Clinical and Cost-effectiveness of Videoconference-based Integrated Cognitive Behavioral Therapy for Chronic Pain: A Randomized Controlled Trial

Consent-EHEALTH Checklist V1.6.2 Report (based on CONSORT-EHEALTH V1.6), available at [http://tinyurl.com/consort-ehealth-v1.6].

Date completed: 7/16/2021 7:27:31

by Kayoko Taguchi

1a-i) Identify the mode of delivery in title

We use "Videoconference-based" as the mode of delivery. It is means web-based.

1a-ii) Non-web-based components or important co-interventions in title

If case that target is children, we think its need subitem 1a-ii, but our study for adults so it's need not subitem, we thought.

ABSTRACT

1b-i) Key features/functionalisities/components of the intervention and comparator in the METHODS section of the ABSTRACT

This study was designed as a prospective randomized open-labeled pilot trial comparing vCBT for the intervention group to treatment as usual (TAU) for the disability, pain-related catastrophic cognition, depression, anxiety, quality of life, and cost utility.

The aim of this study was to verify the cost- and clinical effectiveness of a new integrated CBT program for chronic pain, ICBT, for chronic pain management [23,24,25].

In summary, there is evidence of efficacy, although the effect size of CBT for chronic pain is small and insufficient.

Our results suggested integrated cognitive behavioral therapy delivered by videoconferencing on the regular medical care may be reduced in pain interference "although pain intensity was not changed".

INTRODUCTION

2a-i) Problem and the type of system/solution

While such remote treatment is known by several names, such as delivered CBT (ICBT), web-based CBT, telemedicine, etc., these are all strictly different interventions. Web-based CBT and ICBT were used synonymously in a study in which patients performed CBT on their own as self-help training or received regular therapist feedback that was not face-to-face [19,20].

2a-ii) Scientific background, rationale: What is known about the (type of) system

The latest review on the effect of CBT verified by randomized controlled trials (RCTs) has added 41 new studies to the existing 34 studies, thus creating a larger pool of verified RCTs. Compairisons of CBT with active controls showed a slight benefit in terms of pain intensity, disability, and distress immediately after treatment [10]. It was also observed that there were small merits of each of the three outcomes as compared to no treatment. At follow-up, pain, disability, distress, and other variables were maintained in comparison with no treatment, but there is a lack of rigorous studies that involve active controls [15]. In summary, CBT for chronic pain is small and insufficient.

Only a few studies have examined the effectiveness of videoconference CBT, which is face-to-face CBT using a videoconference system, and not general ICBT, for chronic pain management [23,24,25].

METHODS

3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio

This study was designed as a prospective randomized open-labeled pilot trial comparing vCBT for the intervention group to treatment as usual (TAU) for the chronic pain management.

3b-i) Bug Fixes, Downtimes, Content Changes

There were no important change in our methods because our intervention was videoconference CBT which face to face therapy and we used existing videoconference system.

4a) CONSORT: Eligibility criteria for participants

Eligibility Procedure for Participation and Diagnosis

Written informed consent was obtained from all patients who were fully briefed on the procedure. Following this, a screening eligibility assessment for inclusion and exclusion criteria was carried out. Exclusion criteria were as follows: (1) comorbidity of serious mental disorders such as neurocognitive disorder, psychotic disorder, bipolar disorder, or substance-related disorder based on the criteria in DSM-5; (2) major pain caused by cancer; (3) if their pain did not interfere with their daily life (PDAS: Pain Disability Assessment Scale score of 9 or less); (4) mental retardation, neurocognitive disorders (dementia), and autism spectrum disorder; and (5) litigation or compensation concerning pain symptoms. In this study, patients were required to be able to use a videoconferencing system at home. In case of patients who did not have an internet connection in their houses, we rented tablet computers and mobile Wi-Fi devices for them.

4a-ii) Computer / Internet literacy

This study was designed as a prospective randomized "open-labeled" pilot trial comparing vCBT for the intervention group to treatment as usual (TAU) for the chronic pain management.

"Our developed protocol which face-to-face CBT sessions provided by videoconference system (Web-based CBT)", has been shown to improve catastrophic cognition, did not need higher risk group.

4a-iii) Information giving during recruitment

All recruitment materials referred to our study website, which explained the study in detail. All participants who gave their permission to be enrolled in the study were required to continue treatment with their general practitioners as TAU. Patients who were interested in the study could inquire about the details via e-mail. This mail was also used as an application form to ask patients to record their age, sex, condition of chronic pain, contact information, and so forth.

4b) CONSORT: Settings and locations where the data were collected

All data was properly managed by the submitting case report form to the Clinical Research Data Center. In this center, researchers entered all data using an access-log-restricted data system, which could be verified and created datasets. Independent data monitoring committees were regularly held and performed risk-based monitoring. After all intervention was finished, the responsible doctors confirmed their datasets and locked the data. Then the locked data were transferred to the Pharmaceutical Statistics Office of the Department of Clinical Trials, Chiba University Hospital.

4b-i) Report if outcomes were (self-)assessed through online questionnaires

Our study outcome were self assessed by patients and was reported by mail.

4b-ii) Report how institutional affiliations are displayed

5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered

This study was unblind and participants were recruited face to face in the outpatient department.

1b-v) RESULTS section in abstract must contain use data

"This study was unblind and participants were recruited face to face in the outpatient department."
5-i) Mention names, credentials, affiliations of the developers, sponsors, and owners

Our intervention is CBT program provided by web system, so there were no sponsors except grant.

5-ii) Describe the history/development process

The CBT program we adopted is an integrated CBT program that is longer than conventional interventions and consists of several new sessions not used in traditional CBT protocols. Our developed protocol which face-to-face CBT session was provided by videoconference system (Web-based CBT), has been shown to improve catastrophic cognition, disability, and mood [29].

Compared to CBT programs for chronic pain often comprise 8–12 intervention sessions. In almost all programs, psychoeducation for pain, case formulation for understanding cognitive-behavioral models of chronic pain, relaxation exercises such as breathing, and cognitive reconceptualization, among others, were included [30]. Each of the 16 sessions lasted 50 minutes. We added four new sessions: tactile attention-shift training (session 4), memory work based on peak-end rule (session 10), sharpening behavioral image training (session 11), and video feedback (session 12) to the conventional CBT program shown in Table 1.

5-iii) Revisions and updating

The web based CBT program did not change throughout this trial.

5-iv) Quality assurance methods

As quality control, therapists recorded CBT session during the intervention period and maintained equality of intervention throughout supervision by responsible doctor.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing workflows of the algorithms used

Our intervention was CBT sessions face to face using videoconference system, so there is no source code etc .

5-vi) Digital preservation

Our study did not use application.

5-vii) Access

Our study did not use application.

5-viii) Mode of delivery, features/functionality/components of the intervention and comparator, and the theoretical framework

System Safety
In this study, we adopted the ISO 27001-certified Cisco WebEx as the internet conference system. Countermeasures against unauthorized access, information leakage, etc., were taken, and safety problems were cleared.

5-ix) Describe use parameters

While participating in this study, no patient was permitted to seek any new treatment other than that their primary care doctor ordered. In addition to regular medical care, those allocated to the vCBT group received weekly 50-minute sessions over 16 weeks of integrated CBT program using real-time internet videoconferencing.

5-x) Clarify the level of human involvement

All sessions were provided by therapist.

5-xi) Report any prompts/reminders used

The participants received an email invitation, attended a video conference, and attended a CBT session.

5-xii) Describe any co-interventions (incl. training/support)

There were no co-interventions.

6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Primary Outcome Measures
Pain intensity: The primary outcome was change from baseline to week 16, as indicated by the NRS score. The NRS is a self-rated questionnaire that measures pain intensity on a scale of 0–10, where 0 = "nothing" and 10 = "severe." Patients were made to keep a daily pain diary. They recorded (1) maximum pain throughout the day, (2) minimum pain, (3) usual pain, and calculated the weekly average for pain on the day of the session (each NRS score is the sum of 1-week NRS score / 7). Numerical values were obtained by averaging the values in (1), (2), and (3) as taken as the main evaluation items comprising the composite value of NRS. The measurement has been shown to be reliable and valid [39].

Secondary Outcome Measures
All secondary outcomes except the NRS were measured at 8 weeks and 16 weeks from the baseline.

Pain intensity: The secondary outcome was change in pain intensity (maximum, minimum, usual score) from baseline to week eight by the NRS.

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons

Our intervention was CBT sessions face to face using videoconference system, so there is not source code etc ..

6c) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons

Our intervention was CBT sessions face to face using videoconference system, so there is not source code etc ..

6d) CONSORT: Clarify the level of human involvement

All sessions were provided by therapist.

6e) CONSORT: Report any prompts/reminders used

The participants received an email invitation, attended a video conference, and attended a CBT session.

6f) CONSORT: Describe any co-interventions (incl. training/support)

There were no co-interventions.

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

We did not use online questionnaires.

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was measured/monitored

Our intervention was face to face CBT session using videoconference system, so it is not applicable.

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Our intervention was face to face CBT session using videoconference system, so it is not applicable.

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons

All data was properly managed by the submitting case report form to the Clinical Research Data Center. In this center, researchers entered all data using an access-restricted data system, which could be verified and created datasets. Independent data monitoring committees were regularly held and performed risk-based monitoring. After all intervention was finished, the responsible doctors confirmed their datasets and locked the data. Then the locked data were transferred to the Pharmaceutical Statistics Office of the Department of Clinical Trials, Chiba University Hospital.

7a) CONSORT: How sample size was determined

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

*Sample size*

In this study, we assumed that the difference in the amount of change in the NRS was 1.67 and the standard deviation was 1.8, and set the detection power to 80% and bilateral significance level to 5% in 1-test. As a result, the required number of subjects per group was estimated to be almost 20. In the main analysis, analysis of covariance (ANCOVA) with the allocation factor as the covariate was used, and the detection power was calculated to be 82%. As this study is a pilot study, the number of cases was determined based on its feasibility.

2) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines
Primary Outcome Measures

Pain intensity: The primary outcome was the change from baseline to week 16, as indicated by the NRS score. The NRS is a self-rated questionnaire that measures pain intensity on a scale of 0–10, with 0 = “nothing” and 10 = “severe.” Patients were asked to keep a daily pain diary. They recorded (1) maximum daily pain throughout the weekly average for pain on the day of the session (each NRS score = sum total of 1-week NRS score / 7). Numerical values obtained by averaging the values in (1), (2), and (3) are taken as the main evaluation items comprising the composite value of NRS. The measurement has been shown to be reliable and valid [39].

Secondary Outcome Measures

All secondary outcomes except the NRS were measured at 8 weeks and 16 weeks from the baseline.

Pain intensity: The secondary outcome was in pain intensity (maximum, minimum, usual score) from baseline to week eight by the NRS.

Comprehensive pain score: Comprehensive pain was assessed with the Japanese translation of the Brief Pain Inventory (BPI) [40]. BPI is composed of two factors: one assesses pain severity and the other has high reliability (coefficient alpha greater than 0.80) and established validity. Pain severity on the BPI comprises four items (worst, least, average, and current). They are assessed as 0 = “no pain” and 10 = “severe” with higher scores representing worse pain. Pain severity was calculated as the average of the four factors. Pain interference is a seven-item measure designed to assess pain interference by sleep, mood, social activities, and general activity of life. On an 11-point scale (0 = “does not interfere” to 10 = “completely interferes”), patients indicated how much pain had interfered “in the past 24 hours” with different functional aspects. This score was the average of the seven scores, and the total score was calculated as a composite score.

Cognition related to pain: Categorization of one’s perception of pain was measured using the Pain Catastrophizing Scale (PCS). The scale has been shown to have high internal consistency (Cronbach’s α range: 0.67 to 0.87) [41]. The PCS comprises 13 items that evaluate the degree of catastrophizing cognitions about pain. The response is scored 0 = “not at all” to 4 = “all the time.” The scale’s PCS scores range from 0 to 52, and the clinical cutoff value for the score is over 30 [41,42].

Depression and anxiety: Depressive symptoms were assessed with Beck’s Depression Inventory (BDI-II) [43] and Patient Health Questionnaire-9 (PHQ-9) [44]. BDI-II has an internal consistency of approximately 0.9, and the test-retest reliability ranges from 0.73 to 0.96. It consists of 21 items with four response options: “0” = never, “1” = almost never, “2” = sometimes, “3” = often, and “4” = almost always.

PHQ-9 has diagnostic validity (for the diagnosis of any one or more PHQ disorders, kappa = 0.65; overall accuracy, 85%; sensitivity, 75%; specificity, 90%). It consists of nine items scored on a 4-point Likert scale (0 = “not at all,” 1 = “on several days,” 2 = “half of more days,” and 3 = “almost daily”). The minimum score is 0 and the maximum score is 27 (0–4, 5–9, 10–14, 15–19, and 20–27, indicating “no,” “mild,” “moderate,” “moderate to severe,” and “severe” symptoms, respectively) [44]. The PHQ-9 cutoff score for clinically significant depressive symptoms is 10. Anxiety was measured on the Generalized Anxiety Disorder Scale (GAD-7), which has been shown to have reliability, and criterion and construct validity. GAD-7 consists of seven items that optimize scores (82%) were identified. The scale has seven items that assess the severity of GAD in the previous two weeks on a 4-point Likert scale (0 = “not at all,” 1 = “one episode,” 2 = “on half or more days,” and 3 = “almost daily”). The minimum score is 0 and the maximum score is 21 (0–4, 5–9, 10–14, and 15–21 indicating “no,” “mild,” “moderate,” and “severe” symptoms, respectively). The scale’s scores range from 0 to 21, and the clinical cutoff value for the score is over 10 [45].

The health-related quality of life: EuroQol-5-dimensions 5-level (EQ-5D-5L) is a widely applied, valid, and reliable measure of quality of life. Its reliability was shown to be high in terms of morbidity, self-care, comorbidity, and five items of pain/discomfort, and anxiety/depression. Patients answer each item on a scale of 1 to 5 (good to severe), and based on the score, the utility value, 0 to 1 (death to in good health), is calculated from the conversion formula, which is used for quality-adjusted life year [46].

RESULTS

No additional analyses in our study. No special complementary processing by statistical method is performed for missing values. However, if necessary, complementary analysis using MMRM (Mixed Model Repeated Measured) is carried out exploratory.

12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes

Statistical Analysis

Statistical analysis and reporting of this trial were conducted in accordance with the Consolidated Standards of Reporting Trials guidelines. "Baseline variables were compared using chi-square or Fisher’s exact test for categorical variables, and Student’s t-tests were used for continuous variables. The significance level was set at 0.05 (two-tailed). For the primary analysis of comparing treatment effects, the means of the least squares and their 95% CIs were estimated by ANCOVA with the change in the NRS composite score at week 16. This ANCOVA model took into account the variation caused by treatment effects, and gender and baseline NRS scores (x 2.63 and x 2.6) were entered as covariates. As a sensitivity analysis, we showed the transition over time of the NRS scores of each group, confirmed the course data using a linear mixed effect model, and confirmed that it was not significantly different from the ANCOVA analysis result. All comparisons were planned, and all p-values were two-sided. p-values < 0.05 were considered statistically significant. All statistical analyses were performed using SAS V.9.4. (SAS Institute, Cary, NC, USA)."

12a-i) Imputation techniques to deal with missing values

"No special complementary processing by statistical method is performed for missing values. However, if necessary, complementary analysis using MMRM (Mixed Model Repeated Measured) is carried out exploratory."

12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses

No additional analyses in our study.

13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

Patients' Demographic and Clinical Characteristics

"A total of 93.3% of patients (14/15) completed all 16 sessions of the vCBT program and participated in the intervention throughout its duration; two patients missed one session each due to participants’ living in the TAU group. None of the patients in the TAU group did not report receiving regular medical treatment at week eight and was excluded from the analysis. Finally, 15 patients in the vCBT and 14 patients in the TAU group were analyzed."

13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons

"The recruitment process resulted in a total of 38 applications for participation. Three were excluded due to dementia (n = 1), autism spectrum disorder (n = 1), suspected intellectual disability (n = 1), and five declined to participate. As a result of the eligibility assessment, 30 patients were eventually enrolled and randomized."

13b-i) Attrition diagram

In our study, this item is not applicable because face-to-face intervention using videoconference system.

14a) CONSORT: Dates defining the periods of recruitment and follow-up

"We recruited participants through web-based and newspaper advertisements from April 2018 to November 2019. It wrote in methods section. There were not reported specifically."

14a-i) Indicate if critical “secular events” fell into the study period

14b) CONSORT: Why the trial ended or was stopped (early)

"It is not applicable in our study."

15) CONSORT: A table showing baseline demographic and clinical characteristics for each group

"After comparing the criteria of the baseline characteristics of the patients, we analyzed the following demographic data: age, sex, age, education, marital status, comorbidity, employment status, age at onset of pain, duration of pain, and treatment history before they entered the intervention period (shown in Table 2)."

16) CONSORT: Report demographics associated with digital divide issues

In our study, that item was not applicable.
17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

"Primary Outcomes"

Table 3 shows the adjusted mean reductions of NRS in vCBT and TAU at 16 weeks (primary outcome) and at 8 weeks (secondary outcome) from the baseline. No significant difference was found between the two groups in changes in composite NRS scores at week 16 from baseline (p = 0.357). Table 4 shows raw data on means and standard deviations of NRS scores in vCBT and TAU at 16 weeks and 8 weeks.

"Secondary Outcomes"

Tables 5 and 6 show the results of efficacy on secondary outcomes. No significant difference was found between the two groups regarding changes in maximum, minimum, and usual NRS scores at week 16 from the baseline. In addition, there was no significant difference in the changes in all NRS scores at week 8 from baseline.

17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended

In our study, we did not use binary outcome.

18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

In our study, any other analyses including subgroup analyses and adjusted analyses did not carried out.

19) CONSORT: Subgroup analysis of comparing only users

In our study, any other analyses including subgroup analyses and adjusted analyses did not carried out.

19a) CONSORT: All important harms or unintended effects in each group

"Adverse Events"

In this study, four adverse events were reported by four different patients in the vCBT group. The first patient was hospitalized due to worsening Bechet’s disease, and declined to participate in the eyes due to medically unexplained eyelid pain, and declined to participate in the study for the fifth session. The second patient had a common cold. The fourth patient had temporomandibular joint disorders.

Table 2 shows the demographic data of the patients. There were no significant differences between vCBT and TAU in age, gender, length of education, employment status, and number of families living together (p = 0.236, p = 0.100, p = 0.725, p = 0.700, p = 0.734). Duration of illness in vCBT (M = 110.3 years, SD = 28.47) was significantly longer than that in TAU (M = 72.4 years, SD = 13.84). In both groups, more than 60% of the patients were women. Most of the patients in both groups had an education period of 12 years or more (high school graduate or higher) and were not significantly different (vCBT = 73%, TAU = 57%). At baseline, almost 30% of the patients did not work, be it full-time or part-time (vCBT = 26%, TAU = 35%). Patients were living with at least one family member and only one patient lived alone. The most reported site of chronic pain was lower back pain. Many patients had orthopedic pain, while others had oral pain such as tongue pain, toothache, and general pain such as rheumatism and fibromyalgia.

19-i) Include privacy breaches, technical problems

19-ii) Include qualitative feedback from participants or observations from staff/researchers

DISCUSSION

20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses

20-i) Typical limitations in ehealth trials

"This study has several limitations. First, the sample size was relatively small. In addition, this study was performed as a single-center study at our hospital. In the near future, many multicenter trials are necessary. Second, further studies targeting patients with specific types of chronic pain will be required to examine the effectiveness of this vCBT program. Third, because we did not use a psychological placebo group as a control condition, we were unable to compare specific factors and unravel the concrete effects of the vCBT program. Finally, the lack of follow-up data limited the generalization of the conclusions. Long-term follow-up studies should be conducted in the future."

21) CONSORT: Generalizability (external validity, applicability) of the trial findings

21-i) Generalizability to other populations

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

To our knowledge, this study is the first RCT to evaluate the effectiveness of vCBT for chronic pain. In addition, we performed a cost-effectiveness analysis of the vCBT program using ICER. Although composite pain intensity by the NRS did not change, vCBT significantly improved the total NRS score, especially pain interference and disability in daily life. Furthermore, in the medical economic evaluation, although our results showed no statistically significant difference, there was a difference that vCBT may be more cost-effective than TAU for various reasons we discuss in the following sections.

22-ii) Highlight unanswered new questions, suggest future research

"Further research is needed to examine augmentation strategies, including an examination of the components of CBT that are best suited for different types of pain. Furthermore, while the present study illustrated the cost-effectiveness of this treatment within a small sample, this needs to be verified with a larger sample size."

Other information

23) CONSORT: Registration number and name of trial registry

24) CONSORT: Where the full trial protocol can be accessed, if available

In this study, it is not applicable because our intervention is face-to-face CBT.

25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders

"Funding for this study was provided by the Health and Labor Sciences Research Grant (H29, Refractory, General, 062). The funding body had no role in the design of the study, collection, analysis, and interpretation of data and manuscript writing."

X26-i) Comment on ethics committee approval

Ethics and Dissemination

"This study was conducted with the approval of the Institutional Review Board of Chiba University Hospital (approval ID number: 290049). In addition, the Clinical Research Ethics Review Committee oversaw the proper implementation of the test at least once a year. The trial registration number was University Hospital Medical Information Network: UMIN00031124."

The patients willing to participate in this study were informed of the study objectives and were asked for their consent to participate. Each patient was informed that participation was voluntary and full anonymity would be provided. Each patient was required to provide written consent for participation.

X26-ii) Outline informed consent procedures

"Written informed consent was obtained face-to-face from all patients after they were fully briefed on the procedure."

X28) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders

"Funding for this study was provided by the Health and Labor Sciences Research Grant (H29, Refractory, General, 062). The funding body had no role in the design of the study, collection, analysis, and interpretation of data and manuscript writing."

X26-i) Comment on ethics committee approval

Ethics and Dissemination

"This study was conducted with the approval of the Institutional Review Board of Chiba University Hospital (approval ID number: 290049). In addition, the Clinical Research Ethics Review Committee oversaw the proper implementation of the test at least once a year. The trial registration number was University Hospital Medical Information Network: UMIN00031124."

The patients willing to participate in this study were informed of the study objectives and were asked for their consent to participate. Each patient was informed that participation was voluntary and full anonymity would be provided. Each patient was required to provide written consent for participation.

X26-ii) Outline informed consent procedures

"Written informed consent was obtained face-to-face from all patients after they were fully briefed on the procedure."

X28) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders

"Funding for this study was provided by the Health and Labor Sciences Research Grant (H29, Refractory, General, 062). The funding body had no role in the design of the study, collection, analysis, and interpretation of data and manuscript writing."

X26-i) Comment on ethics committee approval

Ethics and Dissemination

"This study was conducted with the approval of the Institutional Review Board of Chiba University Hospital (approval ID number: 290049). In addition, the Clinical Research Ethics Review Committee oversaw the proper implementation of the test at least once a year. The trial registration number was University Hospital Medical Information Network: UMIN00031124."

The patients willing to participate in this study were informed of the study objectives and were asked for their consent to participate. Each patient was informed that participation was voluntary and full anonymity would be provided. Each patient was required to provide written consent for participation.

X26-ii) Outline informed consent procedures

"Written informed consent was obtained face-to-face from all patients after they were fully briefed on the procedure."
“System Safety

In this study, we adopted the ISO 27001-certified Cisco WebEx as the internet conference system. Countermeasures against unauthorized access, information leakage, etc., were taken, and safety problems were cleared.”

X27-i) State the relation of the study team towards the system being evaluated