the small to moderate effects of face-to-face treatments. Once established, guidance of patients in the form of regular feedback, explanations, motivation, and reminders to adhere to the treatment not only improves treatment effects (19) but also is a central cost factor. Unguided IMIs may therefore be of particular interest for

BOX

Inclusion and exclusion criteria

● Inclusion criteria

- Age ≥ 18 years*
- Chronic pain (duration ≥ 6 months)*
- Pain interference (at least level 2 on the von Korff pain scale)
- Medically eligible to participate in an IMI for chronic pain*
- Sufficient knowledge of German*
- Sufficient computer and the Internet literacy*
- Internet access*

● Exclusion criteria

- Tumor-related pain*
- Psychological pain intervention ongoing or planned within next 3 months*
- Elevated suicide risk (BDI-II suicide item score >1).

* Self-reported; BDI-II, Beck Depression Inventory II; IMI, Internet- and mobile-based intervention

healthcare policy (20). However, little is known about the effectiveness of ACT-based IMIs for chronic pain in general (21) or the effectiveness of guided and unguided IMIs for chronic pain in particular (18).

Therefore, the aim of this study was to investigate the effectiveness of a guided and unguided ACT-based IMI for persons with chronic pain (ACTonPain) in comparison with a waiting-list control group (CG).

Method

Design

The study protocol with a detailed description of this three-armed pragmatic RCT with parallel design has been published (22). The participants were assigned to one of three groups: guided ACTonPain, unguided ACTonPain, or CG.

Participants

Recruitment took place during the period from October 2014 to August 2015. The participants were recruited via a broad-based online and offline advertising strategy involving cooperation with a health insurance provider. The inclusion and exclusion criteria, outlined in the *Box*, were based on online self report. All measurements (eligibility screening and assessments) were carried out online. The assessments were performed at baseline (T0; pre-treatment) and at 9 weeks (T1; post-treatment) and 6 months (T2; follow-up) after randomization.

The ACTonPain program comprises an introduction and seven successive modules. The participants were advised to complete one module per week, spending around 60 min on each module.

In the guided ACTonPain group, e-coaches (psychologists) under the supervision of an experienced psychological psychotherapist (HB) provided personalized and standardized (preformulated) feedback by e-mail within two working days after completion of each module. Guidance took an average of 105 min per participant.

Control group

The participants in the CG were given access to the unguided version of ACTonPain after completion of the T2 assessments.

Instruments

The participants' clinical characteristics were documented using the pain-relevant items of the German Pain Questionnaire (*Deutscher Schmerzfragebogen*) (23). The study outcomes were selected based on the recommendations of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) (24, 25). The instruments are described in detail in the study protocol (22) and thus merely outlined in brief here.

Primary outcome

The primary outcome was pain interference, assessed with the interference subscale of the Multidimensional Pain Inventory (MPI) (26, 27). This subscale comprises 10 questions about daily activities with responses on a 7-point scale ranging from 0 ("no interference") to 6 ("extreme interference").

Secondary outcomes

The secondary outcomes were related to:

- Physical and emotional functioning
- Pain intensity
- Health-related quality of life
- ACT-related variables
- Participants' satisfaction
- Participants' rating of overall improvement
- Intervention adherence

Randomization

To obtain groups of the same size, an independent statistician performed permuted-block randomization with variable block sizes of 6, 9, and 12 (randomly ordered) and an allocation ratio of 1 : 1 : 1 with an automated web-based program (www.sealedenvelope.com).

Statistical analyses

Missing data were imputed using the expectation-maximization algorithm of the Statistical Package for the Social Sciences (SPSS, Version 22). All analyses were carried out with SPSS 22.

The effectiveness of the intervention was analyzed on an intention-to-treat (ITT) basis. The data of those participants who completed at least five of the seven modules and all assessments were additionally included in per-protocol (PP) analyses. In contrast to the originally planned multivariate analysis of covariance

TABLE 1

The participants' demographic and clinical characteristics at baseline*¹

Variable	All participants (n = 302)	Guided ACTonPain (n = 100)	Unguided ACTonPain (n = 101)	Waiting list (n = 101)
Sociodemographic characteristics				
Age	51.7 (13.1)	51.7 (12.3)	53.1 (14.2)	50.3 (12.5)
Women	254 (84.1 %)	86 (86 %)	82 (81.2 %)	86 (85.1 %)
Married / with partner	206 (68.2)	75 (75 %)	68 (67.3 %)	63 (62.4 %)
Education level				
No school qualification	1 (0.3 %)	0 (0 %)	1 (1 %)	0 (0 %)
Basic secondary school	36 (11.9 %)	9 (9 %)	17 (16.8 %)	10 (9.9 %)
Middle secondary school	107 (35.4 %)	39 (39 %)	34 (33.7 %)	34 (33.7 %)
Grammar / technical grammar school	158 (53.3 %)	52 (52 %)	49 (48.5 %)	57 (56.4 %)
Occupational status				
Unemployed	13 (4.3 %)	5 (5 %)	4 (4 %)	4 (4 %)
Student	12 (4 %)	3 (3 %)	5 (5 %)	4 (4 %)
Self-employed / employed	174 (57.6 %)	60 (60 %)	53 (52.5 %)	61 (60.4 %)
Retired	103 (34.1 %)	32 (32 %)	39 (38.6 %)	32 (31.7 %)
Pain-relevant characteristics				
Previous pain treatment	277 (91.7 %)	91 (91 %)	92 (91.1 %)	94 (93.1 %)
Type of pain				
Constant pain with little fluctuations	109 (36.1 %)	34 (34 %)	37 (36.6 %)	38 (37.6 %)
Constant pain with large fluctuations	101 (33.4 %)	33 (33 %)	38 (37.6 %)	30 (29.7 %)
Pain attacks, no pain in between	40 (13.2 %)	18 (18 %)	10 (9.9 %)	12 (11.9 %)
Pain attacks, pain in between	52 (17.2 %)	15 (15 %)	16 (15.8 %)	21 (20.8 %)
Duration of pain in months* ²	114.45 (121.55) (n = 295)	115.94 (136.47) (n = 97)	132.48 (125.16) (n = 99)	94.97 (98.49) (n = 99)
Pain location				
- Back	103 (34.1 %)	28 (28 %)	33 (32.6 %)	42 (41.6 %)
- Head, neck	71 (23.5 %)	25 (25 %)	24 (23.8 %)	22 (21.8 %)
- Shoulders	17 (5.6 %)	7 (7 %)	4 (4 %)	6 (5.9 %)
- Other	111 (36.8 %)	40 (40 %)	40 (39.6 %)	31 (30.7 %)
Comorbid medical conditions* ³	173 (57.3 %)	55 (55 %)	60 (59.4 %)	58 (57.4 %)
Comorbid mental conditions* ³	119 (39.4 %)	40 (40 %)	32 (31.7 %)	47 (46.5 %)

*¹Data expressed as means (standard deviation) or number (%); *²incomplete data; *³self-reported; ACT, acceptance and commitment therapy; ACTonPain, ACT-based guided or unguided online intervention for patients with chronic pain; n = number

(MANCOVA), we used a multivariate analysis of variance (MANOVA) with repeated measures as there were no baseline group differences concerning the potential covariables sex and age. Use of MANOVA also maximized the degrees of freedom of the model. In this model, the interaction effects of group $\times$ time for the three groups and the three assessment times with regard to the primary and secondary outcomes were of particular interest. Whenever significant interaction effects were found, univariate post-hoc tests with repeated measures were carried out to further examine the interaction effect for the corresponding outcome between

the groups and between the assessment times (T0 versus T1 and T0 versus T2).

For significant group $\times$ time interactions in each comparison, the corresponding effect sizes (Cohen's d) and number needed to treat (NNT) were calculated with regard to the group differences at T1 and T2.

A further repeated measures MANOVA was carried out in respect of intervention satisfaction and adherence between the intervention groups, because these variables were only assessed in the two intervention groups at T1 and T2. An additional ANOVA was

FIGURE

Flow chart of inclusion and exclusion

ACT, Acceptance and commitment therapy;

ACTonPain, ACT-based guided or unguided online intervention for patients with chronic pain;

ITT, intention to treat

performed with post-treatment and follow-up data for participants' rating of overall improvement.

Further information on the methods with regard to participants, intervention, study instruments, and statistical analyses, together with study registration, can be found in the *eBox* and in *eTables 1* and *2*.

Results

All study participants completed the baseline survey. Little's Missing Completely at Random (MCAR) test indicates that the data is missing at random. ($\chi^2[1779] = 604.73$; $p = 0.99$). *Table 1* summarizes the participants' demographic and clinical characteristics at baseline, with no clinically relevant differences

among the groups. 24% of the participants dropped out of the study at T1, 39 % at T2 (*Figure*). The PP sample consisted of 43 participants from the guided ACTonPain group, 30 from the unguided ACTonPain group, and 71 from the CG.

Efficacy of interventions

MANOVA with repeated measures revealed a significant interaction effect for group $\times$ time (value $[V] = 0.13$, $F[36.237] = 2.24$, $p < 0.01$; PP: $V = 0.18$, $F[36.1108] = 1.49$, $p = 0.03$). *Table 2* shows the means (M) and standard deviations (SD) of the primary outcomes and summarizes the results of the univariate variance analyses with repeated measures of the group $\times$ time effects for each comparison between T0

TABLE 2

Means and standard deviations for the primary outcome: pain interference*

Outcome	N	T0	T1	T2	Effects of group × time interaction	
		Mean (standard deviation)	Mean (standard deviation)	Mean (standard deviation)	T0 versus T1	T0 versus T2
MPI						
Guided ACTonPain	100	4.06 (0.93)	3.23 (1.16)	3.17 (1.18)	F(2.299) = 11.60 p <0.01	F(2.299) = 7.93 p <0.01
Unguided ACTonPain	101	4.01 (1.02)	3.58 (1.12)	3.40 (1.20)		
Waiting list	101	4.19 (0.94)	3.85 (0.97)	3.82 (1.05)		

*Measured using the Multidimensional Pain Inventory (MPI) at pre-treatment, post-treatment, and follow-up, F values for univariate follow-up tests with repeated measures, intention to treat (ITT) sample; ACT, acceptance and commitment therapy; ACTonPain, ACT-based guided or unguided online intervention for patients with chronic pain

T0 = Pre-treatment, T1 = post-treatment, T2 = follow-up

and T1 and between T0 and T2 of the ITT sample. (M and SD for the secondary outcomes are presented in eTable 1.) These analyses showed significant ($p < 0.05$) group × time effects for pain interference, pain intensity, and pain acceptance, as well as depression, in the comparisons T0 versus T1 and T0 versus T2.

Furthermore, there were significant ($p < 0.05$) group × time effects in the comparison T0 versus T1 for health-related quality of life—mental health subscale—and in the comparison T0 versus T2 for physical functioning (Brief Pain Inventory, BPI) and psychological flexibility (Acceptance and Action Questionnaire, German version: *Fragebogen zu Akzeptanz und Handeln-II*, FAH). Analysis of the PP sample yielded comparable findings. The post-hoc group effects of the comparisons T0 versus T1 and T0 versus T2, the corresponding effect sizes, and the equivalent NNT for T1 and T2 of the ITT sample are listed in Table 3 (see eTable 2 for the secondary outcomes).

Primary outcome

In the post-hoc group comparisons, pain interference was significantly ($p = 0.01$) lower in the guided ACTonPain group than in the CG for both T0 versus T1 and T0 versus T2. Based on Cohen's d, these were moderate to large effects. No significant differences were found between the two ACTonPain groups or between the unguided ACTonPain group and the CG. No significant group differences were found in the PP sample ($p < 0.05$).

Secondary outcomes

In the post-hoc group comparisons, the guided ACTonPain group showed significantly higher pain acceptance than the CG for both T0 versus T1 and T0 versus T2; these were moderate to large effects. In the PP sample, this finding was confirmed only for T0 versus T2. The participants of the unguided ACTonPain group showed to be significantly less depressed than the CG in the comparison T0 versus T2, and this was confirmed in the PP sample. With regard to the remain-

ing secondary outcomes, no significant ($p > 0.05$) group differences for physical and emotional functioning (BPI; Generalized Anxiety Disorder Screener [GAD-7]), pain intensity, physical and mental quality of life, and psychological flexibility (FAH) were found in the post hoc analyses. The additional ANOVA showed that the intervention groups, compared with the CG, reported higher overall improvement (Patient Global Impression of Change [PGIC]) at T1 and T2 in the ITT and PP analyses; the two intervention groups did not differ from one another.

Comparison between guided and unguided ACTonPain groups and negative effects

While the above-mentioned analyses showed no differences between the guided and unguided ACTonPain groups, the participants of the guided ACTonPain group completed more modules (number of modules: 0–8) than those in the unguided ACTonPain group ($M = 5.94$, $SD = 2.80$ versus $M = 4.74$, $SD = 2.89$; $F[1.99] = 8.92$; $p < 0.01$). The attrition rate was 40% in the guided ACTonPain group and 61% in the unguided ACTonPain group. There were no significant differences between the groups with regard to participants' satisfaction ($V = 0.01$, $F[2.198] = 0.81$, $p = 0.45$; PP: $V = 0.00$, $F[2.70] = 0.04$, $p = 0.96$). The participants' overall degree of satisfaction can be interpreted as high, and the majority of participants (81.6 % in both groups) stated at T1 that they would recommend the intervention to a friend who needed psychological assistance (item 4: response “yes, probably” or “yes, definitely”).

In response to the question about possible negative effects—as recommended by Rozetal and colleagues (28, 29)—the participants reported no negative events.

Discussion

This study is the first to investigate the effectiveness of online-based acceptance and commitment therapy for chronic pain (ACTonPain) in Germany. The results show that people with chronic pain can considerably benefit from ACTonPain if the program is guided. The

TABLE 3

Post-hoc group effects of the comparisons between pre-treatment and post-treatment and between pre-treatment and follow-up*

	Post-hoc group comparisons between T0 and T1	Group effects at T1: Cohen's d [95 % CI]; NNT	Post-hoc group comparisons between T0 and T2	Group effects at T2: Cohen's d [95 % CI]; NNT
MPI				
Guided ACTonPain vs. CG	p = 0.01	d = 0.58 [0.30; 0.86]; 3.14	p = 0.01	d = 0.58 [0.30; 0.86]; 3.14
Unguided ACTonPain vs. CG	p = 0.09		p = 0.08	
Guided ACTonPain vs. unguided ACTonPain	p = 0.99		p = 0.99	

*Corresponding effect sizes and number needed to treat (NNT) data for post-treatment and follow-up, intention to treat sample, in relation to the primary outcome pain interference, measured using the Multidimensional Pain Inventory (MPI); ACT, acceptance and commitment therapy; ACTonPain, ACT-based guided or unguided online intervention for patients with chronic pain; CG, control group; CI, confidence interval
T0 = Pre-treatment, T1 = post-treatment, T2 = follow-up

participants of the guided ACTonPain group reported significantly less pain interference and higher pain acceptance at post-treatment and follow-up assessments than persons on the waiting list, which demonstrates the long-term effect of the intervention. Moreover, the participants of both ACTonPain groups stated a high level of satisfaction with the program.

These results are in line with the findings of other guided, ACT-based IMIs for chronic pain, which revealed effect sizes of $d = 0.33$ (30) and $d = 0.56$ (31) for pain interference in comparison with active control groups (e.g., expressive writing [30] and participation in online forums [31]). The results of our study are also comparable with the treatment effects of face-to-face therapies, for which weak to moderate effects on pain interference, pain intensity, depression, anxiety, and disability were reported (standardized mean difference [SMD] = 0.62, 0.24, 0.43, and 0.40 respectively) (12).

The present study makes an important contribution to the growing body of evidence on IMIs for chronic pain and emphasizes the benefit of guided ACTonPain. The effect-facilitating impact of guidance may be attributable to monitoring of treatment adherence rather than to the provision of therapeutic content (19). With regard to unguided IMIs, only one other study has directly compared the efficacy of guided and unguided interventions (32). In contrast to the results of Dear et al. (32), the findings of our study do not confirm the efficacy of unguided ACTonPain, despite its positive effect on depressive symptoms in comparison with the CG and between T0 and T2. This may be partly attributable to the high drop-out rate. However, due to the cost-saving provision, unguided ACTonPain could be clinically important at population level. This aspect is currently being examined in the context of the cost-effectiveness analyses of guided ACTonPain and unguided ACTonPain in comparison with the CG.

Limitations

One limitation of this study lies in the pragmatic implementation of the diagnostic process, which exclusively took place only based on self-reports. We

regarded chronic pain as a disease in its own right (2) in a heterogeneous population that need not be documented in detail. To conduct additional moderator and mediator analyses, the German Pain Questionnaire (23) assesses pain-related variables. These serve to examine which persons benefit most and least from ACTonPain. Furthermore, the external validity of our study seems to be high for well-educated women, who form a high proportion of the sample. The proportion of women with a high level of education is comparable with that in earlier IMI studies (18, 33) and with the uptake rates for face-to-face psychotherapy (34). This appears to be the target group that is particularly interested in this kind of intervention.

Summary

In view of the high prevalence of chronic pain (3) and the challenges related to the availability and accessibility of evidence-based treatments (3, 14), it is crucial to take active steps to implement new, effective treatments such as ACTonPain in the health care system. To date, however, the acceptance of IMIs in various patient populations seems to be ambivalent (35–37). IMIs might be far less effective in the health care context (38) than reported in the efficacy studies, where the high level of administrative support potentially increases adherence to the intervention (39). For successful dissemination and implementation of ACTonPain in various areas of the healthcare system, there is a need for acceptance- and adherence-facilitating strategies focussing on contact initialisation and the participants' utilization patterns.

Within the health care system ACTonPain can be used as a stand-alone treatment or as an adjunct to psychotherapy ("blended care"). Because single treatment measures fail to adequately treat chronic pain, future studies should examine the role of ACTonPain in a bio-psycho-social context. ACTonPain could be implemented in disease management and collaborative care programs and in integrated pain care plans.

The findings of this study suggest the advisability of implementing ACTonPain with therapeutic guidance

into the health care system. ACTonPain can help to shorten waiting times, improve access to pain treatment, and possibly lower treatment costs. Further investigations are required to establish in which routine health care settings ACTonPain can easily be integrated and how it can be best disseminated and implemented.

KEY MESSAGES

- Online-based acceptance and commitment therapy may be effective to treat chronic pain when the patient simultaneously receives online therapeutic guidance.
- This intervention may help to shorten waiting times and broaden the range of options for treating chronic pain.
- Particularly women with a high level of education took part in the study. This seems to be the group that can benefit most from the intervention.

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Conflict of interest statement

Dr. Lin, M.Sc. Psych, Dipl.-Psych. Lüking, Buhrmann, PhD, Prof. Andersson, and Prof. Baumeister are authors and developers of ACTonPain.

Dr. Ebert possesses shares in the GET.On Instituts GesundheitsTrainings.On-line, which works to transfer research findings on Internet- and mobile phone-based health interventions into routine care. He has received payments from several companies and health insurance providers (Lantern Inc., Minddistrict Holding, BARMER, Techniker Krankenkasse, Schön Kliniken, Agaplesion Kliniken, Ebel Kliniken) for advice on the use of Internet-based interventions. He has received payments for lectures from the Federal Psychotherapy Association (Bundespsychotherapeutenkammer) and the psychotherapy associations of the states of Hesse and Lower Saxony, and has been the beneficiary of third-party funding from the health insurance provider BARMER, the German Statutory Pension Insurance Scheme (DRV), Social Insurance for Agriculture, Forestry, and Horticulture (SVLFG), and the Accident Insurance Fund of the state of North Rhine-Westphalia (Unfallkasse NRW).

Dipl.-Psych. Sander has received payments for lectures on the topic of online-based psychotherapy from the Freiburg Institute for Training in Cognitive Therapy (Freiburger Ausbildungsinstitut für Verhaltenstherapie, FAVT GmbH) and the Institute for Training in Psychotherapy, Saarland University (Weiterbildungsinstitut für Psychotherapie an der Universität des Saarlandes, WIPS GmbH).

Prof. Baumeister has received a consultancy fee from the Federal Psychotherapy Association (Bundespsychotherapeutenkammer). He has received reimbursement of congress attendance and travel costs as well as payments for lectures from the Federal Psychotherapy Association, the psychotherapy association of the state of Baden-Württemberg, and the Community Psychiatry Confederation (Dachverband für Gemeindepsychiatrie). He has been the beneficiary of study support (third-party funding) from the health insurance provider BARMER GEK, Social Insurance for Agriculture, Forestry, and Horticulture (SVLFG), and the German Statutory Pension Insurance Scheme (DRV). Moreover, he has received payments for lectures on the topic of online-based psychotherapy from the Freiburg Institute for Training in Cognitive Therapy (Freiburger Ausbildungsinstitut für Verhaltenstherapie, FAVT GmbH).

Dipl.-Psych. Paganini declares that no conflicts of interest exist.

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Supplementary material

For eReferences please refer to:
www.aerzteblatt-international.de/ref4117

eBox, eTables:
www.aerzteblatt-international.de/17m0681

Supplementary material to:

An Internet-Based Intervention for Chronic Pain

A Three-Arm Randomized Controlled Study of the Effectiveness of Guided and Unguided Acceptance and Commitment Therapy

by Jiaxi Lin, Sarah Paganini, Lasse Sander, Marianne Lüking, David Daniel Ebert, Monica Buhman, Gerhard Andersson, and Harald Baumeister

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Method

● Participants

All participants had unlimited access to routine care. For the cost-effective analysis of the study, participants were questioned at T1 and T2 about the treatments they had received. The health economics data are currently being analyzed and will be published in a separate article owing to the complexity of the field.

● Intervention

The intervention was developed on the basis of a previous online-based acceptance and commitment therapy (ACT) for chronic pain developed by Buhman and colleagues in Sweden (e1), and the recommendations of Hayes et al. (e2), and is described in detail in the study protocol (22). Given that reminders have been shown to increase the adherence to Internet- and mobile-based interventions (IMIs) (e3–e7), automatically transmitted text messages (SMS) were offered to support integration of the trained techniques into daily life.

● Measuring instruments

The following secondary outcomes were assessed:

- Physical functioning: the pain interference scale of the Brief Pain Inventory (BPI) (e8) was used to measure the extent to which pain interfered with various aspects of function.
- Emotional functioning: the Patient Health Questionnaire-9 (PHQ-9) (e9) was used for depressive symptoms and the Generalized Anxiety Disorder Screener (GAD-7) (e10) for anxiety symptoms.
- Pain intensity: The current pain level and the worst, least, and average pain in the past week were rated on a scale of 0 to 10.
- Health-related quality of life: we used the short form of the Health Survey (SF-12) (e11), divided into physical and mental health.
- ACT-related variables: the German version of the Acceptance and Action Questionnaire-II (AAQ-II) was used to assess psychological flexibility (e12) and the Chronic Pain Acceptance Questionnaire (e13) for pain acceptance.
- Participants' satisfaction: we used the German version of the Client Satisfaction Questionnaire (CSQ-8), adapted for use with IMIs (e14, e15).
- Participants' rating of overall improvement: we used the Patient Global Impression of Change Scale (PGIC) (e16), ranging from –3 = very much worse to +3 = very much improved.
- The adherence was calculated on the basis of the drop-out rate and the number of modules completed.

● Statistical analyses

The deviation from the protocol (22) with regard to missing data imputation is due to the lack of concrete procedures for performing multivariate analyses with repeated measures with multiple data sets (e17, e18).

The advantages of multivariate analysis of variance (MANOVA) with repeated measures are the simultaneous testing of group effects at various assessment times and for various outcomes as well as the prevention of alpha inflation (e19). A detailed description of the analyses and the corresponding reference values can be found in (e20).

As the primary outcome was used in a confirmatory analysis, alpha Bonferroni adjustment was used for the three post-hoc group comparisons with an adjusted significance level of (rounded up) $p = 0.02$. All other tests of significance are of an exploratory nature and require replication in a confirmatory study design with regard to the given outcome, which is why no alpha adjustment was performed (see [e21]) for a detailed discussion of this issue).

Registration: The study was approved by the ethics committee at the Albert-Ludwigs-University of Freiburg and entered in the German Clinical Trials Registry (DRKS) on 2 October 2014: DRKS00006183.

eTABLE 1

Means and standard deviations for the secondary outcomes at pre-treatment, post-treatment, and follow-up, F values for univariate follow-up tests with repeated measures, intention to treat sample

Outcome	N	T0	T1	T2	Effects of group × time interaction	
		Mean (standard deviation)	Mean (standard deviation)	Mean (standard deviation)	T0 versus T1	T0 versus T2
BPI						
Guided ACTonPain	100	5.07 (2.00)	4.00 (2.01)	4.01 (1.93)	F(2.299) = 2.39 p = 0.09	F(2.299) = 4.90 p = 0.01
Unguided ACTonPain	101	4.96 (2.06)	4.25 (1.93)	4.28 (1.98)		
Waiting list	101	5.16 (2.26)	4.60 (2.10)	4.86 (2.24)		
PHQ-9						
Guided ACTonPain	100	10.54 (4.91)	8.53 (4.96)	8.69 (4.99)	F(2.299) = 3.66 p = 0.03	F(2.299) = 5.97 p < 0.01
Unguided ACTonPain	101	9.93 (5.07)	8.80 (4.72)	8.19 (4.84)		
Waiting list	101	10.95 (4.86)	10.38 (5.21)	10.73 (5.23)		
GAD-7						
Guided ACTonPain	100	7.98 (4.75)	6.11 (3.91)	6.29 (4.05)	F(2.299) = 2.86 p = 0.06	F(2.299) = 0.82 p = 0.44
Unguided ACTonPain	101	7.36 (4.92)	6.27 (3.93)	5.97 (4.00)		
Waiting list	101	8.58 (4.77)	7.99 (4.75)	7.60 (4.84)		
NRS						
Guided ACTonPain	100	5.44 (1.45)	4.65 (1.69)	4.56 (1.69)	F(2.299) = 6.41 p < 0.01	F(2.299) = 8.30 p < 0.01
Unguided ACTonPain	101	5.24 (1.48)	4.72 (1.44)	4.58 (1.65)		
Waiting list	101	5.13 (1.63)	4.92 (1.61)	4.97 (1.56)		
SF-12 _{PH}						
Guided ACTonPain	100	36.69 (8.35)	38.99 (8.69)	39.91 (9.27)	F(2.299) = 0.15 p = 0.60	F(2.299) = 1.58 p = 0.23
Unguided ACTonPain	101	35.12 (8.60)	36.93 (8.67)	38.23 (8.59)		
Waiting list	101	35.98 (8.83)	37.60 (9.27)	37.60 (8.96)		
SF-12 _{MH}						
Guided ACTonPain	100	45.08 (10.12)	48.46 (10.12)	47.35 (9.27)	F(2.299) = 3.23 p = 0.04	F(2.299) = 1.36 p = 0.26
Unguided ACTonPain	101	45.93 (10.04)	47.36 (8.98)	47.04 (9.89)		
Waiting list	101	43.61 (10.60)	43.85 (11.07)	43.45 (10.83)		
CPAQ						
Guided ACTonPain	100	57.97 (20.39)	70.52 (22.46)	71.03 (20.74)	F(2.299) = 14.74 p < 0.01	F(2.299) = 19.57 p < 0.01
Unguided ACTonPain	101	54.30 (20.09)	65.49 (20.67)	63.97 (18.78)		
Waiting list	101	54.62 (18.02)	58.57 (18.12)	55.95 (19.06)		
FAH-II						
Guided ACTonPain	100	15.15 (10.96)	12.48 (9.81)	11.25 (9.68)	F(2.299) = 1.80 p = 0.17	F(2.299) = 6.42 p < 0.01
Unguided ACTonPain	101	14.14 (9.80)	12.04 (9.50)	11.70 (9.24)		
Waiting list	101	16.08 (10.22)	15.19 (9.54)	15.33 (9.37)		

ACT, acceptance and commitment therapy; ACTonPain, ACT-based guided or unguided online intervention for patients with chronic pain; BPI, Brief Pain Inventory; CPAQ, Chronic Pain Acceptance Questionnaire; FAH-II, *Fragebogen zu Akzeptanz und Handeln II*, German version of Acceptance and Action Questionnaire-II; GAD-7, Generalized Anxiety Disorder Screener; NRS, numeric rating scale; PHQ-9, Patient Health Questionnaire-9; SF-12_{PH}, short form of Health Survey, subscale physical health; SF-12_{MH}, short form of Health Survey, subscale mental health; T0 = pre-treatment, T1 = post-treatment, T2 = follow-up

eTABLE 2

Post-hoc group effects of the comparisons between pre-treatment and post-treatment and between pre-treatment and follow-up for the secondary outcomes, corresponding effect sizes and number needed to treat (NNT) data for post-treatment and follow-up, intention to treat sample

	Post-hoc group comparisons between T0 and T1	Group effects at T1: Cohen's d [95 % CI]; NNT	Post-hoc group comparisons between T0 and T2	Group effects at T2: Cohen's d [95 % CI]; NNT
BPI				
Guided ACTonPain vs. CG			p = 0.24	
Unguided ACTonPain vs. CG			p = 0.45	
Guided ACTonPain vs. unguided ACTonPain			p = 0.99	
PHQ-9				
Guided ACTonPain vs. CG	p = 0.24		p = 0.18	d = 0.50; [0.22; 0.78]; 3.60
Unguided ACTonPain vs. CG	p = 0.06		p = 0.02	
Guided ACTonPain vs. unguided ACTonPain	p = 0.99		p = 0.99	
NRS				
Guided ACTonPain vs. CG	p = 0.99		p = 0.99	
Unguided ACTonPain vs. CG	p = 0.99		p = 0.99	
Guided ACTonPain vs. unguided ACTonPain	p = 0.99		p = 0.99	
SF-12 _{MH}				
Guided ACTonPain vs. CG	p = 0.06			
Unguided ACTonPain vs. CG	p = 0.18			
Guided ACTonPain vs. unguided ACTonPain	p = 0.99			
CPAQ				
Guided ACTonPain vs. CG	p = 0.01	d = 0.59; [0.30; 0.87]; 3.11	p < 0.01	d = 0.76; [0.47; 1.04]; 2.45
Unguided ACTonPain vs. CG	p = 0.41		p = 0.41	
Guided ACTonPain vs. unguided ACTonPain	p = 0.27		p = 0.12	
FAH-II				
Guided ACTonPain vs. CG			p = 0.18	
Unguided ACTonPain vs. CG			p = 0.11	
Guided ACTonPain vs. unguided ACTonPain			p = 0.99	

*Only for significant group × time interactions and group differences. ACT, acceptance and commitment therapy; ACTonPain, ACT-based guided or unguided online intervention for patients with chronic pain; BPI, Brief Pain Inventory; CPAQ, Chronic Pain Acceptance Questionnaire; CG control group; CI, confidence interval; FAH-II, *Fragebogen zu Akzeptanz und Handeln II*, German version of Acceptance and Action Questionnaire-II; NNT, number needed to treat; NRS, numerical rating scale; PHQ-9, Patient Health Questionnaire-9; SF-12_{MH}, short form of Health Survey, subscale physical health; T0 = pre-treatment, T1 = post-treatment, T2 = follow-up