Abstract No. : 0236
Presentation Category : Posters
Scientific Streams : Anxiety Disorders

Study protocol for a randomized controlled trial of culturally-adapted and program-adopted cognitive behavioral therapy for children and adolescents' anxiety in Japan: A Multi-, Inter-, and Cross-cultural Clinical Child Study (MIXCS)

Mayuri Yoshioka[1*], Shinaru Kato[1], Hikari N.takashina[1,2], Satsuki Ueda[3], Mie Sakai[4], Fumito Takahashi[5], Hiroshi Sato[6], Jennifer L. Hudson[7], Ronald M. Rapee[8], Shin-ichi Ishikawa[9]

[1] , *Kwansei Gakuin University, Japan*
[2] *Research Center for Child Mental Development, Chiba University, Japan*
[3] *Faculty of Clinical Psychology, Kyoto Bunkyo University, Japan*
[4] *Graduate School of Medical Sciences Department of Anesthesiology and Intensive Care Medicine, Nagoya City University, Japan*
[5] *Institute of Education, Shinshu University, Japan*
[6] *School of Humanities, Kwansei Gakuin University, Japan*
[7] *Black Dog Institute, University of New South Wales, Australia*
[8] *Centre for Emotional Health, School of Psychological Sciences, Macquarie University, Australia*
[9] *Faculty of Psychology, Doshisha University, Japan*

Introduction:Though there is strong support for the effectiveness of cognitive behavioral therapy (CBT) for anxiety disorders in children (Higa-McMillan et al., 2016), there has been limited research on evaluating CBT for children's anxiety in Asia (Hall, Ibaraki et al., 2016). For practitioners who work in diverse cultural contexts, it is important to determine whether they should apply a program-adopted cognitive behavioral therapy (PA-CBT) or a culturally-adapted cognitive behavioral therapy (CA-CBT) for their clients. The aim of this protocol study was to conduct a Multi-, Inter-, and Cross-cultural Clinical Child Study (MIXCS) that examines the efficacy of CA-CBT and PA-CBT in comparison with a psychological control (moral educational control: MEC). Additionally, commonalities and differences in therapy factors between CA-CBT and PA-CBT are explored.
Method:This study has been designed as a randomized, controlled, and assessor-masked multicenter superiority trial with three groups: PA-CBT, CA-CBT, and MEC across three different sites: Kyoto, Hyogo, and Nagano prefectures in Japan from 2022 to 2025. Participants will be allocated to the three groups in equal ratio at the first stage of randomization with biased-coin assignment balancing gender and age.The primary outcome is to examine participants' remission of their primary anxiety disorder by an independent evaluator based on the Anxiety Disorders Interview Schedule for DSM-IV (ADIS; Silverman & Albano, 1996). The secondary

outcomes are clinician's severity ratings, child self-reported anxiety symptoms, depressive symptoms, cognitive errors, and family accommodation, in addition to parent-reported anxiety symptoms and family accommodation. This study additionally measures therapy factors in order to explore commonalities and differences between culturally adapted and program adopted CBTs. Finally, satisfaction and comprehension are also collected. The objective is to recruit at least 99 families for the analysis. Treatment will be delivered ten times weekly, with four evaluations: two weeks before the treatment (pre), three months after the base date when the treatment starts (after), and six months (6FU) and 12 (12FU) months after the post-assessment.This study was approved by Doshisha University Research Ethics Review Committee, Kwansei Gakuin University Committee for Regulations for Behavioral Research with Human Participants, and Shinshu University Certified Review Board of Clinical Research.
Results & Discussion:This study will suggest that if both treatment conditions produce substantial therapeutic gains, practitioners can select either treatment protocol depending on each therapy factor such as clients' preferences and therapists' proficiency. In addition, the study will identify common and different therapy factors between culturally adapted and program adopted CBT sessions such as compliance and proficiency. Therefore, the study will provide practical implications for clinical decision-making in the treatment of child and adolescent anxiety disorders.

Takashina, H. N., Ueda, S., SAKAI, M., Takahashi, F., Sato, H., Hudson, J. L., … Ishikawa, S. (2023, January 20). Multi-, Inter-, and Cross-cultural Clinical Child Study. Retrieved from osf.io/mfqp9

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[1]Kwansei Gakuin University, Japan [2]Research Center For Child Mental Development, Chiba University, Japan [3]Faculty of Clinical Psychology, Kyoto Bunkyo University, Japan [4]Graduate School of Medical Sciences Department of Anesthesiology and Intensive Care Medicine, Nagoya City University, Japan [5]Institute of Education, Shinshu University, Japan [6]School of Humanities, Kwansei Gakuin University, Japan [7]Black Dog Institute, University of New South Wales, Australia [8]Centre for Emotional Health, School of Psychological Sciences, Macquarie University, Australia [9]Faculty of Psychology, Doshisha University, Japan

Background and Purpose

Background

- Though there is strong support for the effectiveness of cognitive behavioral therapy (CBT) for anxiety disorders in children (Higa-McMillan et al., 2016), there has been limited research on evaluating CBT for children's anxiety in Asia (Hall et al., 2016).
- For practitioners who work in diverse cultural contexts, it is important to determine whether they should apply a program-adopted cognitive behavioral therapy (PA-CBT) or a culturally-adapted cognitive behavioral therapy (CA-CBT) for their clients.

Purpose

1. A Multi-, Inter-, and Cross-cultural Clinical Child Study (MIXCS) that examines the efficacy of CA-CBT and PA-CBT in comparison with a psychological control (moral educational control: MEC).
2. Commonalities and differences in therapy factors between CA-CBT and PA-CBT are explored.

Methods

Trial Design

- This study has been designed as a randomized, controlled, and assessor masked multicenter superiority trial with three groups: PA-CBT, CA-CBT, and MEC across three different sites: Kyoto, Hyogo, and Nagano prefectures in Japan from 2022 to 2025 .
- Participants will be allocated to the three groups with equal ratio at the first stage of randomization with biased-coin assignment balancing gender and age.
- Block and stratified randomization will be used to minimize imbalances in 1) biological gender and 2) age range.

Eligibility Criteria

- Individuals fulfilling the following inclusion criteria will be registered to participate in the trial: (1) children aged 8 to 15 years old, (2) parent/s and child are available to attend the treatment in person, (3) children who meet DSM criteria for an anxiety disorder, (4) children free from any other treatments or these treatments can be controlled.

Outcome

- The primary outcome is to examine remission in the participant's primary anxiety disorder evaluated by independent evaluators based on the Anxiety Disorders Interview Schedule for DSM-IV for children (ADIS; Silverman & Albano, 1996).
- The secondary outcomes are clinician's severity ratings, child self-reported anxiety symptoms, depressive symptoms, cognitive errors, and family accommodation, in addition to parent-reported anxiety symptoms, and family accommodation.
- Therapy factors are measured to explore commonalities and differences between culturally adapted and program adopted CBTs.
- Satisfaction and comprehension are collected.

Intervention

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

Ethical Considerations

- This study was approved by the ethics committees of the respective institutions.

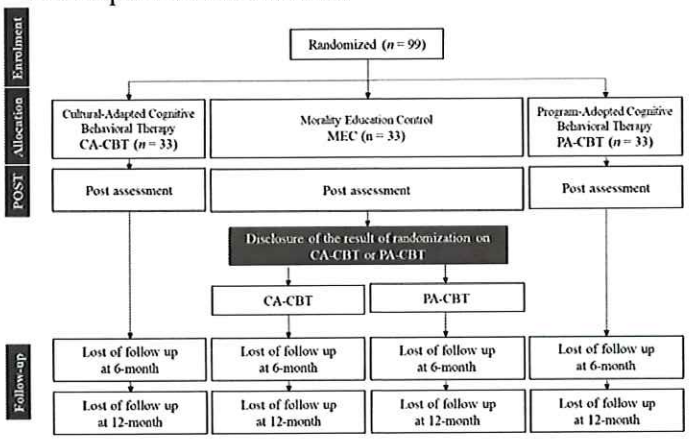

Figure 1. CONSORT flowchart of the study design.

Results and Discussion

- This study will suggest that 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.
- In addition, the study will identify common and different therapy factors between culturally adapted and program adopted CBT sessions such as compliance and proficiency.

The study will provide practical implications for clinical decision making in the treatment of child and adolescent anxiety disorders.

OSF
Takashina, H. N., Ueda, S., SAKAI, M., Takahashi, F., Sato, H., Hudson, j. L., ...Ishikawa, S. (2023, January 20). Multi-, Inter-, and Cross-cultural Clinical Child Study.

UMIN-ICDR Clinical Trial
https://center6.umin.ac.jp/cgi-open-bin/icdr_e/ctr_view.cgi?recptno=R000043456

発表概要報告書

【大会概要】

2023年6月1日から6月4日にかけて、韓国で開催された、認知行動療法の専門国際学会である、World Congress of Cognitive and Behavioral Therapies (WCCBT) に参加した。3年に1度行われる大会であるが、昨年度まではCOVID-19の影響により開催が延期されていた。この度4年ぶりに、韓国ソウルにて対面開催となった。本大会では、「Global CBT Dissemination、Accessibility、 and New Technology」をテーマに掲げ、世界中のCBTの専門家とCBTの今後について議論を行うことのできる機会が提供された。

【発表内容の概要】

“Study protocol for a randomized controlled trial of cultural-adapted and program-adopted cognitive behavioral therapy for children and adolescents’ anxiety in Japan: Multi-、 Inter-、 and Cross-cultural Clinical Child Study (MIXCS)”という演題で、ポスター発表を行った。

本研究プロトコルでは、不安症の子どもを対象に、海外で普及している認知行動療法プログラム (PA-CBT) と、本邦で実施されているプログラム (CA-CBT) の効果を比較して、心理療法の世界的な共通要素と各文化に特有の要素を明らかにすることを目的としている。

本研究プロトコルは、PA-CBT、CA-CBTおよび読書による道徳教育 (MEC) の3群によるランダム化比較試験を用い、主要なアウトカムとして、半構造化面接Anxiety Disorders Interview Schedule for DSM-IV for children (ADIS) によるブラインド性評価を行っている。

両治療条件において実質的な治療効果が得られるのであれば、クライアントの好みやセラピストの熟練度などの各治療要因に応じて、実践者はどちらの治療プロトコルを選択してもよいことが示唆されるであろう。さらに、本研究では、コンプライアンスや熟練度など、文化的に適応されたCBTセッションとプログラム採用のCBTセッションに共通する治療因子と異なる治療因子を明らかにする。したがって、本研究によって、児童・思春期の不安障害の治療における臨床的意思決定のための実践的な示唆を与えるであろう。

【学会体験記】

ポスター発表は、前半と後半の2部に分かれており、それぞれの掲示時間は4時間と十分な時間が設けられていたため、様々な領域のポスターを見ることができた。本学会のポスター作製においては、2019年ぶりの対面開催となったため、視覚的に見やすくなるよう意識した。オンラインと異なり口頭で質疑を行うことができた点は対面開催の大きな利点であった。

シンポジウムでは、実際の介入における詳細な技法を聞くことができるなど、今後のセラピーに活かすことのできる知識をつけることができた。また、同時翻訳機が導入されたことで、言語的な制約が緩和され、理解がより深まることを体験した。

1度目の国際学会参加時は、初めてということもあり、戸惑いが多く、落ち着いてポスター発表やシンポジウムを聞くことができなかった。本学会では、その反省を活かし、効率的にポスター発表やシンポジウムへ参加できたことで、多くの知見を得ることができ、とても有意義な時間となった。今後も、意欲的に国際学会に参加し、他国の研究者と交流を通じて、これからの研究や臨床活動に活かしていきたいと思う。

採用された方についてはウェブページ等で内容が公開される場合があります。