Received: 22 January 2024 | Revised: 26 April 2024 | Accepted: 7 May 2024

DOI: 10.1002/hsr2.2141

ORIGINAL RESEARCH

Health Science Reports Open Access WILEY

Clinical effects of online cognitive behavioral group therapy for chronic pain patients and developing a therapeutic alliance: A pre–post pilot trial

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Funding information
KAKENHI, Grant/Award Number: 22K18647; JST Moonshot Program Goal 9, Grant/Award Number: JPMJM S2296

Abstract

Background and Aims: Research suggests that various psychosocial factors influence chronic pain, with psychotherapies like cognitive behavioral therapy proving effective. However, the limited availability and accessibility have prolonged suffering among patients with chronic pain. This challenge has led to a growing demand for accessible online interventions. We developed an online cognitive behavioral group therapy (CBGT) program, building upon our existing face-to-face CBGT program. We compared the scores obtained by patients during the treatment-as-usual (TAU) period with those collected at the beginning and at the end of the intervention.

Methods: Patients with chronic pain ($N = 22$) agreed to participate in the online CBGT program, which was conducted once a week for 12 sessions. The sample size was decided based on the effect sizes of our past face-to-face CBGT. We assessed pain intensity [Visual Analogue Scale (VAS)], pain catastrophizing [pain catastrophizing scale (PCS)] and psychiatric assessment [Beck Depression Inventory-Second Edition (BDI)-II], State-Trait-Anxiety Inventory (STAI), and Short Form Health Survey (SF-36) at three points: entry, pretreatment, and posttreatment. We also evaluated the participants' therapeutic alliance with the treatment staff [short-form version of the Working Alliance Inventory (WAI-S)]. We utilized analyses of variance, Friedman test, paired *t*-tests, Wilcoxon signed-rank test, and Pearson correlation analysis for data evaluation.

Results: Results indicated a significant posttreatment improvement in VAS, PCS, and BDI-II scores compared to the TAU period. Furthermore, posttreatment WAI-S scores increased significantly compared to pretreatment scores. Also, positive correlations were observed among pre- and posttreatment changes in WAI-S, pain intensity, and pain catastrophizing scores.

Conclusion: There is a possibility that a therapeutic alliance can be established, and therapeutic effects achieved through an online CBGT intervention; however, additional research is required to substantiate this potential. We have registered this clinical trial in UMIN-CTR on 04/21/2021 with the number UMIN000043982.

KEYWORDS
chronic pain, group therapy, online cognitive behavioral therapy, pain catastrophizing, therapeutic alliance

1 | INTRODUCTION

Chronic pain is characterized as pain that continues beyond the expected period of healing, persisting after the initial cause of the pain is believed to have been resolved, or as pain associated with a chronic condition lasting more than 3 months.[1] The treatment of chronic pain involves pharmacotherapy and nonpharmacological approaches, including psychotherapy like cognitive behavioral therapy (CBT).[2] A recent Cochrane review has demonstrated the effectiveness of CBT in chronic pain management, showing significant improvements in various aspects such as pain intensity and psychological symptoms.[3] However, access remains a challenge, prolonging the suffering of many chronic pain patients.[4]

In response to the growing need for improved healthcare delivery, innovative methods like internet-based interventions have gained prominence.[5] These interventions, encompassing websites, videoconferencing, telephone, and email, are increasingly recognized as effective ways to empower patients. However, a systematic review that examined internet-based interventions for a range of musculoskeletal conditions found that, although these interventions can be effective when used alongside standard treatments with the help of a therapist, their efficacy as standalone options has yet to be definitively established.[6] Additionally, although group therapy, leading to better outcomes and improvements, is crucial in pain psychotherapy,[7] there have been limited studies on real-time online cognitive behavioral group therapy (CBGT), further emphasizing the need for more comprehensive research in this area.[8] Therefore, we developed a real-time online CBGT program for patients with chronic pain. This program mirrors our face-to-face CBGT [9,10] in duration, content, tasks, and structure. We conducted a pilot study to assess the efficacy of this online intervention, aiming to contribute to the existing body of knowledge in this field.

Previous studies have shown that improving the working alliance enhances CBT's efficacy for chronic pain.[11,12] However, a disadvantage of internet-based interventions has been reported to be the lack of support from staff and/or management during treatment.[13] Therefore, to examine whether a therapeutic alliance can be established online, we used the short-form version of the Working Alliance Inventory (WAI-S). We hypothesized a positive correlation between positive changes in the therapeutic alliance and improvements in the variables assessing treatment outcomes.

2 | METHODS

This study was conducted as a single-center, pre–post pilot trial. We referred to the guidelines for reporting statistics for clinical research in urology [14] and the Consolidated Standards of Reporting Trials [15] for proper reporting, analysis, and interpretations of clinical research.

2.1 | Participants

Patients ($N = 23$) were recruited from the Departments of Psychiatry and Neurosciences, Anesthesiology and Critical Care, and Rheumatology at Hiroshima University Hospital. Our previous face-to-face CBGT studies have indicated an effect size of 0.94 and 0.80 (mean score; 0.87) on pain intensity,[9,10] and we calculated that a sample size of at least 15 was needed to detect this association (power = 0.95, $\alpha = 0.05$) using a paired t-test. The sample size was ascertained using G*Power software (version 3.1.9.7). Before participation, all the participants provided their written informed consent to undergo the treatment. Before the participants joined the program, we conducted at least one face-to-face intake interview at the Hiroshima University Hospital's psychiatric outpatient clinic. At this interview, we completed the in-person screening, explained the treatment, obtained the participants' informed consent, confirmed their psychiatric and physical condition, and assessed whether they could access online CBGT, including having a home Internet environment and familiarity with digital media. The research protocol of this study was approved by the Hiroshima University ethics committee (approved number C2021-0321). The detailed inclusion and exclusion criteria were shown in Supplementary methods sections. Figure 1 illustrates the study participants' flow, including one who declined to participate due to unfamiliarity with online tools. We ascertained the patients' physical condition through a detailed patient history, physician-conducted physical exams, and laboratory results analysis. Table 1 shows the patients' physical comorbidities.

We established a period (mean length was 66.5 days, SD = 21.0, range 32–94 days) for examining conditions under treatment-as-usual (TAU) among all participants. The participants were contacted during the TAU period, and face-to-face, structured clinical interviews were conducted according to the DSM-IV-TR to identify psychological symptoms, and clinical assessments were conducted to identify physical symptoms. Table 1 shows that all the participants were taking medication.

2.2 | Clinical assessments

Short-form McGill Pain Questionnaire (SF-MPQ), Beck Depression Inventory-Second Edition (BDI-II), State-Trait-Anxiety Inventory (STAI), and Short Form Health Survey (SF-36) were used to assess the patients at Time 0 (entry), Time 1 (pretreatment), and Time 2 (posttreatment). SF-36 comprises the physical component summary (SF-36 PCS), and the mental component summary (MCS). WAI-S was assessed at Times 1 and 2 only. These questionnaires were completed when the participants visited the outpatient clinic. Each detailed questionnaire's description is provided in Supplementary methods.

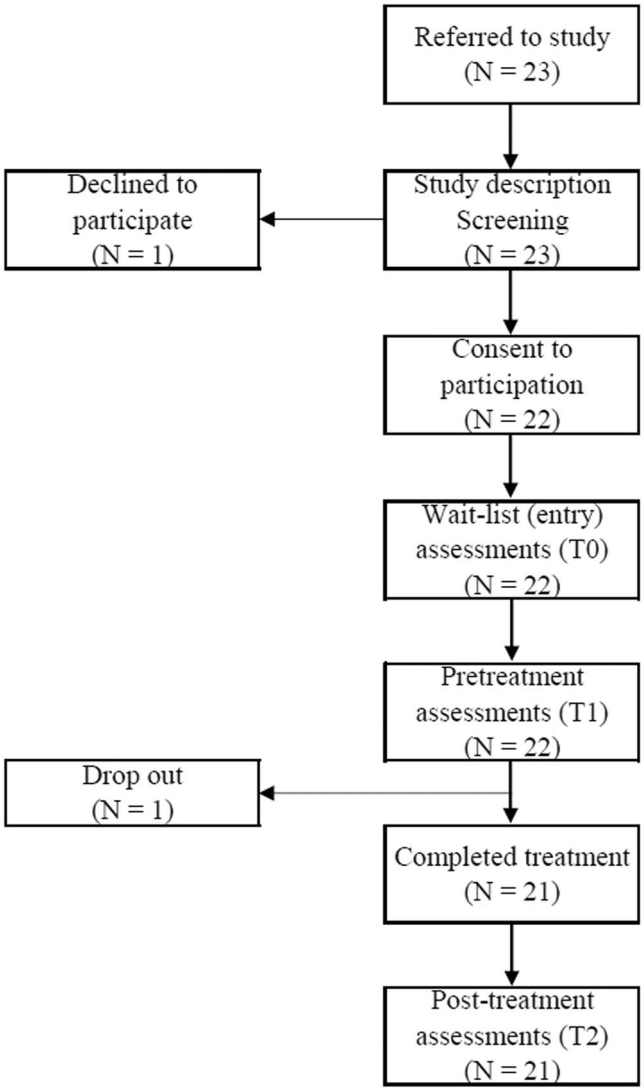

FIGURE 1 Participants flow through the study.

TABLE 1 Descriptive statistics and demographics ($N = 22$).

Demographic variables	*N*
Age, mean (SD), year	49.6 ± 12.6
Female/male	16/6
Employed	6
Single	10
Married	10
Divorced	2
Education, mean (SD), year	14.1 ± 1.7
Pain duration (months)	92.5 ± 97.4
Psychiatric diagnosis	
Somatoform pain disorder	16
Current major depressive episode	5
Major depression in history	3
Panic disorder in history	3
Physical diagnosis	
None	13
Basedow's disease	1
complex regional pain syndrome	1
Rheumatoid arthritis	1
Disc herniation	3
Others	3
Medication	
Antidepressants	14
Anticonvulsants	5
Antipsychotics	7
Minor tranquilizers	14
Analgesics	5

Abbreviation: SD, standard deviation.

2.2.1 | Pain characteristics

The SF-MPQ comprises 15 descriptors (11 for sensory and four for affective) rated on an intensity scale of 0 (*none*), 1 (*mild*), 2 (*moderate*), and 3 (*severe*). It also incorporates the Present Pain Intensity index and a Visual Analogue Scale (VAS). In our study, we employed the PCS from Sullivan et al.,[16] which is a 13-item survey aiming to measure the level of catastrophic thinking one might exhibit when exposed to pain stimuli. This scale instructs patients to reflect on a painful experience and indicates how much they thought about the statements using a 5-point Likert scale ranging from 0 (*not at all*) to 4 (*all the time*).

2.2.2 | Psychiatric assessment

We used the BDI-II to assess depressive symptoms.[17] The STAI distinguishes between situational anxiety, represented by STAI-S, and trait anxiety with STAI-T,[18] the latter being a more constantly stable characteristic in individuals. The SF-36 is a 36-item questionnaire assessing functional status and well-being.[19] The scale score spans from 0 to 100, where 0 indicates the worst health and 100 denotes the best possible health.

2.2.3 | Therapeutic alliance assessments

We used the WAI-S to assess participants' perception of their therapeutic alliance with the treatment staff providing online CBGT.[20]

2.3 | Outcome variables

We used the SF-MPQ VAS to assess pain intensity as our primary outcome. We considered pain cognition assessed by PCS and

psychiatric assessments like BDI-II, STAI, and SF-36 as the secondary outcomes.

2.4 | Treatment interventions

The online CBGT program consisted of 12 weekly sessions, each lasting 90 min. The program was based on a manualized group treatment approach. The sessions were conducted by experienced psychiatrists or psychologists, all with over 10 years of clinical experience and at least 5 years of CBT experience. The primary treatment aims included supporting self-monitoring techniques that facilitated the identification of pain, thinking, behavior, and mood; learning self-control techniques, such as relaxation and behavioral activation; and modifying specific pain-related dysfunctional beliefs. Previous studies [9,10] and Supplementary methods have described the details of this CBT intervention.

2.4.1 | Online intervention

The online CBGT intervention included content identical to that of the face-to-face version and provided a clear structure. Unfamiliarity with mobile phone technology created difficulties in understanding the intervention's content.[21] Therefore, before starting the program, we demonstrated how to use the digital content to all the participants, who were not confident about using it until they became familiar with its use. The online CBGT intervention used digital platforms (Supplementary methods). After the program started, the participants continued using the online system to access teaching materials and daily worksheets during the sessions. Following each session, our team conducted follow-ups via email to gather comments from participants and identify any adverse events.

2.5 | Statistical methods

All analyses in this study were conducted as prespecified. Taking the small sample size into account, we used the Shapiro–Wilk test to test for normal distribution.[22] We examined differences in all the outcome variables except WAI-S scores across the three assessment points using univariate repeated measures analyses of variance (ANOVAs) or Friedman test (see Figure 2). Multiple comparisons between treatment periods were made using paired-sample *t*-tests or Wilcoxon signed-rank tests with Bonferroni corrections which require a $p < 0.05/2 = 0.025$ for the two analyses between three points of time. We analyzed the WAI-S scores using paired-sample *t*-tests to assess pre- and post-treatment changes in the therapeutic alliance with $p < 0.05$ indicating statistical significance. We also calculated effect sizes. For the data on which parametric tests were conducted, Cohen's *d* was used,[23] and for the data on which nonparametric tests were conducted, the approach based on the literature[24] was used.

To assess the role of depression in the current treatment, we conducted a reanalysis incorporating the change in BDI-II scores as a covariate for comparing groups on pain measures such as VAS and PCS. Concurrently, changes in VAS and PCS scores were used as covariates in the analysis for BDI-II scores.

To evaluate the relationship between changes in the therapeutic alliance and treatment results, we explored Pearson correlations between alterations in WAI-S and alterations in pain intensity, psychological metrics (PCS, BDI-II, and STAI scores), and quality of life (QOL) measures (SF-36 scores). Using the intent-to-treat method, all examinations were completed. Missing data were filed using the "last observation carried forward" procedure. We set the Pearson correlations' statistical significance thresholds as $p < 0.05$. All analyses were two-sided with a priori levels of significance set. All data were analyzed using SPSS for Windows, version 21.0.

3 | RESULTS

One participant (4.5%) dropped out after the first session due to unfamiliarity with the treatment concept, resulting in 21 participants completing the treatment. Among these, one participant required one make-up session, and another required two due to absences. There were no adverse events, including suicidal ideation, reported.

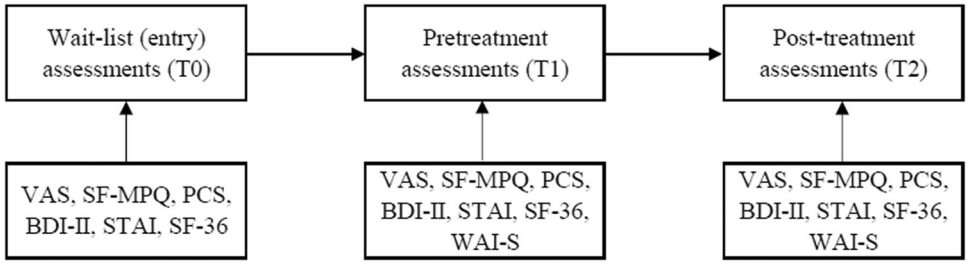

FIGURE 2 Evolution items used at each assessment point. BDI-II, Beck Depression Inventory Second Edition; PCS, pain catastrophizing scale; SF-36, short form 36; SF-MPQ, short-form McGill Pain Questionnaire; STAI, State-Trait Anxiety Inventory; T0, at entry; T1, pretreatment; T2, posttreatment; VAS, Visual Analogue Scale; WAI-S, short-form version of the Working Alliance Inventory.

3.1 | Participants and clinical background

Table 1 and Supplementary results outline the demographic and clinical characteristics of the participants.

3.2 | Effects of online CBGT

Table 2 and Supplementary results show the results of treatment outcomes. The Shapiro-Wilk test results indicated that the distributions for VAS, PCS, BDI-II, STAI, WAI-S, and SF-PCS at *T*0, *T*1, and *T*2 were normal, but those for SF-MPQ and MCS at *T*0, *T*1, and *T*2 were nonnormal.

3.2.1 | Primary outcome (SF-MPQ VAS)

An ANOVA indicated a significant main effect of the assessment period on SF-MPQ VAS (at *T*0, mean = 73.6, SD = 19; at *T*1, mean = 75.9, SD = 17.2; at *T*2, mean = 55.5, SD = 23.1; $p < 0.001$). Post-hoc analysis showed that scores for SF-MPQ VAS significantly decreased from pretreatment (Time 1) to posttreatment (Time 2).

3.2.2 | Secondary outcomes: summary (see Supplementary results for full details)

1. PCS, BDI-II, SF-MPQ sensory, and MCS scores exhibited significant improvements following treatment.
2. Reanalysis with covariates related to treatment changes in BDI-II showed no significant effects on VAS or PCS scores, and reanalysis with covariates related to treatment changes in VAS and PCS showed no significant changes in BDI-II scores.

3.2.3 | Therapeutic alliance in online CBGT

Table 2 shows that the WAI-S scores increased significantly after the treatment compared to before (*T*1; mean = 60.5, SD = 11.1, *T*2; mean = 68.7, SD = 11.6, $p = 0.003$). Table 3 shows a positive association between pre-post changes in WAI-S scores and pre-post changes in pain intensity ($r = -0.55$; $p = 0.008$) and PCS scores ($r = -0.49$; $p = 0.02$).

4 | DISCUSSION

This study evaluated the efficacy of an online CBGT intervention in chronic pain patients. The study demonstrated significant improvements in patients with chronic pain before and after the online CBGT intervention. Furthermore, we revealed the positive relationships between a therapeutic alliance and treatment effects on pain

4.1 | Online CBGT and previous research

A prior study has demonstrated the effectiveness of online CBT for chronic pain through various indicators, including pain levels, mood, and QOL.[3] However, the diversity in treatment methods (including websites, videoconferencing, telephone, and email), along with the presence or absence of therapist support, has made it challenging to form a consensus, highlighting the need for additional research in this area.[8] Among these methods, website-based interventions without the help of a therapist are predominant, comprising about 75% of the approaches. Thus, a gap exists in the research on online CBGT, conducted as a group treatment, for chronic pain, making the exploration of its effectiveness an important endeavor.

In this study, the size of this effect was nearly identical to that of our previously reported face-to-face CBGT intervention (Table 2). This indicates that, at least with support from clinicians, treatment effects could be achieved online.

4.2 | Enhancing engagement in internet-based interventions

Several studies have investigated barriers to engaging in internet-based interventions without support from clinicians. One study has reported higher dropout rates for online treatment when no support was provided.[12] Another study has suggested that remote therapy can be equally effective as regular face-to-face therapy, when clinician support is available.[6] We frequently checked their daily worksheets during treatment, and maintained regular contact by email, as detailed in Supplementary methods. We considered that these active engagement with patients would contribute to a high attendance rate and high posttreatment WAI-S scores, indicative of a positive therapeutic alliance.

4.3 | Data privacy and security

Stringent data privacy and security measures are particularly crucial for online interventions. Our study emphasized these aspects initially by securing informed consent from all participants. This consent process entailed a detailed explanation of our data privacy and security protocols shown in Supplementary methods. We recognize the necessity of vigilance regarding potential confidentiality challenges in online interventions and have taken these comprehensive measures to mitigate such risks effectively.

4.4 | Therapeutic alliance during online CBGT

The study demonstrated statistically significant correlations between pre- and posttreatment changes in WAI-S scores and clinical outcomes, including pain intensity and PCS scores. These results may show that therapeutic alliances are especially

TABLE 2 Treatment effect of the online GCBT for chronic pain (n = 22).

	T0		*T1*		*T2*			Bonferroni post hoc		Effect size in the present online GCBT				Effect size in our previous face-to-face GCBT	
								T0 < *T1*		*T1* < *T2*		*T1* < *T2*			
	Mean	SD	Mean	SD	Mean	SD	*p*-Value	*T0* < *T1*	*T1* < *T2*	ES	95% CI	ES	95% CI	ES	95% CI
Intensity of pain (VAS)	73.6	19.0	75.9	17.2	55.5	23.1	<0.001[c]	1	<0.001*	0.13	[−0.29, 0.55]	1.01	[0.47, 1.56]	1.11	[0.60, 1.62]
SF-MPQ															
Sensory	14.0[a]	6.0[b]	12.0[a]	5.5[b]	10.0[a]	7.5[b]	<0.001[d]	0.068	0.006*	0.39	[−0.04, 0.82]	0.59	[0.14, 1.04]	0.69	[0.32, 1.06]
Affective	4.0[a]	5.5[b]	4.0[a]	4.0[b]	3.0[a]	4.5[b]	0.051[d]	0.22	0.083	0.26	[−0.17, 0.69]	0.37	[− 0.06, 0.80]	0.41	[0.06, 0.76]
PCS	34.4	11.1	34.0	10.2	27.1	12.8	<0.001[c]	1	0.007*	0.04	[−0.38, 0.46]	0.68	[0.22, 1.15]	0.90	[0.50, 1.30]
BDI-II	26.8	10.8	26.1	12.2	19.3	10.7	<0.001[c]	1	<0.001*	0.06	[−0.36, 0.48]	0.56	[0.11, 1.01]	0.38	[0.03, 0.73]
STAI															
State	50.2	11.0	52.6	10.3	48.3	11.5	0.13[c]	0.53	0.11	0.23	[−0.19, 0.65]	0.42	[−0.02, 0.86]	0.47	[0.12, 0.83]
Trait	53.0	11.1	55.8	11.3	52.2	11.1	0.062[c]	1	0.055	0.25	[−0.17, 0.67]	0.32	[−0.11, 0.75]	0.33	[−0.02, 0.68]
SF-36															
SF-PCS	23.6	10.8	25.4	12.4	28.8	12.4	0.005[c]	0.23	0.19	0.17	[−0.25, 0.59]	0.28	[−0.15, 0.71]	0.12	[−0.22, 0.46]
MCS	32.4[a]	23.6[b]	21.2[a]	25.3[b]	35.8[a]	25.3[b]	0.016[d]	0.033	0.002*	0.45	[0.01, 0.89]	0.68	[0.22, 1.14]	0.48	[0.13, 0.84]
WAI-S			60.5	11.1	68.7	11.6	0.003					0.74	[0.27, 1.21]		

Abbreviations: BDI-II, Beck Depression Inventory Second Edition; CI, confidence interval; ES, effect size; MCS, mental component summary; PCS, pain catastrophizing scale; SD, standard deviation; SF-36, short form 36; SF-MPQ, short-form McGill Pain Questionnaire; SF-PCS, physical component summary; STAI, State-Trait Anxiety Inventory; T0, at entry; T1, pretreatment; T2, posttreatment; VAS, Visual Analogue Scale; WAI-S, short form version of the Working Alliance Inventory.

[a]Median.

[b]Interquartile range.

[c]Analysis of variance.

[d]Friedman test.

*$p < 0.05/2 = 0.025$.

TABLE 3 Correlations between therapeutic alliance and clinical outcomes.

Changes of variables between pre- and posttreatments									
		SF-MPQ				STAI		SF-36	
	Pain intensity	Sensory	Affective	PCS	BDI-II	State	Trait	SF-PCS	MCS
WAI-S	−0.55**	−0.24	−0.40	−0.49*	−0.07	0.07	0.19	0.07	−0.11

Abbreviations: BDI-II; Beck Depression Inventory-Second Edition; MCS, mental component summary; PCS, pain catastrophizing scale; SF-36, short form 36; SF-MPQ, short-form McGill Pain Questionnaire; SF-PCS, physical component summary; STAI, State-Trait Anxiety Inventory; WAI-S, short form version of the Working Alliance Inventory.

*$p < 0.05$.; **$p < 0.01$.

essential for dealing with cognitions. Previous research has reported similar correlations between WAI-S and treatment effects.[11] Therefore, strengthening the therapeutic alliance is critical for achieving positive outcomes. On the other hand, the improvements in the WAI-S scores assessed at the start and the end of the treatment suggest a relationship between symptom amelioration and establishing a positive therapeutic alliance by the end of the treatment. Future studies should aim for a more thorough validation of these results.

4.5 | Study limitations

The findings of this study are constrained by several limitations, narrowing their generalizability. First, this study was not a randomized controlled trial. Therefore, we must account for general factors present during psychotherapy, such as the anticipation of treatment and interactions with others who have pain, when considering CBGT's treatment effects. Second, the limited sample size and only including Japanese participants from a single facility diminish the strength of our conclusions. Third, it was necessary to consider follow-up measurements to analyze the temporal effects of the intervention, such as 1 month and 3 months later. Finally, after incorporating BDI-II score changes as a covariate in group comparison tests, no significant VAS and PCS differences were shown between pre- and posttreatment. And after incorporating VAS and PCS score changes as covariates in group comparison tests, no significant BDI-II differences were shown between pre- and posttreatment. Previous research examining the treatment of pain and depression in patients with chronic pain has revealed that these factors influence each other.[25] Our results might suggest that the treatment effects of pain and depression by CBGT influence each other. Further investigation is needed to understand the mechanisms behind the effects of this CBGT.

The results of this pilot study suggest that online CBGT has clinical benefits for chronic pain patients. However, we could not identify specific aspects of the intervention, such as the frequency of treatment, means of communication, and treatment content critical for treatment effects. Therefore, further research is needed to clarify the effects of this intervention on chronic pain.

AUTHOR CONTRIBUTIONS

Atsuo Yoshino: Methodology; conceptualization; writing—original draft; writing—review and editing. **Satoshi Yokoyama**: Methodology; writing—review and editing. **Akiko Kurata**: Methodology; writing—review and editing. **Ryuji Nakamura**: Methodology; writing—review and editing. **Tatsuro Nagami**: Methodology; writing—review and editing. **Shima Taguchi**: Methodology; writing—review and editing. **Shigeto Yamawaki**: Writing—review and editing.

ACKNOWLEDGMENTS

This study was supported by KAKENHI Grant Number 22K18647 and JST Moonshot: Grant Number JPMJM S2296. The supporting source/financial relationships had no involvement in the study design, data collection, analysis, interpretation of data, writing of the report, or in the decision to submit the report for publication.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

TRANSPARENCY STATEMENT

The lead author Atsuo Yoshino affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Yoshino A, Yokoyama S, Kurata A, et al. Clinical effects of online cognitive behavioral group therapy for chronic pain patients and developing a therapeutic alliance: a pre–post pilot trial. *Health Sci Rep*. 2024;7:e2141. doi:10.1002/hsr2.2141