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Randomised controlled trial of cultural-adapted and programme-adopted cognitive behavioural therapy for children and adolescents' anxiety in Japan: protocol for a Multi-, Inter-, and Cross-cultural Clinical Child Study (MIXCS)

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ABSTRACT

Introduction The primary objective of the Multi-, Inter-, and Cross-cultural Clinical Child Study (MIXCS) is to evaluate the hypothesis that the effects of cultural-adapted cognitive behavioural therapy (CA-CBT) and programme-adopted cognitive behavioural therapy (PA-CBT) for children and adolescents' anxiety are both superior to a psychological control (moral education control: MEC) for reducing child and adolescent anxiety disorders and symptoms as well as related constructs. The secondary objective is to explore commonalities and differences in therapy factors between CA-CBT and PA-CBT.

Method and analysis The study has been designed as a randomised, controlled and assessor masked multicentre superiority trial with three groups: CA-CBT, PA-CBT and MEC. Primary outcome is remission of primary anxiety disorders evaluated by independent evaluators. Secondary outcomes are clinician's severity ratings, child self-reported anxiety symptoms, depressive symptoms, cognitive errors and family accommodation, as well as parent-reported anxiety symptoms, and family accommodation. Competence and adherence of treatment, therapy factors in treatment sessions are also measured based on behavioural observation. Finally, satisfaction and comprehension are collected. We aim to recruit at least 99 families for the analysis. Treatment will be delivered weekly for 10 sessions and assessment will be conducted 2 weeks before the treatment (pre), 3 months after the base date when the treatment starts (post), 6 months (six months follow-up) and 12 months (12 months follow-up) after the postassessment.

Ethics and dissemination The MIXCS study was approved by Doshisha University Research Ethics Review Committee, Kwansei Gakuin University Institutional Review Board for Medical and Biological Research Involving Human Subjects and Shinshu University Certified Review Board of Clinical Research. Regardless of the results, the primary outcome will be published in a journal, and if the efficacy and effectiveness of CA-CBT and/or PA-CBT are empirically supported, the authors will encourage dissemination of the programmes including the assessment system through key stakeholders in education, health, and welfare areas.

Trial registration number UMIN000038128

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study is the first randomised, controlled and assessor masked trial including a programme-adopted and a cultural-adapted cognitive behavioural therapies for children with anxiety disorders.
⇒ This study will assess remission of primary anxiety disorders, clinical severity ratings, anxiety symptoms, depressive symptoms, cognitive errors and family accommodation.
⇒ This study will assess competence/adherence of therapists and satisfaction/comprehension of families when two cognitive behavioural therapies are implemented.
⇒ This study will compare outcomes against a control condition at only postintervention, and thus the follow-up effects will be examined with a within-subject design.

INTRODUCTION

Background and rationale

Cognitive behavioural therapy (CBT) has been established as the first choice of psychotherapy for child anxiety.[1] However, research evaluating CBT for child anxiety in Asia is very limited.[2] Only two randomised controlled trials (RCTs), one in Hong Kong[3] and one in Japan,[4] have been conducted in Asia. Lau *et al* (2010) adapted the Coping Cat group treatment programme,[5] one of the most

widely used evidence-based CBT treatment programmes originally developed in the USA with efficacy being supported by a multisite RCT (eg, Walkup *et al*[6]). Ishikawa *et al* (2019) applied the Japanese Anxiety Children/Adolescents (JACA) CBT programme that is derived from previous studies but not a translation of existing manuals.[4] The first RCT in Japan showed that 50% children with anxiety disorders in the CBT treatment condition were free from their primary diagnoses compared with 12% in the wait-list control condition. Therefore, two different approaches were adopted in the previous trials in Asian countries; (1) a programme-adopted (PA) CBT that was a translated version of an extant evidence-based treatment programme originally derived from Western countries and (2) a cultural-adapted (CA) CBT that is a novel indigenous treatment programme based on previous studies.

Evidence-based practice consists of (1) the usage of available best evidence, (2) therapists' variables including expertise, experience and resources and (3) clients' variables including characteristics, needs/values, preferences (eg, Barlow *et al*[7]). For example, two-thirds of Japanese children did not disclose their anxious stimulus in the JACA-CBT at the first session, whereas the other one-third could discuss their anxiety.[8] Therefore, children in the latter group might prefer a programme to deal with their main concerns very early in treatment, while most might prefer a gradual approach. Therefore, it is imperative to demonstrate the efficacy of both CA-CBT and PA-CBT in Japan where CBT for children and adolescents is still not disseminated proportionately to its efficacy. Moreover, little is known about the effect of the two types of CBT programmes on competence and adherence of therapists in Asia. A cultural-adapted psychotherapy for an Asian heritage population could enhance consumers' satisfaction, knowledge about therapeutic skills and buy-in of the treatment process and methods.[9] However, given the principal of flexibility in fidelity (eg, Kendall[10]), PA-CBT can also include any modifications from the original settings maintaining its fidelity when it is introduced to another cultural context. Although these variables in CA-CBT and PA-CBT could affect efficacy and effectiveness of CBT for children and adolescents with anxiety disorders, few studies have examined these issues.

Therefore, the purpose of this study (Multi-, Inter-, and Cross-cultural Clinical Child Study: MIXCS) is to compare the effects of CA-CBT and PA-CBT with an active control condition on anxiety symptoms/disorders. As PA-CBT, Cool Kids[11] is applied in this study, because it was one of the most widely used treatment manuals among CBT interventions for children with anxiety disorders in addition to Coping Cat.[12] This study uses JACA-CBT as CA-CBT because it was the only empirically supported CBT intervention for children/adolesctents anxiety in Japan as discussed earlier. The results will provide empirical data on culture-specific applications and universal mechanisms of action in CBT.

Choice of comparators

The control group in MIXCS is referred to as a moral education control (MEC). Participants allocated to the MEC are instructed to read school textbooks about moral education published by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and discuss the contents of the book with therapists. This comparator aims to control for the effect of reading materials related to psychological issues and discussing these concepts with psychologists while excluding active components of CBT. Therefore, the condition can be considered as an attention control group.

Hypothesis and objectives

The objective of this trial is to evaluate the hypothesis that the effects of PA-CBT and CA-CBT are both superior to MEC for remission from primary anxiety disorders. We also expect that there are no significant differences between two CBT groups regarding primary and secondary outcomes, whereas CA-CBT outperforms PA-CBT for indices of acceptability, such as children's and parents' satisfaction and understanding as well as therapists' compliance and proficiency. In addition, this study explores commonalities and differences in therapy factors between CA-CBT and PA-CBT.

METHODS AND ANALYSIS

Trial design

The MIXCS has been designed as a randomised, controlled and assessor masked multicentre superiority trial with three groups: CA-CBT, PA-CBT and MEC across three different sites: Kyoto, Hyogo and Nagano prefectures in Japan from 2022 to 2025. Recruitment was started on 1 January 2022, trial started on 1 April 2022, and the trial will end on 31 March 2025. The trial flowchart is depicted in the Consolidated Standards of Reporting Trials diagram (figure 1).

Participants will be allocated to the three groups with equal ratio (ie, 1:1:1) at the first stage of randomisation with biased-coin assignment balancing gender and age. The allocation will be performed by personnel in an independent data management centre (Shinshu University Hospital, Centre for Clinical Research) using University Hospital Clinical Trial Alliance Clinical Research Support System (UHCT ACReSS). Block and stratified randomisation will be used to minimise imbalances in (1) biological gender (male, female) and (2) age range (child: 8–12 years, adolescent: 12–15 years).

After completion of MEC, participants in the control group will attend either CA-CBT (MEC-C) or PA-CBT (MEC-P) based on a predetermined random allocation with 1:1 ratio. MEC-P and MEC-C is supposed to be integrated into CA-CBT and PA-CBT for secondary analyses, respectively. A power analysis of the superiority trial is computed based on the first randomization of three groups.

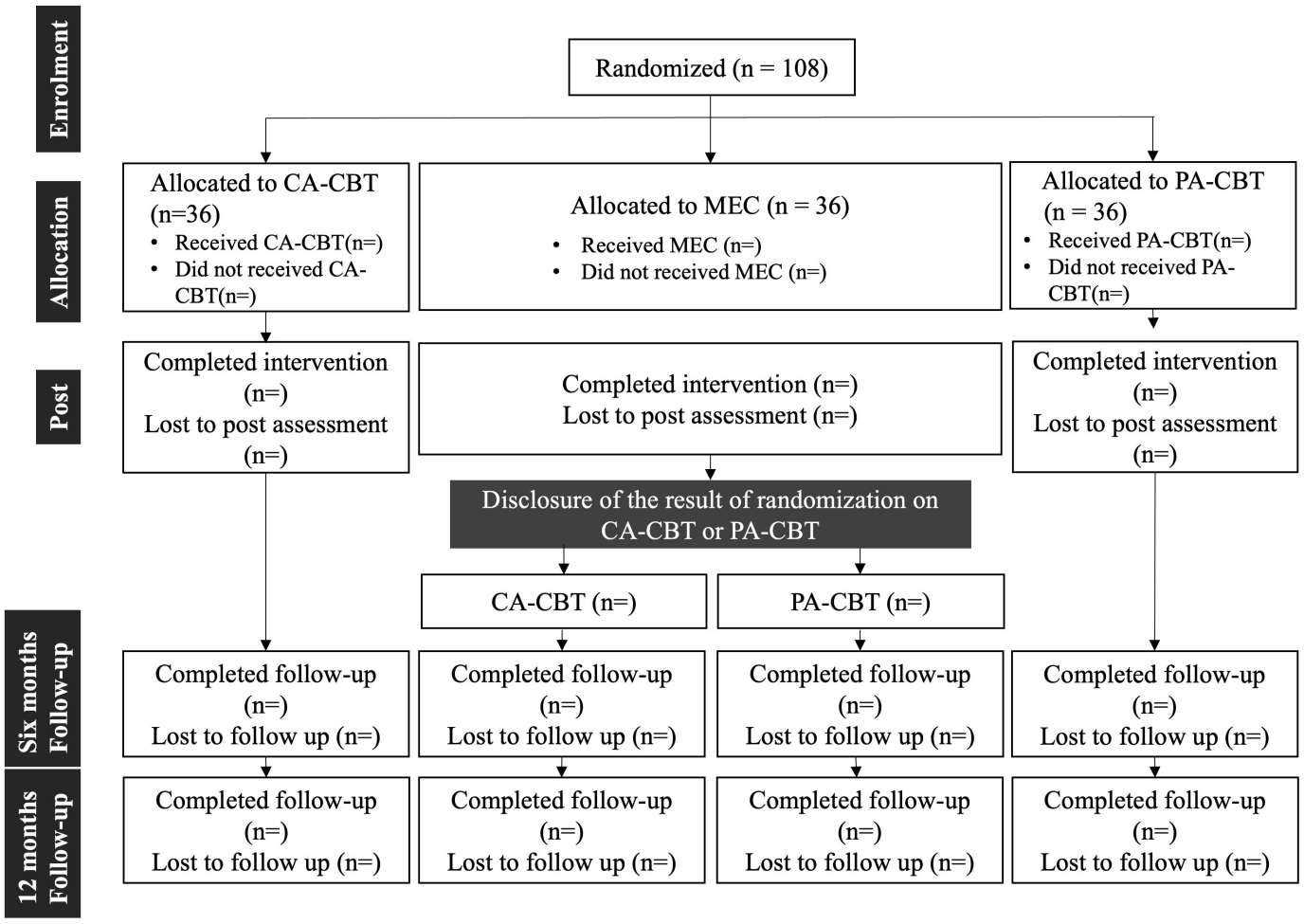

Figure 1 CONSORT flowchart of the study design. CONSORT, Consolidated Standards of Reporting Trials. CA-CBT, cultural-adapted cognitive behavioural therapy. MEC, moral education control. PA-CBT, programme-adapted cognitive behavioural therapy.

Eligibility criteria

Individuals fulfilling the following inclusion criteria will be registered to participate in the trial:(1) children aged 8–15 years old, (2) parent/s and child are available to attend the treatment in person, (3) children who meet Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) criteria for an anxiety disorder (ie, separation anxiety disorder, social anxiety disorder, specific phobia and generalised anxiety disorder) and (4) children free from any other treatments or these treatments can be controlled (eg, washout or fixed period for pharmacotherapies). Exclusion criteria is as follows: (1) children with intellectual developmental disorder (2) children with externalising disorders, substance abuse and schizophrenia as primary and secondary diagnoses and (3) children with autism spectrum disorder, attention deficit/hyperactivity disorder, specific learning disorder and other developmental disorders as primary diagnoses.

Interventions

The intervention groups in the study will receive either (1) PA-CBT which is a translated version of an extant evidence-based treatment programme originally derived from Western countries and (2) CA-CBT which is an indigenous programme based on previous studies aiming at developing a novel treatment (table 1). Participants in both groups will participate in 10 sessions of 60 min each. The period between the beginning of intervention and the postassessment is approximately two and a half months.

Cultural-adapted cognitive behavioural therapy (CA-CBT)

The CA-CBT programme was developed based on existing evidence-based CBT for anxious youth.[4] After the development, it was elaborated through both theoretically driven modifications and feedback from clinicians in the indigenous cultural group for approximately 10 years.[4] While the original protocol consists of eight sessions and several booster sessions, this study provides 10 sessions to be comparable with PA-CBT. Therapists training consists of (1) watching training videos (144 min) and reading treatment resources, (2) observing a past treatment session and (3) conducting a pilot case. If therapists have a question about implementation of CA-CBT, they can discuss the issues with supervisors who are in charge of

Table 1 Components of the interventions

No.	Components of CA-CBT	No.	Components PA-CBT
1	Psychoeducation	1	Psychoeducation
2	Psychoeducation	2	Realistic thinking
3	Cognitive restructuring	3	Anxiety hierarchy
4	Cognitive restructuring	4	Anxiety hierarchy
5	Cognitive restructuring	5	Review exposure progress
6	Anxiety hierarchy	6	Review exposure progress, in-session exposure
7, 8, 9	In-session exposure, cognitive restructuring and relaxation	7, 8, 9	Review exposure progress, in-session exposure
10	Conclusion, future exposure	10	Review, maintenance and future plans

CA-CBT, cultural-adapted cognitive behavioural therapy; PA-CBT, programme-adopted cognitive behavioural therapy.

each site (ie, Kyoto, Hyogo and Nagano) in person or via online.

Programme-adopted cognitive behavioural therapy (PA-CBT)

In PA-CBT, children and parents will receive 10 sessions of Cool Kids.[11] Cool Kids was translated into Japanese by first and last authors (HNT and SI) according to the standardised procedure of the developers (ie, Centre for Emotional Health, Macquarie University) supervised by the sixth author (JLH). Therapists training consists of (1) watching training videos (273 min) and reading a treatment manual, (2) watching a Q and A session including tips of the implementation of Cool Kids, (3) observing a roleplay or past treatment session and (4) conducting a pilot case.

Morality education control (MEC)

Participants in the MEC condition will be given a supplementary reading book on morality education recommended by MEXT. They will have three individual sessions (over 10 weeks) to introduce and discuss the contents in the textbook with a practitioner. After the period of morality education, children in the MEC condition will then be randomly assigned to either CA-CBT or PA-CBT group. The assigned group will be sealed until the end of the morality education, then the result will be opened to the practitioner.

Outcomes

The assessment of outcomes will be conducted according to the schedule shown in table 2. See table 2 and online

Table 2 Summary and schedule of assessments

Item	Reception (telephone and/or online)	Pre	Intervention	Post	6 months FU	12 months FU	Dropout
Time		2 weeks before CBT	Approx. 10 weeks	3 months±1 month	6 months±1 month	12 months±1 month	
Visit	Time 0	Time 1		Time 2	Time 3	Time 4	
Background information	●						
Informed consent		●					
Eligibility	●	●					
Diagnostic interview		●		●	●	●	●
Child-report/parent-report outcomes		●		●	●	●	●
Behavioural observation			●				
Satisfaction and comprehension (child/parent)				●	●		
Checking-in		●	●	●	●	●	

CBT, cognitive behavioural therapy; FU, follow up.

supplemental material 1 for a summary of study measurements collected at preintervention (baseline), postintervention, 6 months follow-up and 12 months follow-up. The assessment will be done by independent evaluators (IEs) who are clinical psychologists or psychologists in training. They will receive a one day training by the third author (MS) who is an experienced clinical psychologist regarding implementing the Anxiety Disorders Interview Schedule (ADIS) and observed previous interview sessions. Diagnoses will be based on information provided by both informants (ie, composite diagnoses).

The efficacy of the interventions will be assessed by comparing CA-CBT/PA-CBT with MEC at postintervention. After 6 and 12 months, the acceptability (ie, satisfaction, understanding, compliance and proficiency) will be assessed by comparing CA-CBT with PA-CBT.

Primary outcome

The primary outcome is to examine remission in the participant's primary anxiety disorder evaluated by IEs based on the ADIS for DSM-IV for children[13] from Time 1 assessment to Time 2 assessment. IEs cannot access allocation status which is in an independent cloud storage system and managed by a data management centre as described below.

Secondary outcomes

As a secondary measure, self-report and parent-report questionnaires will be used to assess the efficacy of the interventions. The secondary outcomes are clinician's severity ratings (CSRs), child self-reported anxiety symptoms, depressive symptoms, cognitive errors and family accommodation, as well as parent-reported anxiety symptoms and family accommodation. CSRs are evaluated by the IEs based on the ADIS. Self-reported and parent-reported anxiety symptoms are measured by the Spence Children's Anxiety Scale for children (SCAS)[14] and SCAS for parents (SCAS-P),[15] respectively. This study uses the translated versions of the SCAS and SCAS-P, which have shown good reliability and validity in previous studies.[1617] Self-reported depression symptoms are measured by the Japanese version of the Depression Self-Rating Scale for Children,[18] which was developed based on the original version of the DSRS[19] and demonstrated good reliability and validity. Cognitive errors are assessed by the Children's Cognitive Error Scale (CCES).[20] The scale was developed and validated in Japan. Self-reported and parent-reported family accommodation is measured by the Family Accommodation Scale for Anxiety (FASA)[21] and child report version (FASA-CR).[22] The FASA and FASA-CR are translated into Japanese and the reliability and validity of these scales are currently being confirmed.

Other measures

The MIXCS also measures therapy factors to explore commonalities and differences between cultural-adapted and programme-adopted CBTs. Competence and Adherence Scale for Cognitive Behavioural Therapy (CAS-CBT)[23] and Cross-cultural Behavioural Observation System (C-BOS)[24] are used for the purpose. The coders for the C-BOS will receive training based on the procedure of the previous study.[8] In addition, satisfaction and comprehension for both children and parents, compliance, familiarity and sustainability by therapists and the level of understanding by participants are measured.

Recorded videos of the interventions will be used for the analysis of CAS-CBT and C-BOS. The video is recorded using existing equipment in each facility (eg, video monitoring systems). Video recording and management will follow each facility's regulations. The data required for the final analysis, which does not contain personal data, are shared in a secure and controlled system, as described in 'Data Management'. Researchers at Macquarie University will train therapists, but not provide data.

Sample size and recruitment

Based on a meta-analysis of individual CBT versus waitlist/no treatment and child-focused CBT versus attention control,[12] we predict a differential remission from primary anxiety disorder between active treatments and MEC of 27.20%. To provide power=0.80 to detect this difference at an alpha=0.05, we will require 99 participants, that is, 33 participants for each group. It is possible that the number of participants may vary slightly between sites depending on the recruitment situation and attrition is expected at less than 10% after allocation based on the previous trial (9.80%).[4] Therefore, the study aims to collect 108 participants (36 in each group) in total.

Masking

Assessments will be conducted by IEs blinded to the allocated interventions. The allocation will not be revealed to IEs until the final data set has been fixed. Due to the nature of the intervention, neither participants nor staffs can be blinded to allocation but will be strongly discouraged from disclosing the allocation status of the participant to the IE at the post and follow-up assessments. An outsourced data centre outside the research team will manage and monitor the data in the electronic data capture (EDC) system.

Criteria for discontinuing or modifying allocated interventions

The intervention or follow-up assessment will be discontinued when any of the following issues occur: (1) the participant requests to be removed from the study or withdraws consent, (2) inability to contact the participant, (3) the entire clinical trial has been discontinued, (4) found to be ineligible after the enrolment and/or (5) any other reasons that the primary investigator, practitioner or supervisor have deemed worthy of discontinuation (eg, hospitalisation or suicide attempt). If the primary investigator, practitioners or supervisor feel that the participant should discontinue, they will explain the reason for discontinuation to the participant. If the participant cannot be contacted or drops out of the study, therapists will make efforts to confirm the situation (eg, phone

call or e-mail), including any exacerbation of symptoms. These details will be documented and saved in a case report form. Additionally, the availability of data use and continuation of evaluation will be recorded.

Plan to promote participant retention and complete follow-up

No monetary or physical incentives will be provided to participants at any point during the assessment or intervention. For participants included in the study, the researchers explain that they will be randomly allocated to the CA-CBT, PA-CBT or MEC group and even if they are in the MEC group, they will be randomly allocated to either the CA-CBT or PA-CBT group after the post assessment regardless of their diagnostic status at that time point.

Data management

This clinical study will use an EDC system for clinical research to collect the data required. We use an EDC system, UHCT ACReSS Cloud Service. The one who prepares the case report should promptly enter the data into the EDC system and ensure that the information on individual subjects is recorded correctly. The principal investigator, research assistants and coinvestigator should submit the data using EDC by the predetermined reporting time. Approval is obtained from the principal investigator or coinvestigator if the data are to be submitted by the research assistant. Interim analyses are not planned at present.

Statistical methods

Multiple imputation will be used to handle missing data. All outcome analyses will be an intention-to-treat analysis. For primary outcomes, the proportion of participants who no longer meet criteria for a primary anxiety diagnosis at post-treatment (Time 2) in the three conditions (CA-CBT, PA-CBT and MEC) will be compared using χ^2 tests. A mixed-effects model will be used for analyses of secondary outcomes including CSRs, child self-reported anxiety symptoms, depressive symptoms, cognitive errors and family accommodation and parent-reported anxiety symptoms in addition to satisfaction and understanding for children and parents as well as therapists' compliance and proficiency.

For exploratory analyses, MEC conditions will be incorporated into two CBT conditions as MEC-C and MEC-P, respectively. Several significant differences in therapy factors captured by the C-BOS were found when comparing between Cool Kids in Australia and JACA-CBT in Japan with the n=30 for each group, respectively.[8] However, to detect moderate effect sizes (d=0.3) with alpha=0.05 and power=0.80, the total sample size should be reached up to 82. Therefore, we will integrate MEC-C into CA-CBT (aggregated CA-CBT) and MEC-P into PA-CBT (aggregated PA-CBT), respectively, and compare therapy factors obtained from behavioural observations between two groups. For the analyses, Time 1 data for two CBT conditions as well as Time 2 data for MEC group will be handled as a baseline of behavioural observation data and 6 months and 12 months data will be used as dependent variables for predictive examination. We will also conduct exploratory analyses to examine whether any therapeutic factors can predict primary and secondary outcomes.

Data monitoring and auditing

Data monitoring and auditing have not been planned as the invasiveness of the MIXCS study was deemed sufficiently low.

Assessment of harm and invasiveness

Children and parents participating in these programmes are asked to refer to the subject of their anxiety to formulate steps to overcome their problems. Therefore, a temporal increase in anxiety can be expected. Other general risks associated with psychotherapy are also assumed. On that account, at check-in of each session, we will ask about the existence of an increase in uncomfortable physical or psychological symptoms, changes in the treatment received outside the study, changes in the living environment and any adverse events will be recorded. If an adverse event occurs, the principal investigator and/or coinvestigators will deal with it in good faith and provide a full explanation in writing and orally that psychological consultation services are available at the facility concerned. The content of the services, fees and other arrangements in such cases shall be following the regulations of the facility concerned.

Patient and public involvement

Since the patients targeted by this study are children and adolescents who require parental consent, patient involvement in the research was unfeasible. Besides, a community member who represents the public is involved in the institutional review board (IRB process).

ETHICS AND DISSEMINATION

Research ethics approval, protocol amendments and consent

The MIXCS has been approved by Doshisha University Research Ethics Review Committee (approved number: 19046-2; 30 January 2020), Kwansei Gakuin University Institutional Review Board for Medical and Biological Research Involving Human Subjects (approved number: KG-IRB-20-03; 28 July 2021) and Shinshu University Certified Review Board of Clinical Research (approved number: 330; 28 February 2022). Approval from these committees will be required to change the protocol, forms and documents used to obtain informed consent. Details of the MIXCS will be explained to parents and a child/adolescent prior to their participation in the study. Written informed consent will be obtained from parents who agree to participate in the study and verbal assent from a child/ adolescent.

Confidentiality

All data obtained will be securely stored at each site where psychological counselling facilities in universities are

experts in the protection of personal data. The storage and location of the data, as well as the handling of the data, is handled by the terms of reference of each site. The collected paper documents will be filed separately according to the participant. These files will be stored in a locked cabinet located in a doubly locked room. Personal identity-related information will not be entered into the electronic database. The key connecting the participant numbers and names will be kept separate from the data files and the access to the file is regulated to the principal investigator and coinvestigates who are the head of each site. All other electronic data will be saved to an encrypted hard drive or USB with a password lock. The hard drive or USB will be stored in the locked cabinet. All other papers with identifying information (ie, signed informed consent forms) will also be stored in the locked cabinet.

Access to data

The principal investigator and coinvestigators of the MIXCS have access to the final study data set. Prior to publication of the primary outcome paper, the data manager will have access to the full data set. The data manager will verify any problems (eg, missing data and illogical data) in the data by consulting with the principal and coinvestigators when necessary. After completion, the data manager will finalise the data set for statistical analysis. Following publication, only the principal investigator, coinvestigators and those individuals who receive approval from the principal investigator will have access to the cleaned data set.

Ancillary and post-trial care

The principal investigator and the coinvestigators of this study are all specialised in clinical psychology. From their professional perspectives, they will supervise therapists and IEs in this trial and refer participants to appropriate agencies or take other action if they are deemed to have any unforeseen circumstances. Even for subjects who were not included in the study or who were dropout from the programme, a full explanation will be given in writing and orally that psychological consultation services will be available at the institution concerned. The content of the services, fees and other arrangements will follow the regulations of the institution concerned. The research team will provide a full written and verbal description of psychological services available at the sites, even if the participant is excluded from the study or drops out from the intervention.

Dissemination policy

Regardless of the results, the primary outcome will be published in a peer-reviewed journal. If the efficacy and effectiveness of CA-CBT and/or PA-CBT are empirically supported, the authors will encourage dissemination of the programmes including the assessment system through key stakeholders in education, health and welfare areas.

DISCUSSION

The MIXCS trial is designed to examine whether both CA-CBT and PA-CBT are superior to an attention control condition. Evidence has consistently shown that CBT is the first-line psychosocial intervention for anxiety disorders in children and adolescents, but there is no guideline in which empirically validated treatment manual should be chosen depending on diverse cultural backgrounds. If the both treatments produce substantial treatment gains, practitioners can select either treatment protocol depending on each therapy factor such as clients' preferences and therapists' proficiency. Moreover, the trial will identify common and different therapy factors between cultural-adapted and programme-adopted CBT sessions such as compliance and proficiency. Based on a transdisciplinary model of evidence-based practice, best available research evidence should be applied after considering client parameters such as characteristics, state, needs, values and preferences and provider parameters such as infrastructures and therapists' expertise.[7] Therefore, the study will provide practical implications for clinical decision making for treatment of child and adolescent anxiety disorders.

There are three major limitations of the study. The first limitation is that we cannot set large enough sample size to directly compare CA-CBT and PA-CBT groups. In a previous trial conducted by the authors in a similar setting to the MIXCS,[4] only 51 participants were recruited from 2012 to 2015: the same length of the MIXCS. Based on the experience, it would only be possible to recruit a maximum of 150 in 3 years with three centres. Due to the limitation of operations during COVID-19, it is not realistic to recruit a directly comparable number of participants for a short-term study with a defined grant period. Furthermore, because participants in the MEC condition also receive active treatments after the post-assessment (Time 2), this study is unable to examine group differences for 6 months and 12 months data (Times 3 and 4). Second, since there is no official treatment as usual condition for Japanese children and adolescents' anxiety, we have a moral education group as a control group: it is impossible to compare active controls with so-called treatment as usual. Finally, we have been experiencing repeated postponements of recruitment due to restrictions on admission to the facilities where the programme is to be conducted caused by the COVID-19 outbreak. Since it is difficult to predict the future infectious status, various restrictions on the trials implementation and participant recruitment are anticipated. Despite these limitations, this study is expected to provide useful data regarding the adoption of psychosocial intervention into non-western regions.

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Contributors SI conceived of the study. MS, FT, HS, JLH, RMR and SI initiated the study design and HNT and SU helped with implementation. SI is a grant holder. HS, SU and FT provided statistical expertise in clinical trial design. All authors contributed to refinement of the study protocol and approved the final manuscript.

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Competing interests SI developed the CA-CBT programme as well as the Japanese versions scales which will be used in this study (ie, SCAS, SCAS-P and CCES), and he will not receive any personal financial benefit from the trial. JLH and RMR were the authors of the PA-CBT programme and they will not personally receive royalties from the sale of the programme in this trial.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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