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Cristiane Flôres Bortoncello

Manual de Terapia Cognitivo-Comportamental em Grupo para Adolescentes com Transtorno Obsessivo-Compulsivo

Porto Alegre

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Orientador: Prof. Dr. Ygor Arzeno Ferrão

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De acordo com o estabelecido previamente pela Comissão Coordenadora do Curso de Pós-Graduação em Ciências da Saúde da Universidade Federal de Ciências da Saúde de Porto Alegre, realizou-se no dia 28/09/2022, às 09 horas, na modalidade remota, via Google Meet, a defesa de Tese de Doutorado do(a) aluno(a) Cristiane Flôres Bortoncello, orientado(a) pelo(a) professor(a) Ygor Arzeno Ferrão do Programa de Pós-graduação em Ciências da Saúde da UFCSPA. O trabalho defendido intitula-se "Manual de Terapia Cognitivo-Comportamental em Grupo para Adolescentes com Transtorno Obsessivo-Compulsivo". A Banca Examinadora foi composta pelos(as) professores(as) Ana Luiza Camozzato de Pádua, Gabriela Mourão Ferreira, Wagner de Lara Machado e Aristides Volpato Cordioli. Após a abertura da sessão o(a) aluno(a) dispôs de 40 minutos para expor seu trabalho. Ao término da apresentação, foi realizada a arguição do(a) aluno(a) pelos membros da banca examinadora. Cada examinador teve até 20 minutos para sua arguição, tendo o aluno igual tempo para resposta. Ao término da Sessão foi anunciada a **APROVAÇÃO** do(a) aluno(a) que, após a homologação da tese de doutorado, receberá o título de Doutora em Ciências da Saúde: Terapêutica Clínica e Cirúrgica. Nada mais havendo a tratar, foi encerrada a sessão e lavrada a presente ata, que será assinada pelo(a) orientador(a) do(a) aluno(a) e pela Coordenação do Programa.

Porto Alegre, 28 de setembro de 2022.

Prof. Pedro Roosevelt Torres Romão
Coordenador

Ygor Arzeno Ferrão

Prof. Ygor Arzeno Ferrão

Orientador

Dedicatória

Este trabalho é dedicado a todas as pessoas que sofrem com os sintomas obsessivo-compulsivos e suas famílias, que são incansáveis na procura de tratamentos efetivos para o TOC. Espero que essa obra possa ajudar todos vocês.

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Epígrafe

“É preciso que eu suporte duas ou três larvas se quiser conhecer as borboletas.”

Pequeno Príncipe.

RESUMO

Introdução: o transtorno obsessivo-compulsivo (TOC) é uma doença mental grave, muito comum na infância e adolescência, com prevalência entre 2 e 3% nesta faixa etária, seu curso é crônico e, caso não seja tratado, se mantém por toda a vida, raramente desaparecendo por completo. A Terapia Cognitivo-Comportamental (TCC) é considerada a primeira escolha de tratamento em crianças e adolescentes que apresentam sintomas leves e moderados e associada à farmacoterapia nos casos de sintomas de intensidade moderada à grave podendo ser realizada de forma individual ou em grupo. Contudo, não existe no Brasil, um manual de tratamento em grupo validado para os adolescentes com TOC. **Objetivo:** desenvolver, avaliar e apresentar as primeiras evidências de validade de um manual de Terapia Cognitivo-Comportamental em Grupo (TCCG) para o tratamento de adolescentes brasileiros com TOC. **Metodologia:** Inicialmente foi realizada uma revisão sistemática com metanálise, a qual objetivou avaliar a eficácia da TCCG em adolescentes com TOC (artigo 1). O artigo dois teve como objetivo apresentar as seis etapas de confecção do manual de TCCG para adolescentes com TOC: 1) Revisão Sistemática em busca de manuais com evidências científicas (artigo 1); 2) Apreciação dos manuais existentes; 3) Confecção do novo manual; 4) avaliação por especialistas; 5); Avaliação do manual por adolescentes; 6) Apreciação das avaliações. **Resultados:** os principais resultados do artigo 1 revelaram que a TCCG é eficaz na redução dos sintomas de adolescentes com TOC (*d* = -1.32) e que não existe um manual de TCCG para adolescentes com TOC validado no Brasil. A partir desses resultados foi elaborado o manual de TCCG denominado Camaleo TOC, apresentando excelente evidência de validade de conteúdo, em adequação (Finn = 0.98) e relevância (Finn = 0.99 escore médio = 4.0; numa escala de avaliação de 0 a 4), tanto por parte dos especialistas como dos adolescentes (artigo 2). **Conclusão e Perspectivas**: a presente tese apresenta as evidências preliminares de validade de conteúdo do Camaleo TOC, tal evidência contribui para melhor compreensão do manual por adolescentes, o que pode implicar em maior eficácia da intervenção. Ademais, destaca-se que este manual apresenta algumas vantagens em comparação a outros manuais disponíveis para o tratamento do TOC. Até onde se tem conhecimento, o Camaleo TOC é o único instrumento que seguiu rigorosamente as etapas sugeridas para o desenvolvimento de instrumentos na área da saúde. Outra vantagem do Camaleo TOC é o maior tempo de participação dos pais/familiares durante as sessões, o que também pode contribuir para maior eficácia da intervenção. Espera-se que este manual possa ser disponibilizado como um protocolo de tratamento fundamentado e especializado, que proporcione aos adolescentes um tratamento efetivo na rede pública ou privada. Por fim, destaca-se que um terceiro estudo quase-experimental derivado desta tese está sendo

conduzido com o objetivo de avaliar e apresentar as primeiras evidências de eficácia do Camaleo TOC no tratamento de 20 adolescentes (10 a 19 anos) brasileiros com TOC.
Palavras-chave: Transtorno Obsessivo-Compulsivo; TOC; Adolescência; Terapia Cognitivo-Comportamental; Protocolo de tratamento.

ABSTRACT

Introduction: Obsessive-compulsive disorder (OCD) is a severe mental illness, very common in childhood and adolescence, with a prevalence between 2 to 3% in this age group, its course is chronic and if untreated persists throughout life, rarely disappearing completely. Cognitive-Behavioral Therapy (CBT) is considered the first choice of treatment for children and adolescents with mild and moderate symptoms, also associated with pharmacotherapy in cases of moderate to severe symptoms and can be performed individually or in groups. However, there is no validated group treatment manual in Brazil for adolescents with OCD. **Objective:** To develop, evaluate and present the first evidence of validity of a Group Cognitive-Behavioral Therapy (GCBT) manual for the treatment of Brazilian adolescents with OCD. **Methodology:** Initially, a systematic review with meta-analysis was performed, which aimed to evaluate the effectiveness of GCBT in adolescents with OCD (article 1). Article two aimed to present the six stages of preparing the GCBT manual for adolescents with OCD: 1) Systematic Review in search of manuals with scientific evidence (article 1); 2) Appreciation of existing manuals; 3) Preparation of the new manual; 4) Expert assessment; 5); Assessment of the manual by adolescents; 6) Appreciation of the assessments. **Results:** The main results of the article 1 indicate that GCBT is effective in reducing the symptoms of OCD in adolescents ($d = -1.32$) and that there is no validated GCBT manual for adolescents with OCD in Brazil. Based on these results, the GCBT manual named Camaleo TOC was developed, presenting excellent evidence of content validity in terms of adequacy (Finn = 0.98) and relevance (Finn = 0.99, mean score = 4.0; on an evaluation scale from 0 to 4), both by specialists and adolescents (article 2). **Conclusion and Perspectives:** This thesis presents preliminary evidence of content validity of the Camaleo TOC, such evidence contributes to a better understanding of the manual by adolescents, which may imply greater effectiveness of the intervention. Furthermore, this manual has some advantages compared to other manuals available for treating OCD. As far as is known, the Camaleo TOC is the only instrument that rigorously followed the stages suggested for instrument development in the health area. Another advantage of Camaleo TOC is the longer participation of parents/family members during the sessions, which can also contribute to greater intervention effectiveness. This manual is expected to be made available as a grounded and specialized treatment protocol that provides adolescents with effective treatment in the public or private sector. Lastly, it should be noted that a third quasi-experimental study derived from this thesis is being conducted to evaluate and present the first evidence of effectiveness of the Camaleo TOC for the treatment of 20 Brazilian adolescents (10 to 19 years old) with OCD.

Keywords: Obsessive-compulsive disorder; OCD; Adolescence; Cognitive behavioral therapy; Treatment protocol.

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1 INTRODUÇÃO

1.1 Transtorno Obsessivo Compulsivo (TOC)

O TOC é uma doença mental grave e multifatorial, com fatores de risco que envolvem questões genéticas e ambientais (Pauls et, al., 2014). Indivíduos com familiares de 1º grau com TOC apresentam quatro vezes mais chances de desenvolverem a doença (American Psychiatric Association, 2014; Chacon et al., 2018; Hettema et. al., 2001). O curso deste transtorno é crônico e, caso não seja tratado, se mantém por toda a vida, raramente desaparecendo por completo (APA, 2014).

O TOC é caracterizado pela presença de obsessões (i.e., pensamentos repetitivos e persistentes) e compulsões (i.e., comportamentos repetitivos). Embora a frequência e a gravidade das obsessões e compulsões tenham variação em cada indivíduo (e.g. poucas horas ou constantes ao longo do dia) a sintomatologia do TOC costuma causar prejuízos físicos, psicológicos e sociais ao paciente e a seus familiares (APA, 2014; Hollander et al., 2016).

De acordo com a quinta versão do manual diagnóstico e estatístico dos transtornos mentais (DSM-5), estima-se que a prevalência de TOC em adultos no mundo varie entre 1,1% e 1,8% (APA, 2014). Dados atualizados provenientes de uma revisão sistemática indicam prevalência média de 2% (Coles et al., 2018). Existindo evidências de países como prevalência muito acima da média, como a Grécia (2,8%), Suiça (3.5%) e Iraque (4.6%) (Coles et al., 2018; Skapinakis, Politis, Karampas, Petrikis, & Mavreas, 2019). Estima-se que a cada 40 pessoas no mundo uma têm TOC (Hollander et al., 2016). No Brasil a prevalência de TOC em adultos varia entre 3,9% (Andrade et al., 2012) e 6,7% (Viana & Andrade, 2012). Sabe-se que o TOC costuma ser ainda mais prevalente em adolescentes (APA, 2014; Vivan et al., 2014), sendo estimado que até 25% dos casos iniciam até os 14 anos de idade (APA, 2014).

1.2. TOC na adolescência

O TOC é muito comum na infância e adolescência, pouco frequente em crianças pequenas e muito frequente na adolescência (APA, 2014). A prevalência de TOC em crianças e adolescentes tende a variar em cada país, contudo, essa variação costuma ocorrer entre 1% em pré-adolescentes até 4% em adolescentes (Leonard, Ale, Freeman & Garcia, 2005; Merlo & Storch 2006; Moore, Mariaskin, March & Franklin, 2007).

No Brasil, um estudo multicêntrico com 842 pacientes clínicos verificou que o início dos sintomas nos homens foi em média aos 12,4 anos e nas mulheres aos 12,7 anos (Ferrão

et. al., 2006). Estima-se que a prevalência do TOC nas crianças e adolescentes brasileiros esteja entre 2 e 3% (Alvarenga et al., 2016; Hollander & Simeon, 2012; Vivan et al., 2014). As próprias crianças e adolescentes com TOC percebem as alterações em suas rotinas diárias, da mesma forma percebem seus comportamentos como estranhos e diferentes do comportamento dos seus colegas, sentem vergonha e às vezes se escondem ou disfarçam quando sentem necessidade de realizar rituais compulsivos. Geralmente apresentam pouco *insight* sobre a natureza de suas obsessões, associada à dificuldade de expressão verbal tornando o diagnóstico mais difícil (Alvarenga et al., 2016; Geller, 2006).

Por se tratar de um transtorno que acarreta muito sofrimento, é importante que o diagnóstico e o tratamento ocorram o mais breve possível (Alvarenga et al., 2016; Saad et al., 2017). Um estudo, realizado em Porto Alegre com adolescentes, verificou que 9,3% dos que foram diagnosticados com TOC, sabiam da doença, e destes, apenas 6,7% haviam realizado algum tipo de tratamento (Vivan et. al., 2014). Os sintomas nem sempre são percebidos pela família, ocasionando um longo período entre o início dos sintomas e a procura do tratamento (Alvarenga et al., 2016; Saad et al., 2017; Stengler-Wenzke et. al., 2004).

1.3. Tratamento do TOC na infância e na adolescência

Com relação ao tratamento de crianças e adolescentes com TOC, tanto a TCC (individual ou em grupo) quanto os psicofármacos são efetivos em reduzir os sintomas obsessivo-compulsivos (SOC), sendo recomendado combinar as duas modalidades de tratamento (Freeman et al., 2013; Hojgaard et al., 2019; Pots, 2004; Torp et al., 2015). A eficácia/efetividade da TCC para o TOC nessa faixa etária foi verificada através de ensaios clínicos, revisão sistemática e metanálise (Ashbar 2005; Freeman et al., 2013; Hojgaard et al., 2019; Pots, 2004; Prazeres et. al., 2007; Torp et al., 2015;), sendo considerada a primeira escolha de tratamento em casos de crianças e adolescentes com TOC com sintomas leves e moderados (Benazon et. al., 2002; Freeman et al., 2013; Hojgaard et al., 2019; Mancuso et. al., 2010; Pots, 2004; Practice Parameters, 2012; Torp et al., 2015). Como segunda escolha, a TCC associada à farmacoterapia nos casos de sintomas com intensidade moderada à grave ou quando existe depressão associada (Freeman et al., 2013; Hojgaard et al., 2019; Mancuso et. al., 2010; Ost, Riise, Wegeland, Hansen & Kvale, 2016; Practice Parameters, 2012; Torp et al., 2015).

Embora os estudos costumem reportar ótimos resultados no tratamento do TOC com a TCC, individualmente ou combinada com o tratamento farmacológico (Pots, 2004; Cordioli, 2008; Freeman et al., 2013; Torp et al., 2015; Ost et al., 2016; Hojgaard et al., 2019), cabe

ressaltar que entre 20% e 50% das crianças com TOC permanecem com alguns sintomas após as intervenções (Benazon et. al., 2002; Ost et al., 2016; Pots, 2004).

A TCC pode ser administrada de forma individual ou grupal tanto em adultos como em crianças e adolescentes. Diversos estudos demonstram que ambos os formatos apresentam eficácia similar em adultos. No entanto, o formato grupal apresenta como vantagem a possibilidade de tratar um maior número de participantes simultaneamente (Jaurrieta et al., 2008; Jonsson & Hougaard, 2009; Jonsson, Hougaard & Bennedsen, 2011).

A terapia cognitivo-comportamental em grupo (TCCG) para TOC em crianças e adolescentes é muito semelhante à de adultos, com duração geral de 4 meses (entre 10 a 16 sessões semanais), com sessões que podem ou não ser acompanhadas por um familiar (Martin & Thienemann, 2005; Schoting & Third, 2011; Selles et al., 2018; Thienemann, Martin, Cregger, Thompson & Dyer-Friedman, 2001; Vattimo et al., 2019).

Uma revisão sistemática com metanálise recente evidenciou que o número médio total das sessões dos tratamentos com TCCG para adolescentes é 12. Foi observado ainda que a duração média de cada uma das sessões é 1,5h e a frequência costuma ser semanal. Destaca-se que ao menos um dos familiares costuma participar de alguma forma (e.g. nos últimos 15 minutos de cada sessão, grupo para pais e/ou treinamento de habilidades) no tratamento de TCCG com as crianças e adolescentes (Bortoncello, Cardoso, Salvador, Machado & Ferrão, 2022). A participação de ao menos um responsável costuma ser solicitada devido ao fenômeno da acomodação familiar (Calvocoressi et al., 1999; Wu et al., 2016).

1.4. Acomodação Familiar no TOC

A acomodação familiar (AF) dos familiares de pacientes com TOC pode ser observada na medida em que os indivíduos que residem com o paciente com TOC começam a modificar sua rotina. Tais modificações costumam ocorrer para acomodar as compulsões do familiar com TOC (i.e., evitar gatilhos) (Calvocoressi et al., 1999; Wu et al., 2016, 2019).

É comum que os familiares acreditem que os sintomas do TOC irão reduzir se realizarem os mesmos rituais que o paciente (e.g. lavagem excessiva das mãos) ou evitarem locais/situações que possam acionar algum gatilho (Storch et al., 2010; Wu et al., 2016). No entanto, sabe-se que esses comportamentos de AF são um dos principais responsáveis pela manutenção dos sintomas do TOC, sendo evidenciado por diversos estudos que a AF está correlacionada com a gravidade dos sintomas de TOC (i.e., quanto maior for a AF, mais graves serão os sintomas de TOC) (Ferrão & Florão, 2010; McKenzie et al., 2020; Wu et al., 2016, 2019), e mais difícil será a resposta ao tratamento, estando associada a refratariedade em alguns pacientes com TOC (Ferrão et. al., 2006).

Para além dos impactos da AF no prognóstico do indivíduo acometido pelo TOC, também existem os efeitos da AF nos familiares. Em especial o aumento do “fardo” reportado pelos cuidadores de pacientes com TOC, principalmente pelas mães (Hollander et al., 2016; Lee et al., 2015; Siu, Lam & Cham, 2012).

Por fim, destaca-se que tanto a severidade dos sintomas de TOC (i.e., nível de funcionalidade do paciente) quanto o nível de AF estão diretamente associados a qualidade de vida (QDV) do indivíduo acometido pelo TOC e de seus familiares (i.e., quanto mais graves forem os sintomas e o nível de AF menor será a QDV) (Hollander et al., 2016; Siu et al., 2012).

1.5. Qualidade de vida no TOC

A qualidade de vida (QDV) pode ser definida como "a percepção do indivíduo de sua posição na vida no contexto da cultura e sistema de valores nos quais ele vive e em relação aos seus objetivos, expectativas, padrões e preocupações". A QDV está diretamente relacionada ao quanto um indivíduo está satisfeito com a sua vida e pode ser afetada pelas relações interpessoais, habilidade de trabalhar e cumprir com suas obrigações sociais (WHOQOL Group, 1994).

A sintomatologia do TOC costuma causar prejuízos significativos na QDV do paciente e de seus familiares (APA, 2014; Hollander et al., 2016). Especialmente no nível de funcionalidade do indivíduo acometido pelo TOC. Sendo comum que em casos mais graves, os indivíduos com TOC apresentem dificuldade em sair de casa, o que acaba prejudicando todos os aspectos sociais da vida do indivíduo (Asnaani et al., 2017). Entre os transtornos mentais, o TOC é o segundo com maior impacto negativo na QDV dos pacientes, ficando atrás apenas da esquizofrenia (Bobes et al., 2001; Pozza, Lochner, Ferreti, Cuomo & Coluccia, 2018).

Embora seja possível melhorar a QDV dos pacientes com TOC, os estudos têm demonstrado que mesmo os pacientes em total remissão dos sintomas de TOC seguem apresentando níveis de QDV inferior aos da população saudável (Asnaani et al., 2017; Pozza et al., 2018; Remmerswal et al., 2019). Alguns pesquisadores atribuem os níveis inferiores de QDV aos sintomas de ansiedade e depressão que permaneceram após a remissão do TOC. Sendo sugerido que tais sintomas sejam avaliados e se possível, tratados durante ou após as intervenções direcionadas ao TOC (Remmerswal et al., 2019).

O TOC é muito prevalente no Brasil, sobretudo em adolescentes (2% a 3%) (Alvarenga et al., 2016; Hollander & Simeon, 2012; Vivan et al., 2014). Os sintomas do TOC podem reduzir significativamente a QDV do paciente, chegando ao ponto de comprometer o seu nível de funcionalidade (i.e., capacidade de trabalhar, estudar e se relacionar com as pessoas).

Sendo comum que os familiares do indivíduo com TOC também sofram com a doença, apresentando níveis reduzidos de QDV (Hollander et al., 2016; Siu et al., 2012).

Considerando todos os prejuízos psicológicos, sociais e físicos causados pelos transtornos mentais, tanto para a pessoa com a patologia quanto aos familiares do indivíduo (APA, 2014), o governo federal brasileiro, por meio do Ministério da Saúde, emitiu um documento intitulado “Agenda Nacional de Prioridades de Pesquisa em Saúde”, o qual é dividido em subagendas classificadas por ordem de prioridade. De acordo com este documento, a saúde mental é a segunda prioridade de pesquisa na área da saúde (Brasil, 2015).

Tendo em vista este cenário, a ausência de um manual de TCCG validado para o tratamento de adolescentes brasileiros com TOC, a necessidade de se tratar cada vez mais precocemente o TOC nos adolescentes, melhorar a sua qualidade de vida, diminuir o sofrimento, a interferência negativa nas relações sociais, no funcionamento familiar e no rendimento escolar, o presente trabalho tem o objetivo de desenvolver um manual de TCCG para o tratamento de adolescentes brasileiros com TOC e avaliar suas primeiras evidências de validade.

Tendo como base os resultados da revisão sistemática (artigo 1), optou-se pelo desenvolvimento de um novo manual, ao invés da adaptação de existentes, considerando que os manuais internacionais utilizados em sua maioria eram versões mais infantis (i.e., figuras infantilizadas), ou versões de adultos adaptadas para adolescente ou versões muito extensas (i.e., 298 páginas), o que pode gerar baixa adesão pelos adolescentes. Nos manuais internacionais também não havia espaço reservado para que o adolescente realizasse as tarefas das sessões da TCCG, servindo de suporte durante o tratamento. Ademais não foi descrito nestes manuais o fenômeno sensorial, que costuma ser muito prevalente nos adolescentes.

Para além da contribuição do desenvolvimento de um manual brasileiro para o tratamento de TOC em adolescentes, pretende-se incentivar o desenvolvimento de novas políticas e intervenções públicas de saúde que visem o bem-estar biopsicossocial dos indivíduos acometidos por transtornos mentais. Assim como aderir e contribuir com a Agenda Nacional de Prioridades de Pesquisa em Saúde (Brasil, 2015).

2 OBJETIVOS

2.1. Objetivo Geral

Desenvolver, avaliar e apresentar as primeiras evidências de validade de um manual de TCCG para o tratamento de adolescentes brasileiros com TOC.

2.2. Objetivos específicos

1. Avaliar a eficácia da TCCG para o tratamento de adolescentes com TOC através de uma revisão sistemática com metanálise.
2. Apresentar o processo de construção do manual de TCCG para adolescentes brasileiros com TOC.
3. Avaliar a validade de conteúdo do manual de TCCG para TOC em adolescentes.

3 MÉTODO

Este projeto foi divido em dois estudos. No primeiro (já publicado no artigo 1) foi realizada uma revisão sistemática com metanálise, com o seguinte objetivo: “avaliar a eficácia da TCCG em adolescentes com TOC” (Bortoncello et al., 2022). No segundo estudo foi realizado todo o processo de confecção do manual, avaliação por especialistas e por adolescentes sem transtorno mental (artigo 2).

3.1. Delineamento do estudo

No primeiro estudo deste projeto foi realizada uma revisão sistemática com metanálise seguindo os passos propostos pelo modelo *PRISMA* (Moher, Liberati, Tetzlaff, & Altman, 2009). No segundo estudo foi utilizada abordagem quantitativa e qualitativa, conforme sugerido por diretrizes internacionais de elaboração e adaptação de instrumentos na área da saúde (International Test Comission, 2017). O novo manual de TCCG foi elaborado tendo como base a apreciação dos manuais que foram localizados no estudo 1 deste projeto (Bortoncello et al., 2022). A validade de conteúdo do novo manual foi obtida por meio da avaliação de especialistas (Haynes, Richard & Kubany, 1995) e dos adolescentes por meio de questões quantitativas e qualitativas, que avaliaram a clareza/adequação da linguagem (validade de conteúdo) do manual (Pasquali, 1997).

4 ELABORAÇÃO DO MANUAL

A elaboração do manual de TCCG para adolescentes com TOC ocorreu em seis etapas: 1) Revisão Sistemática em busca de manuais com evidências científicas (artigo 1); 2) Apreciação dos manuais existentes; 3) Confecção do novo manual; 4) avaliação por especialistas; 5); Avaliação do manual por adolescentes; 6) Apreciação das avaliações. Os itens 2 à 6 constam detalhadamente no artigo 1. A Figura 1 ilustra o fluxo dos procedimentos seguidos para a elaboração do manual.

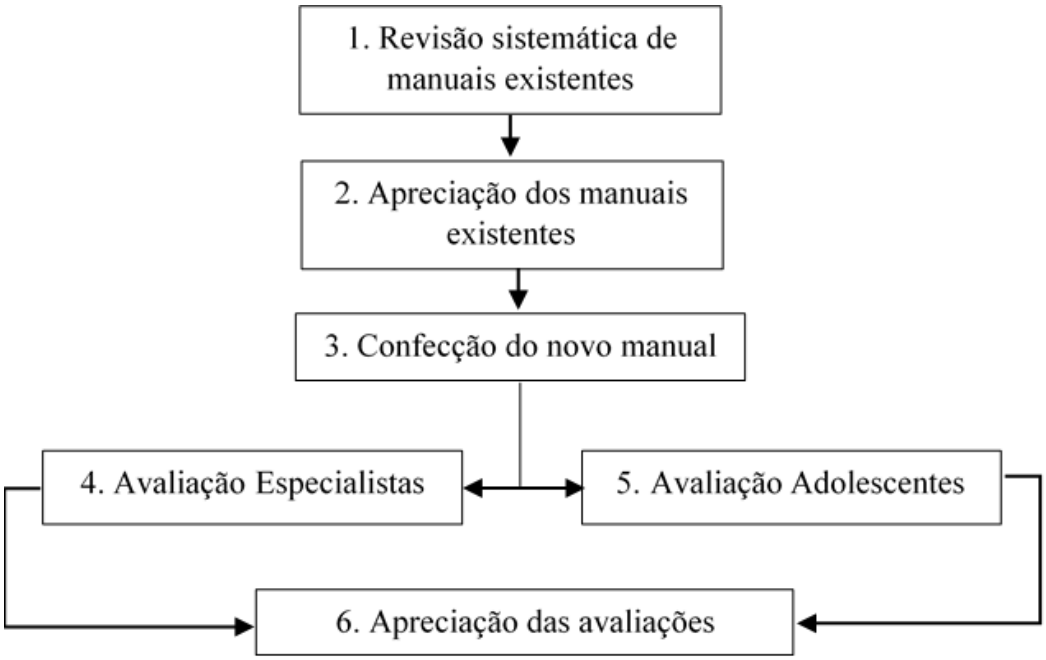

Figura 1. *Procedimentos para construção do manual de TCCG para adolescentes com TOC*

O processo de confecção do manual até a sua aplicação final, passou pelas seguintes etapas:

1) Condução de uma revisão sistemática e metanálise para localizar os manuais existentes e suas evidências de eficácia;

2) Leitura dos manuais de TCCG eficazes para o tratamento de TOC em adolescentes localizados na revisão sistemática e utilização de dados estatísticos obtidos na metanálise (Bortoncello et al., 2022). Nesta etapa foram obtidos todos os manuais/protocolos utilizados nos estudos incluídos na revisão sistemática e metanálise que apresentarem evidências de eficácia nos resultados da metanálise (mensuração pelo tamanho de efeito). Além disso, foram levadas em consideração para confecção do manual de TCCG para adolescentes brasileiros as médias de: número de sessões semanais e duração total do tratamento, duração de cada sessão e estrutura dos grupos. Nessa etapa, somente uma psicóloga especialista em TOC na infância e adolescência (Cristiane Flores Bortoncello) realizou a leitura dos manuais. Isso ocorreu devido ao tamanho dos manuais/protocolos (alguns apresentavam 300 páginas), que tornou inviável a participação não remunerada de outros especialistas em TOC na infância e adolescência.

3) Redação do novo manual tendo como base os resultados das etapas um e dois, utilizando linguagem acessível aos adolescentes;

4) Avaliação do manual por especialistas. A versão inicial do manual foi enviada para apreciação de 4 psicólogos e 1 psiquiatra especialistas em TOC na infância e adolescência.

Esses profissionais foram convidados a realizar a validade de conteúdo (Haynes, Richard & Kubany, 1995; Pasquali, 1997) do manual por meio da análise crítica e detalhada do manual. Para cada sessão do manual, os especialistas avaliaram a relevância/validade de face (*i.e.,* grau em que a sessão é apropriada para o tratamento do TOC) e adequação (*i.e.,* é uma situação comum e pode ser facilmente compreendida pelos adolescentes com TOC?), por meio de duas perguntas fechadas em formato de escala tipo-*likert* (*i.e.,* 0 Nada adequado/relevante e 4 Totalmente adequado/relevante) e outras duas questões fechadas com opção de resposta dicotômica (Sim/Não).

As perguntas foram apresentadas no seguinte formato: 1) A linguagem das informações apresentadas é clara e adequada para o público adolescente? (adequação); 2) A sessão utiliza pressupostos da TCC e é adequada para utilização em tratamento de adolescentes com TOC? (relevância); 3) O texto está muito extenso e/ou poderia ser resumido (Sim/Não?); 4) Alguma palavra ou frase não ficaram claras para você? (Sim/Não?). Em caso de assinalamento da opção “Sim”, nas perguntas dicotômicas, o especialista foi convidado a especificar qual palavra ou frase não ficou clara e a sugerir uma alternativa para aprimoramento do trecho indicado.

5) Avaliação do manual pelos adolescentes. Após o retorno dos especialistas e com o objetivo de avaliar a clareza do formato de apresentação e linguagem do manual (*i.e.,* validade de conteúdo/adequação - Pasquali, 1997), 7 adolescentes saudáveis (sem diagnóstico psiquiátrico) e que nunca realizaram psicoterapia, foram convidados a responder uma questão quantitativa (escala tipo-*likert* 0-4) e duas dicotômicas com campo de texto para justificar a resposta em caso de assinalamento da opção “Sim”. As questões apresentadas aos adolescentes foram as mesmas respondidas na etapa anterior pelo grupo de especialista, exceto pela questão 2, a qual foi removida por não ser esperado que os adolescentes tenham conhecimento técnico sobre TCC e/ou métodos científicos.

6) Apreciação das avaliações. As respostas qualitativas dos especialistas e dos adolescentes foram apreciadas por uma psicóloga especialista em TOC (Cristiane Flores Bortoncello). Todas as sugestões de modificação de palavras/frases foram atendidas, exceto algumas sugestões de redução da quantidade de texto, pois algumas informações são importantes e não podem ser removidas da estrutura de cada sessão e/ou do manual. As avaliações quantitativas foram conduzidas por um psicólogo especialista em psicometria. Considerando que haviam poucas sugestões de modificações e que os escores de adequação e relevância das sessões foram (≥ 3.5), não foi observada necessidade de reenvio do manual, após modificações, para reavaliação dos especialistas e/ou público-alvo. Todas as etapas do processo de construção do manual e o resultado obtido estão descritos mais adiante no artigo 2.

5 ANÁLISE ESTATÍSTICA

A revisão sistemática com metanálise foi realizada de acordo com as recomendações do *Preferred Reporting Items for Systematic Reviews and MetaAnalyses* (PRISMA) (Moher, Liberati, Tetzlaff, Altman & The PRISMA Group, 2009) e conforme os passos pré-estabelecidos no protocolo registrado no PROSPERO (CRD42020158475) conforme artigo 1.

As evidências de validade de conteúdo do manual de TCCG para adolescentes com TOC foram obtidas considerando a relevância e adequação de cada uma das sessões do manual, por meio da avaliação de juízes especialistas e adolescentes (público-alvo). Todas as análises foram realizadas na versão 4.1.2 do software R (R Core Team, 2022). O índice de confiabilidade entre especialistas e participantes do estudo piloto foi mensurado por meio do coeficiente Finn (Finn, 1970), o qual foi desenvolvido para análise da concordância quando existe baixa variabilidade nas respostas. Para isso, foi utilizado o pacote de dados Various Coefficients of Interrater Reliability and Agreement - IRR (Gamer, Lemon, Fellows, & Singh, 2019). As análises de confiabilidade consideraram o método *listwise* para tratamento de *missing values*. Todo o processo de validade de conteúdo do manual de TCCG para adolescentes com TOC está descrito no artigo 2.

6 PROCEDIMENTOS ÉTICOS E DE COLHEITA DE DADOS

O planejamento deste estudo priorizou o bem-estar e a não maleficência dos participantes, de forma que o projeto seguiu todas as condições estabelecidas na Resolução 466/12, do Conselho Nacional de Ética em Pesquisa e Saúde. O estudo foi aprovado pelo comitê de ética em pesquisa da Universidade Federal de Ciências da Saúde de Porto Alegre (CAAE: 30918720.9.0000.5345), através da plataforma Brasil parecer no. 4.098.340 (anexo 1).

Todos os participantes (adolescentes e os pais/responsáveis) receberam os esclarecimentos necessários sobre os objetivos do projeto, os procedimentos realizados, os possíveis riscos e benefícios diretos e indiretos decorrentes da participação e informações quanto aos direitos do participante durante a participação. O consentimento dos pais do participante ocorreu através da assinatura do termo de consentimento livre e esclarecido (TCLE) e o consentimento dos participantes menores de 18 anos de idade por meio da assinatura do Termo de assentimento (TA). Os adolescentes com 18 ou 19 anos assinaram apenas o TCLE, sem necessidade da assinatura de um responsável conforme instruções da resolução 466/12. Os modelos de termos de consentimento livre e esclarecido (TCLE) e o de assentimento utilizados neste estudo encontram-se no apêndice A e B.

A respeito da confidencialidade, o pesquisador responsável garantiu o armazenamento das informações, mantendo-as em sigilo. Apenas os membros da equipe, diretamente ligados à pesquisa, tiveram acesso aos dados coletados.

O manual de TCCG para adolescentes com TOC foi enviado via e-mail para os especialistas e entregue em mãos aos adolescentes. Em ambos os casos, foi disponibilizado um link no *Google Forms* para avaliação do conteúdo do manual. Os adolescentes foram selecionados por conveniência e bola de neve (*snowball sampling*) (Johnson, 2014).

7 ARTIGOS CIENTÍFICOS

7.1. Artigo 1: Efficacy of group cognitive-behavioral therapy in adolescents with obsessive compulsive disorder: a systematic review and meta-analysis

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Title

Efficacy of group cognitive-behavioral therapy in adolescents with obsessive compulsive disorder: a systematic review and meta-analysis

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Abstract

Objective: To evaluate the effectiveness of group cognitive-behavioral therapy (GCBT) for the treatment of adolescents with obsessive compulsive disorder (OCD). **Methods:** This review was registered in PROSPERO under number CRD42020158475. Five databases (PubMed, Virtual Health Library, Web of Science, Scopus, and PsycINFO) were searched. After applying the inclusion and exclusion criteria, 13 studies were analyzed in the qualitative synthesis (i.e., systematic review) and eight in the quantitative synthesis (i.e., meta-analysis). For the latter, fixed-effect modeling was used to assess the primary outcome (i.e., OCD symptoms). **Results:** The main findings suggest that GCBT is effective in reducing the symptoms of OCD in adolescents (d = -1.32). However, these results must be interpreted with caution, since all of the included studies showed some bias in their design. **Conclusions:** GCBT is effective in reducing OCD symptoms in adolescents.

Keywords: Group cognitive-behavioral therapy; obsessive compulsive disorder; adolescents

Introduction

Obsessive compulsive disorder (OCD) is a serious mental illness, uncommon in young children (between 2-3 years old) and very common in adolescence,[1] and is among the ten diseases that most cause disability.[2] In Brazil, a study with 842 clinical patients found an average age at symptom onset of 12.4 years in men and 12.7 years in women,[3] with similar findings reported in the international literature,[4,5] and a prevalence of approximately 2 to 3% among children and adolescents.[4,6,7]

Considered multifactorial, with both genetic and environmental aspects involved in its pathogenesis,[8-10] OCD is four times more likely to develop in first-degree relatives of persons with the disorder.[11,12] In addition, as the course is chronic, it is usually lifelong if untreated, rarely remitting completely.[1] Establishing diagnosis and treatment as early as possible is important to prevent worsening of symptoms and increase the odds of complete remission.[13-15] A study with adolescents in southern Brazil found that only 9.3% of those diagnosed with OCD were aware of their diagnosis, and, of these, only 6.7% had undergone some type of treatment.[7] Since OCD is not always perceived by the family, there is often a long interval between the onset of symptoms and the search for treatment,[16-18] which can be a predictor of poor prognosis.[19]

In children and adolescents with OCD, both cognitive-behavioral therapy (CBT) and psychoactive drugs are effective in reducing obsessive-compulsive symptoms (OCS).[20,21] Treatment with CBT is superior to isolated pharmacotherapy.[22,23] The efficacy and effectiveness of CBT for OCD in this age group has been verified through clinical trials, systematic reviews, and meta-analyses. [20,22,24] Therefore, CBT is considered the first-line treatment of choice in children and adolescents with mild and moderate symptoms of OCD (e.g., predominance of compulsions, absence of comorbidities).[20,25,26] As a second-line choice, CBT combined with pharmacotherapy is recommended in cases of moderate to severe symptom intensity or when there is comorbid depression.[26,27]

Although the literature shows a reduction in symptoms after treatment, in practice there are some difficulties: 20 to 32% of children with OCD do not respond (or respond only partially) to individual CBT (ICBT), with or without concomitant medication.[15,20,25] Therefore, some researchers recommend the use of group CBT (GCBT) for the treatment of children and adolescents with OCD,[14,22,28-31] since there is evidence of a significant reduction in symptoms in adults undergoing this treatment

modality. [32,33] In addition, evidence suggests that GCBT is more effective in treating OCD in adults than the use of fluoxetine.[32] Furthermore, it is highlighted that GCBT can treat a greater number of patients at the same time, thus making psychotherapy more accessible for the population.

Unfortunately, there are few studies evaluating the effectiveness of GCBT in children and adolescents with OCD.[34] Finally, considering that OCD symptoms usually start between 10 and 12 years of age,[3-5] and that, as far as we are aware, there are no systematic reviews with or without meta-analysis exclusively evaluating the effects of GCBT in adolescents with OCD, this study aims to evaluate the effectiveness of GCBT for the treatment of adolescents with OCD.

Method

A systematic review with meta-analysis was performed following the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[35] and according to pre-established steps defined in the study protocol, as registered in PROSPERO (CRD42020158475). Data collection occurred through online searches of five databases: Virtual Health Library (BVS), Web of Science, Scopus, American Psychological Association database (PsycINFO), and PubMed (via MEDLINE).

To identify scientific studies related to the objective of this review, the following key descriptors were used: (‘‘behavioral therapies’’ or ‘‘behavioral therapy’’ or ‘‘cognitive behavioral therapy’’ or ‘‘cognitive behavioral therapies’’) and (adolescent * or adolescence or teen * or teenager * or youth *) and (obsessive compulsive disorder or obsessive-compulsive disorders or obsessive behavior or obsessive behaviors) and (group psychotherapy or group therapy). All descriptors were drawn from the Medical Subject Headings (MeSH/PubMed) and The-Saurus (PsycINFO) controlled vocabularies.

The searches were performed by two independent evaluators in April 2021. Although the same key descriptors were used in all databases, search strategies were customized for each database. For BVS, PubMed, Web of Science, and PsycINFO, all descriptors were used in a single line. This required the advanced search tab in BVS to ensure coverage of the titles and summary of articles. For Scopus, due to the inability of the database to group all descriptors on a single line, the query was divided

into four lines: first line: (‘‘behavioral therapies’’ or ‘‘behavioral therapy’’ or ‘‘cognitive behavior therapy’’ or ‘‘cognitive behavioral therapies’’); second line: (adolescent * or adolescence or teen * or teenager * or youth *); third line: (obsessive compulsive disorder or obsessive-compulsive disorders or obsessive behavior or obsessive behaviors); fourth line: (group psychotherapy or group therapy). The filter ‘‘article’’ was used in Scopus, BVS, and Web of Science, while in PsycINFO, the filter ‘‘journal’’ was used. No filters were used in PubMed.

The total yield of the search of databases was imported into Rayyan,[36] an online tool developed to help authors of systematic reviews and meta-analyses store their results in a single online database and produce articles with higher quality and methodological rigor. This online platform has a blind review mode, which allows two or more reviewers to individually select articles. Reviewers can add comments to each article and group them into three categories: 1) included, 2) excluded, or 3) perhaps. In addition, Rayyan automatically identifies all duplicate articles and allows the blind review mode to be removed, automatically revealing a fourth category of articles called ‘‘conflicts,’’ which contains all the articles on which the reviewers had divergent opinions.[36] After excluding duplicate articles, the evaluators read the titles and abstracts of the remaining studies based on the following inclusion and exclusion criteria.

Eligibility criteria (PICOS)

Participants (P)

A study was eligible if its sample met the following criteria: 1) adolescents (age between 10 and 19 years) of any gender; 2) established diagnosis of OCD (any stage of illness) using any standard diagnostic criteria (e.g., DSM- 5 or ICD-10).

A study was ineligible if its sample met the following criteria: 1) heterogeneous sample in the same intervention group (i.e., children and adolescents or adolescents and young adults), with group mean age under 10 or over 19; 2) sample composed exclusively of children (under 10); 3) sample composed exclusively of adults (over 19).

Interventions and comparators (I and C)

A study was eligible if its intervention and comparators met one of the following criteria: 1) at least one group in GCBT condition (alone or in combination with

medication); 2) comparison of GCBT with itself (pre/post-test); 3) comparison of GCBT with ICBT or another form of individual or group psychotherapy (both online and face-to-face); 4) comparison of GCBT with medication use; 5) comparison of GCBT with any other forms of treatment (e.g., no treatment/waiting list/treatment as usual). A study was ineligible if it used only behavioral or only cognitive therapy.

Outcomes (O)

A study was eligible if its outcomes met the following criteria: 1) changes in OCD symptoms measured by Yale- Brown Obsessive-Compulsive Scale (Y-BOCS)[37] or Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS),[38] which is an adaptation of the Y-BOCS developed specifically for the assessment of children and adolescents, being the gold standard for measuring OCD symptoms in this age group[39]; 2) measurement of OCD symptoms on at least two time points (e.g., baseline and end of treatment).

Study design (S)

A study was eligible if its design met the following criteria: 1) randomized controlled trial or single group pre-post trial or any experimental and quasi-experimental design, regardless of the level of blinding (qualitative synthesis); 2) provides sufficient statistics to be included in the metaanalysis (quantitative synthesis). The year of publication and language of the papers were not restricted, aiming to find as many articles as possible. These criteria were first applied by two independent researchers during the screening of titles and abstracts in Rayyan. In the second stage, the remaining papers were read in full. The included papers were assessed for risk of bias using two tools: 1) Cochrane Collaboration risk of bias tool (RoB), which covers selection, performance, detection, attrition, reporting, and other bias for RCTs[40]; and 2) the Cochrane risk of bias tool to assess non-randomized studies of interventions (ROBINS-I), which covers confounding, selection, classification, deviation, missing data, and reporting bias, for non-RCTs.[41] Any inconsistencies between the two independent researchers were resolved by a third senior author. After these steps were completed, a manual reference search was conducted on all included full-text articles.

Data extraction

After selecting the articles, the extraction of all data was performed by two independent evaluators. To address the objectives of this systematic review, the following data were extracted from the included articles: 1) study identification (authors last name, design, year of study or publication); 2) country; 3) diagnosis (i.e., OCD and comorbidities); 4) sample size; 5) sample age (mean); 6) gender distribution; 7) study population; 8) OCD assessment measures; 9) main findings; 10) mean, standard deviation, or percentage in all groups at pretest and post-test; 11) type and duration of interventions; 12) time point(s) of outcome measurement; 13) previous experience with psychotherapy; 14) risk of bias. Studies that did not present enough data to perform meta-analysis (e.g., number of participants in each group after drop-out, mean scores in the pre- and post-test, standard deviation [SD]) were excluded from the quantitative synthesis (i.e., meta-analysis), but were retained for the qualitative synthesis (i.e., systematic review).

Data synthesis

Meta-analyses were performed to evaluate the effectiveness of GCBT and other interventions in adolescents with OCD. The post-treatment effects and different control conditions or comparison to other interventions were evaluated. The meta-analyses were performed in R software 3.6, using the ‘‘meta’’ package, which allows estimation of fixed and random effects and the assessment of heterogeneity.[42] An I2 statistic of X 75% was deemed to indicate substantial levels of between-study heterogeneity.[43] The effects of GCBT were presented as standardized effect sizes (Cohen’s d). An effect size ≥ 0.8 is considered a large clinical effect; an effect size ≥ 0.5, moderate; and ≥ 0.2, small.[44]

Results

Initially, 713 articles were found, with 13 studies remaining after application of the pre-established inclusion and exclusion criteria. A hand search of the references of these studies yielded no additional publications. Figure 1 shows a PRISMA flow diagram of data selection.[35] Table 1 lists the main characteristics of the studies and interventions. Table 2 lists the main characteristics of the participants.

Most of the included studies were conducted in Australia (n=5; 38.5%) and in the United States (n=4; 30.8%). Only two studies (15.3%) were performed in Brazil,

one (7.7%) in Canada, and one (7.7%) in Iran. Of the 13 studies, six (46.1%) were RCTs and seven (53.9%) were non-randomized (i.e., quasi-experimental). Only three (23.1%) studies performed follow-up, and each used a different time to assess the effect after treatment (12, 18, and 84 months). Among the seven protocols used by the included studies, only two were followed by more than one of the studies. The most used protocol was ‘‘How I ran OCD off My Land’’ (n=4; 39.8%), which was tested on Brazilian samples.[22,52] Furthermore, only two (15.4%)[14,52] of the 13 included studies used the Y-BOCS measure OCD symptoms in adolescents. The other 11 (84.6%) studies used CY-BOCS.

Regarding the interventions and comparisons used, most protocols (n=7; 53.8%) used only pre- and post-test comparisons to identify the effectiveness of GCBT in adolescents with OCD. The Australian RCTs[13,14,30] all followed a similar methodology, with three groups: waiting list, individual cognitive-behavioral family therapy (ICBFT), and group cognitive-behavioral family therapy (GCBFT). Two other RCTs[22,52] compared the use of medication (sertraline and fluoxetine, respectively) with GCBT. Finally, the Iranian RCT compared individuals in three groups: acceptance and commitment therapy (ACT) + selective serotonin reuptake inhibitors (SSRI); GCBT + SSRI; and SSRI only.

The treatment lasted 7 to 14 weeks, with an average duration of ± 12.3 weeks. Sessions occurred once a week in all included studies. The duration of each session ranged from 60 to 120 minutes (average, 90 minutes). In addition, there was parental participation in all sessions of all included studies, except for study three, where parents could choose to participate in an extra weekly session. However, the time of participation and level of parental involvement in each study varied considerably: the briefest intervention with parents lasted 15 minutes at the end of the sessions,[55] while the longest had a group dedicated exclusively to parents with a duration of 60 minutes.[49]

The sample size of the included studies ranged from 15 to 85 participants. The sum of samples from all studies was 549, with an average of 45.75 (SD = 27.62) participants. The distribution by sex was matched in all studies, resulting in a total of 290 male (52.9%) and 258 female (47.1%) subjects. Anxiety disorders were the most prevalent comorbidities. However, four articles did not report whether the participants had any comorbidities.

Part of the samples from all included studies used some medication before or during GCBT interventions, with SSRIs being the most often used class of drugs. Although most studies (n = 8; 61.5%) reported which drugs were used, only RCTs controlled for the effect of these medications. In addition, most studies (n = 7; 38.5%) did not report how long the participants had been on medication. Among those studies that reported this variable (n = 4; 30.8%), participants remained on the same medication and dosage for 3 weeks to 3 months before the start of the GCBT intervention.

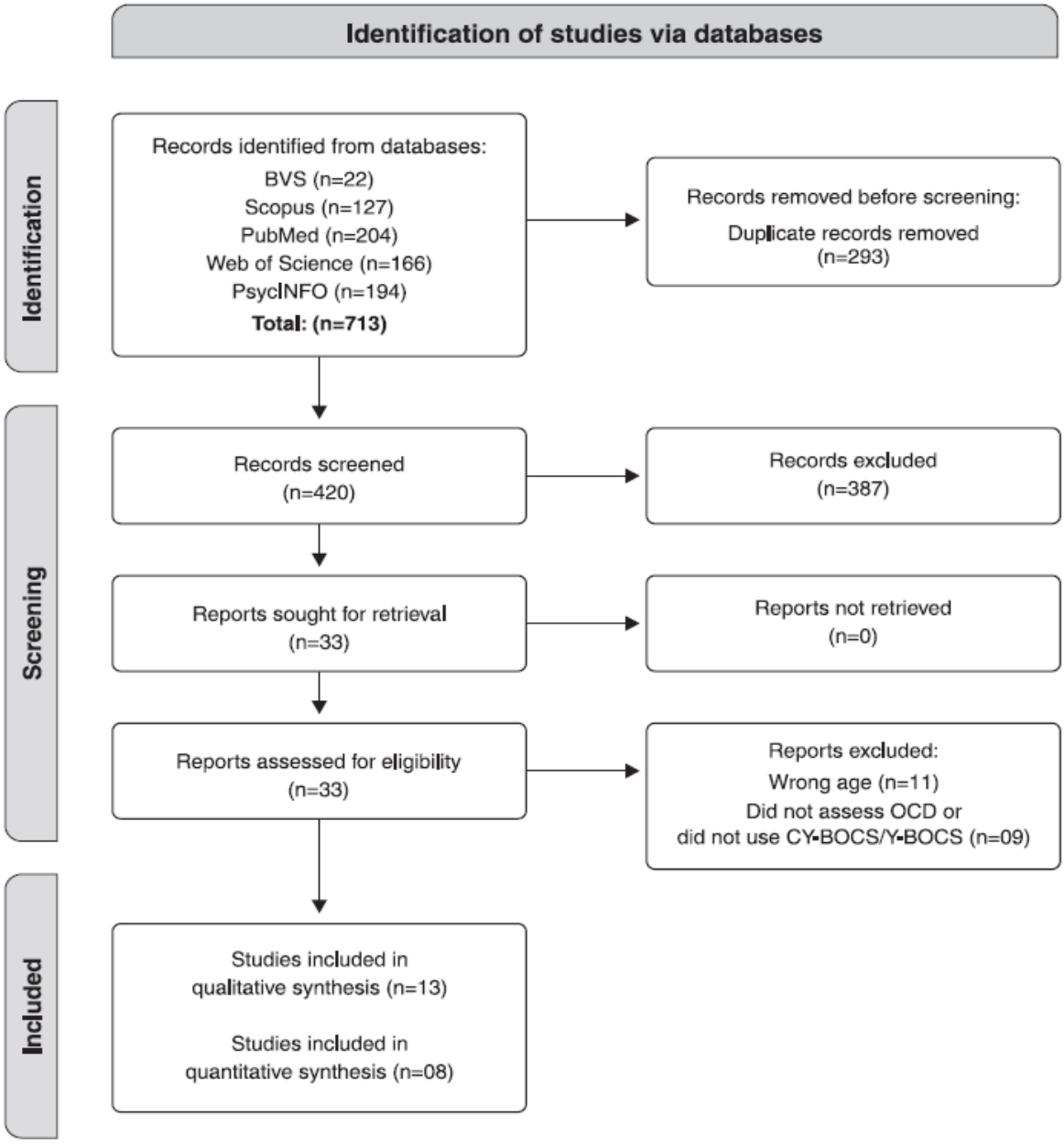

Figure 1 Flowchart. CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; OCD = obsessive-compulsive disorder; Y-BOCS = Yale-Brown Obsessive Compulsive Scale.

Table 1 Characteristics of studies and interventions

Reference and country	Study design	Protocol used	Intervention (comparison)	Duration of treatment	Weekly sessions (duration)	Family participation (how many/ which sessions)	Outcome measures
Fischer,[28] United States	NRCT	A standardized behavioral group treatment program for obsessive-compulsive disorder[45]	GCBT (pre/ post-test)	7 weeks	1 (1.5h)	7 educational sessions (optional) open to everyone (family and clients)	CY-BOCS
Thienemann,[29] United States	NRCT	OCD in Children and Adolescent: A Cognitive-Behavioral Treatment Manual[46] - How I ran OCD off My Land	GCBT (pre/ post-test)	14 weeks	1 (2h)	Last 15 min of each session + 1 session with the participation of parents and siblings	CY- BOCS
Himle,[47] United States	NRCT	Group behavioral therapy for adolescents with obsessive-compulsive disorder[48]	GCBT (pre/ post-test)	7 weeks	1 (1.5h)	1 optional weekly session with patients and family	CY-BOCS
Barrett,[30] Australia	RCT	Freedom From Obsessions and Compulsions Using Cognitive-Behavioral Strategies (FOCUS)	GCBFT (ICBFT and waitlist)	14 weeks + 2 booster sessions after 1 month and after 3 months of the intervention	1 (1.5h)	50 min children10 min parents + children30 min parents (skills training)	CY-BOCS
Barrett,[13] Australia	12 and 18 months follow-up						
O'Leary,[14] Australia	7-year follow-up						Y-BOCS
Martin,[49] United States	NRCT	How I ran OCD off My Land[46]	GCBT (pre/ post-test)	14 weeks	1 (1.5h)	Two simultaneous groups:60 min children (G1)60 min parents (G2) At the end of each session, the groups got together for 30 min	CY-BOCS
Asbahr,[22] Brazil	RCT	How I ran OCD off My Land[46]	GCBT (sertraline)	12 weeks	1 (1.5h)	Last 15 min of each session + 1 session with the participation of parents and siblings	CY-BOCS
Farrell,[50] Australia	NRCT	OCD Busters (Child and Adolescent Versions)	GCBT (pre/pos-test)	13 weeks + 2 booster sessions after 1 month and after 3 months of the intervention	1 (1.5h)	Last 15 min of each session + 3 group sessions with parents (1 h) and two individual sessions with each family (1 h)	CY-BOCS
Lavell,[51] Australia	12 months follow-up						

Continued on next page

Table 1 (*continued*)

Reference and country	Study design	Protocol used	Intervention (comparison)	Duration of treatment	Weekly sessions (duration)	Family participation (how many/ which sessions)	Outcome measures
Fatori,[52] Brazil	RCT	How I ran OCD off My Land[46] > with language adaptation for Brazil through the Cordioli[53] protocol	GCBT (FLX)	14 weeks	1 (1.7h)	Parents of the FLX group were invited to accompany their children during biweekly consultations with the doctor. Last 15 min of each session + 1 session with the participation of parents and siblings	Y-BOCS
Selles,[54] Canada	NRCT	OCD is Not the Boss of Me	GFCBT (pre/ pos-test)	12 weeks	1 (1.5h)	Parents participated in a Parent Group and in the final 15-30 min of each session they join their children to answer questions and receive the homework	CY-BOCS
Shabani,[55] Iran	RCT	How I ran OCD off My Land [46]	GCBT + SSRI (ACT + SSRI and SSRI)	12 weeks	1 (1h)	Last 5 min of each session, they received a summary of what was discussed and were instructed not to reinforce obsessive behaviors	CY-BOCS

ACT = acceptance and commitment therapy; CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; FLX = fluoxetine; GCBT = group cognitive-behavioral therapy; GCBFT = group cognitive-behavioral family therapy; GFCBT = group family-based cognitive behavioral therapy; ICBFT = individual cognitive-behavioral family therapy; NR = not reported; NRCT = non-randomized clinical trial; OCD = obsessive compulsive disorder; RCT = randomized clinical trial; SSRI = selective serotonin reuptake inhibitors; Y-BOCS = Yale-Brown Obsessive Compulsive Scale.

Table 2 Characteristics of the participants

Study	Sample size	Mean age (SD)	Sex ratio	Psychiatric comorbidities	SMP	Medication	Time of use
Fischer[28]	15	14.5 (NR)	9M; 6F	NR	67%	SSRI	3 weeks BI
Thienemann[29]	18	15.2 (NR)	12M; 6F	SOPH (n=3); MD (n=3); ED (n=1); SPPH (n=1); TD (n =1); TS (n=1); ID (n=1)	83%	NR	NR
Himle[47]	19	14.63 (1.71)	11M; 8F	MD (n=7); DYS (n=1); ADHD (n=4); ODD (n=2); SAD (n=4); PD (n=1); SOPH (n=1); AG (n=2); SPPH (n=2); GAD (n=1)	68%	SSRI (n=17) Stimulant for ADHD (n=6)	3 weeks BI
Barrett[30]	77	ICBFT – 10.75 (2.54)	ICBFT (12M;12F)	GAD (n=46); SPPH (n=27); SOPH (n=15); SAD (n=13); DYS (n=4); MD (n=2)	ICBFT (12.5%)	NR	3 months BI
		GCBFT – 12.90 (2.30) Waitlist – 11.75 (3.05)	GCBFT (13M;16F) Waitlist (13M;11F)		GCBFT (20.7%) Waitlist (21%)		
Barrett[13]	48	ICBFT – 12.91 (2.57) GCBFT – 14.65 (2.30)	ICBFT (11M;11F) GCBFT (12M;14F)	NR	ICBFT (9%) GCBFT (15%)	NR	NR
O'Leary[14]	38	ICBFT – 17.6 (2.75) GCBFT – 19.2 (2.81)	ICBFT (9M;10F) GCBFT (11M;8F)	NR	34%	SSRI	NR
Martin[49]	14	11.3 (NR)	4M; 9F	ADHD (n=5); PDD or NVLD (n=4); TTM (n=2); SSPH (n=2); GAD (n=1); TD (n=1); SOPH (n=1)	64%	SSRI(n=9); Stimulant for ADHD (n=4)	NR
Asbahr[22]	40	GCBT – 13.7 (2.32)	GCBT (15M; 5F)	MD (n=7); mania (n=1); anxiety disorders (n=12); ODD (n=6); TD (n=21); enuresis (n=4); ADHD (n=9); ED (n=1)	Only group Sertraline	SSRI	-
		Sertraline – 12.4 (2.76)	Sertraline (11M; 9F)				
Farrell[50]	43	11.09(2.52)	30M 13F	GAD (n=14); SAD (n=4); SOPH (n=8); SPPH (n=11); MD (n=3); DYS (n=2); ADHD (n=8); ODD (n=1); PDD (n=15)	67%	SSRI	NR
Lavell[51]							
Fatori[52]	83	GCBT – 11.4 (3.2)	GCBT (22M; 18F)	MD (n=16); anxiety disorders (n=65); disruptive disorders (n=23); TD (n=17)	Only group FLX	SSRI	-
		FLX – 12.1 (3.1)	FLX (18M; 25F)				

Continued on next page

Table 2 (*continued*)

Study	Sample size	Mean age (SD)	Sex ratio	Psychiatric comorbidities	SMP	Medication	Time of use
Selles[54]	85	13.9 (2.49)	39M;46F	GAD (n=21); TD; (n=13); ADHD (n=12); AS (n=12); SPPH (n=4); SAD (n=4); ODD (n=2); MD (n=1)	44.7%	NR	NR
Shabani[55]	69	GCBT – 14.95 (1.78) ACT – 14.95 (1.43) SSRI – 14.96 (1.24)	GCBT (12M;10F) ACT (12M;10F) SSRI (14M;11F)	NR	100%	SSRI	3 months BI

ACT = acceptance and commitment therapy; AG = agoraphobia; ADHD = attention deficit/hyperactivity disorder; BI = before intervention; DYS = dysthymic disorder; ED = eating disorder; F = female; FLX = fluoxetine; GAD = generalized anxiety disorder; GCBT = group cognitive-behavioral therapy; GCBFT = group cognitive-behavioral family therapy; ICBFT = individual cognitive-behavioral family therapy; ID = intellectual disability; M = male; MD = major depression; NR = not reported; NVLD = non-verbal learning disorder; ODD = oppositional defiant disorder; PD = panic disorder; PDD = pervasive developmental disorder; SA = social anxiety; SAD = separation anxiety disorder; SD = standard deviation; SMP = sample medication use; SOPH = social phobia; SPPH = specific phobia; SSRI = selective serotonin reuptake inhibitors; TD = tic disorder; TS = Tourette syndrome; TTM = trichotillomania.

Meta-analysis

To perform the meta-analysis of the effect sizes of GCBT interventions, only the pre- and post-test measures of the studies included in the qualitative synthesis stage were considered. Follow-up measures were not evaluated due to incompatibility of time periods and regression toward the mean.[56,57] In addition, two of the studies (8 and 11) did not provide sufficient data (i.e., mean, and standard deviation of the groups) for inclusion in the meta-analysis. Therefore, quantitative analyses were performed with eight of the 13 studies included in the qualitative synthesis (Figure 2).

All eight studies reported data on OCD symptom scores using the same psychometric instrument (i.e., Y-BOCS or CY-BOCS) and intervention (i.e., GCBT). A fixed-effect meta-analysis was estimated using mean, standard deviation, and sample size for each study and standard mean difference (SMD) as a measure of effect size. The main findings indicated an overall significant difference (d = -1.32) between pre-test and post-test scores in favor of GCBT. There was a slight difference between experimental and quasi-experimental designs. The effect observed in the experimental studies was greater (d = -2.07) compared to the quasi-experimental studies (d = -1.15), probably due to greater control for intervening variables. In addition, the study intervention conducted by Shabani et al.,[55] which consisted of a combination of GCBT and SSRI, had an effect like that of a GCBT-only intervention in the study by Barrett et al.[30]

As for quasi-experimental studies, those of Selles et al.[54] and Farrell et al.[50] represent 52.1% of the weight of this meta-analysis. This may be associated with their considerably greater number of participants. Finally, there is a significant level of heterogeneity in the overall model (I2 = 60%), which may be related to participants' comorbidities, previous experience with individual CBT, and/or medication use.

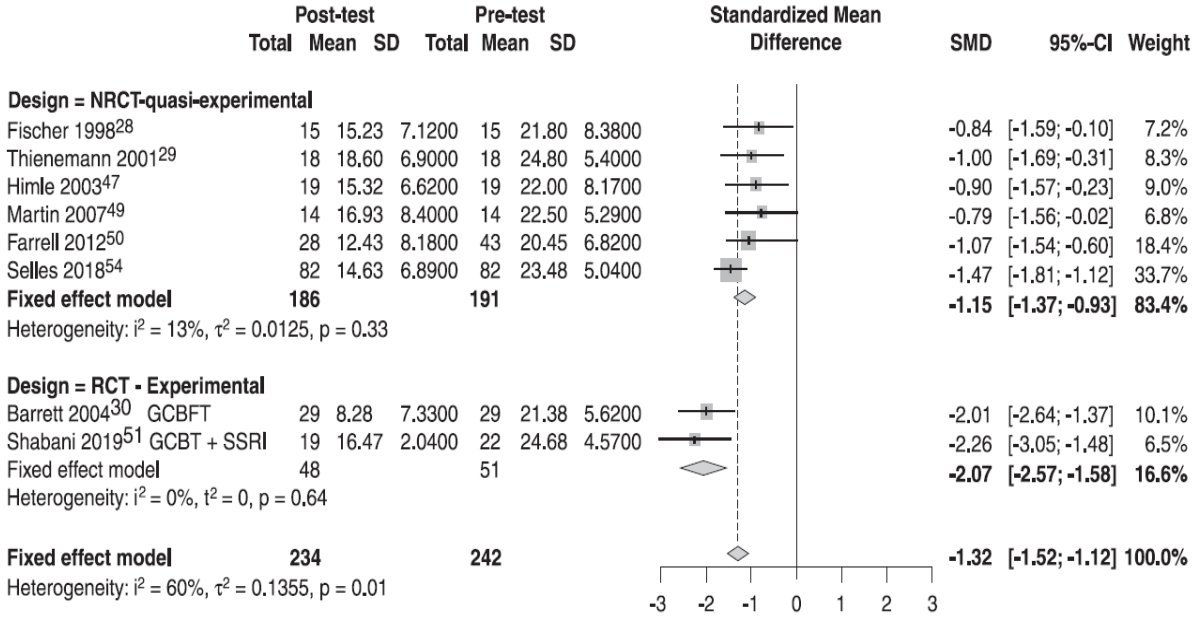

Figure 2 Fixed effects, standard mean difference (SMD), and accompanying 95% confidence interval (CI) for group cognitive-behavioral therapy (GCBT) interventions on OCD scores. GCBFT = group cognitive-behavioral family therapy; ICBFT = individual cognitive-behavioral family therapy; NRCT = non-randomized controlled trial; RCT = randomized controlled trial; SD = standard deviation; SSRI = selective serotonin reuptake inhibitors.

Risk of bias in included studies

A summary of the possible biases in the selected studies (evaluated with ROBINS-I for NRCTs,[41] and with RoB for RCTs[40]) is presented in Table 3. All studies showed a high risk of bias in at least one of the topics analyzed. All NRCTs were classified as having a high risk of confounding bias due to sample medication use, multiple comorbidities, or previous treatment with CBT. One study was classified as high risk of selection bias due to selection of participants for the intervention based on the clinical perception that these individuals would benefit from the treatment modality. Three studies were classified as unclear risk of measurement bias due to the lack of information regarding use of the CY-BOCS/Y-BOCS by raters who were not involved in providing group treatment. All studies were classified as unclear risk of reporting bias due to non-presentation of the registration number of the clinical trial and/or non-publication of the study protocol. None of the studies were classified as having a high risk of classification or deviation bias.

All RCTs were classified as having a low risk of selection, performance, detection, and attrition bias. Half of the RCTs (n=2) were classified as unclear risk of reporting bias due to non-presentation of the registration number of the clinical trial and/or non-publication of the protocol. Other sources of bias involved the assessment of bias from previous experience with CBT. This bias was classified as high risk in one RCT since at least one-third of the samples had already undergone CBT in the past. In addition, although five NRCTs also included participants with previous experience with CBT, only one of these trials (study 3) reported how long the participants underwent prior treatment. Thus, at least four NRCTs (studies 1, 2, 7, 12) and one RCT (study 11) may not have controlled for possible effects related to previous experience with psychotherapy.

Table 3 Risk of bias in included studies

Study: ROBINS-I	Confounding bias	Selection bias	Classification bias	Deviation bias	Missing data bias	Measurement bias	Reporting bias
Fischer[28]	+	+	-	-	-	-	?
Thienemann[29]	+	-	-	-	-	?	?
Himle[47]	+	-	-	-	-	-	?
Martin[49]	+	-	-	-	-	-	?
Farrell,[50] Lavell[51]	+	-	-	-	-	?	?
Selles[54]	+	-	-	-	-	?	?

Study: RoB	Selection bias	Performance bias	Detection bias	Attrition bias	Reporting bias	Previous experience with CBT (%)†	When
Barrett,[13] O'Leary,[14] Martin[49]	-	-	-	-	?	-	-
Asbahr[22]	-	-	-	-	?	-	-
Fatori[52]	-	-	-	-	-	+ (34%)	?
Shabani[55]	-	-	-	-	-	-	-

† Percentage of the sample with previous experience with CBT. + = high risk of bias; - = low risk of bias; ? = unclear risk of bias; RoB = Cochrane Collaboration risk of bias tool; ROBINS-I = Cochrane risk of bias tool to assess non-randomized studies of interventions.

Discussion

This systematic review with meta-analysis aimed to assess the effectiveness of GCBT in adolescents with OCD. After an extensive review of the scientific literature, 13 studies (RCTs or NRCTs) were identified, which used seven different intervention protocols. The main results suggest that GCBT for adolescents is effective in reducing the symptoms of OCD, with a reduction of approximately one standard deviation in symptoms between pre-intervention and post-intervention time points; in experimental studies, this reduction reached two standard deviations. Similar results (g = 1.21) were also found in another meta-analysis that evaluated the effectiveness of ICBT in children and adolescents. Even so, our results should be interpreted with caution, especially considering the small number of RCTs and the fact that all NRCTs were classified as having a high risk of bias in at least one of the topics analyzed, especially in confounding bias due to previous experience with CBT and medication use. In this sense, it is not possible to ensure that the effects observed in the metanalysis of NRCTs are exclusively due to the GCBT interventions.

In addition, most of the protocols (n=6) included in this review were tested by only one study. This small number of RCTs and NRCTs assessing the effectiveness of CBT in adolescents with OCD was also reported by another meta-analysis that aimed to investigate the effect size of CBT interventions in children and adolescents with several conditions, including OCD, anxiety, and depression.[34]

Some evidence suggests that treatment structure (e.g., parental involvement, relapse maintenance/prevention sessions, reinforcement sessions) can influence the effect size of an intervention.[34] This finding is not corroborated by our meta-analysis, since the interventions that used reinforcement sessions (i.e., booster sessions)[30,50] had no larger effect size than most of the other studies included. Although the study by Shabani et al.[55] showed the largest effect size in our metaanalysis, this effect may be associated with the use of combined treatment (i.e., GCBT + SSRI). In the case of the study by Selles et al.,[54] which had the largest effect size among NCRTs, this effect may have been associated with the level of previous experience with psychotherapy and/or medication use by 44.7% of the sample. Thus, these variables may have been poorly controlled during the sample selection.

In this sense, some studies indicate the possible influence of medication use (i.e., dosage and time of use) by part of the sample[58] and/or previous experience with

individual CBT or other psychotherapies on the results of GCBT interventions – especially considering that even individuals who do not respond well to individual CBT may experience some symptomatic improvement of OCD or comorbidities.[59] In addition, some authors suggest that, compared to GCBT (40.9%), individual CBT yields a higher recovery rate (68.75%) in adults treated for OCD, and this rate remains higher in individual CBT (62.5%) even 1 year after the interventions.[60] On the other hand, meta-analyses suggest that there is no significant difference in the effectiveness of individual CBT compared to GCBT in adult samples, with greater use of GCBT being recommended, as this modality can reduce waitlisting in health services.[59,61]

Thus, there is a need for additional studies that investigate the effectiveness of GCBT in the treatment of adolescents with OCD considering the possibility of differences in the effect size that may be associated with the use of different intervention protocols or structures. In addition, the need for greater control of possible intervening variables (e.g., previous experience with individual CBT and/or use of medication) must be emphasized.

No conclusive evidence was identified considering the influence of a greater or lesser number of sessions (e.g., 7 or 14 sessions) or the duration of each session (e.g., 90 or 120 minutes) on the effect size of the interventions. The effect size of the protocols that provided for seven sessions lasting 90 minutes[28,47] was similar to the effects of studies that followed protocols that recommended 14 sessions lasting 90 minutes[49] and 120 minutes.[29] This finding is corroborated by other systematic reviews, which also found no evidence to support that the number or duration of sessions is associated with the effect size of the interventions.[34,62] In any case, the hypothesis that increasing the number or duration of sessions will not result in greater efficacy in treatments with GCBT in adolescents with OCD must be confirmed by new RCTs.

The main limitations of this systematic review and meta-analysis concern the fact that only five databases were searched. Although these are the main databases in the field, other relevant studies may have been indexed in other databases. Another limitation concerns our absence of subgroup analyses (e.g., comparison between the effects of other interventions and GCBT) as proposed in the PROSPERO protocol. Such analyses were not performed since the included studies used different types of interventions that were not repeated between the studies and/or did not present enough data for inclusion in the meta- analysis (i.e., mean, and standard deviation of the groups). In addition, most of the studies found were NRCTs with a sample allocated

to a single pre- and posttest comparison group. Therefore, more RCTs that assess the effectiveness of GCBT compared to ICBT and control groups are recommended

Finally, regardless of the country of origin of the seven intervention protocols located in our review, all were written in English. Considering the small number of protocols and their publication in a single language, the development and/or cross-cultural adaptation of protocols for the treatment of adolescents with OCD from other cultures/nationalities is recommended.

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Disclosure

The authors report no conflicts of interest.

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7.2. Artigo 2: CAMALEO TOC: construction of a Manual for the Treatment of Adolescents with Obsessive Compulsive Disorder

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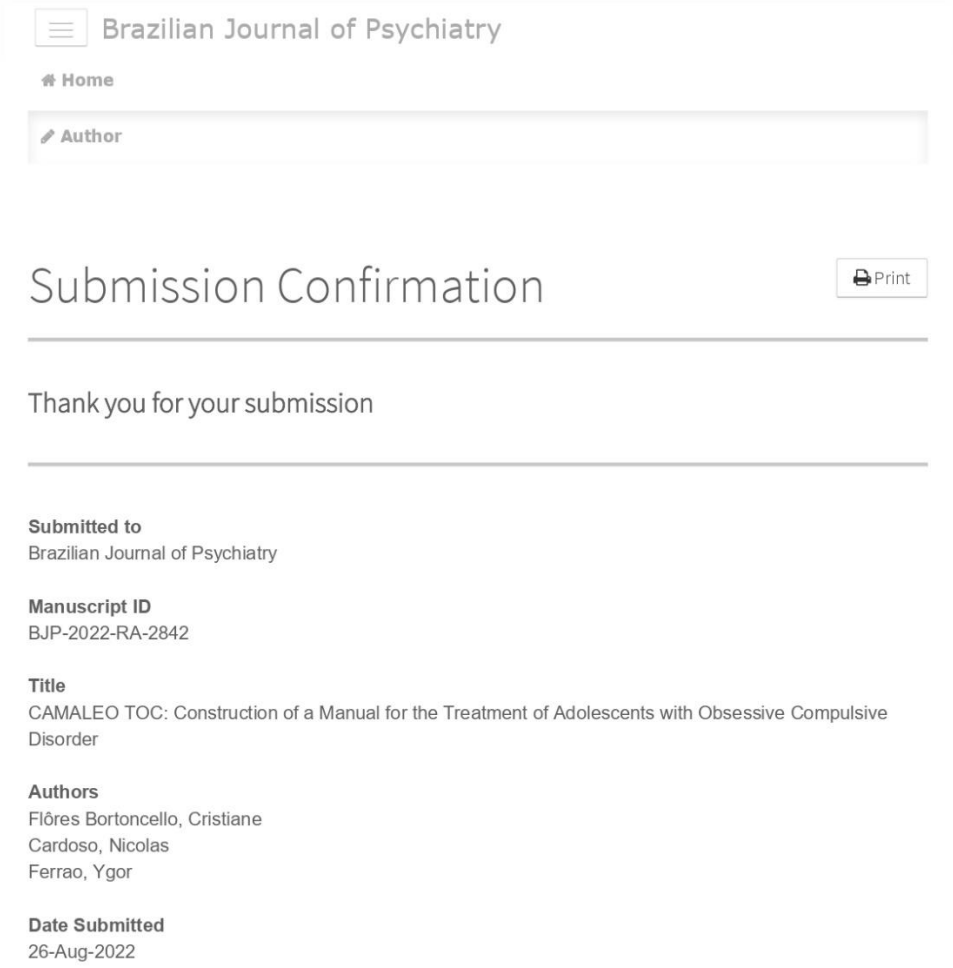

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O artigo segue abaixo, exatamente conforme submetido.

Title

CAMALEO TOC: Construction of a Manual for the Treatment of Adolescents with Obsessive Compulsive Disorder

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Abstract

Objective: This study aimed to present the construction process and the evidence of content validity of CAMALEO TOC, a manual of group cognitive-behavioral therapy (GCBT) for Brazilian adolescents with obsessive compulsive disorder (OCD). **Methods:** This study was structured in the following stages: 1) Systematic review in search of manuals with scientific evidence; 2) Appreciation of existing manuals; 3) Preparation of the new manual; 4) Expert assessment; 5); Assessment of the manual by adolescents; 6) Appreciation of the assessments; 7) Adjustments according to expert and adolescent assessments. The CAMALEO TOC content was evaluated by a psychiatrist, four psychologists' experts in adolescents with OCD, and seven adolescents. **Results:** The manual showed excellent applicability and evidence of content validity, both in adequacy (Finn = 0.98 mean score = 4.0; on a rating scale from 0 to 4) and relevance (Finn = 0.99 mean score = 4.0; on a rating scale of 0 to 4). **Conclusion:** More studies should be conducted to test this intervention.

Keywords: Obsessive compulsive disorder; Cognitive-behavioral therapy; Group therapy; Adolescents; Treatment manual.

Introduction

Obsessive compulsive disorder (OCD) is considered a heterogeneous disorder, associated with several different symptoms and can be divided into at least four (*i.e.* contamination, symmetry, harm, taboo/intrusive thoughts)[1] or six (*i.e.* aggression, injury, natural disasters; sexual and religious; symmetry, ordering, counting and arranging; contamination and cleaning compulsions; hoarding; miscellaneous)[2] subcategories according to the content of obsessive or compulsive symptoms. Regardless of category, intrusive thoughts and images that generate anxiety and lead to compulsive behaviors are symptoms that affect most individuals with OCD.[3] These symptoms cause several social and occupational damages in the daily lives of individuals with OCD, including the impacts of the stigma associated with the disease, thus contributing to the worsening of symptoms.[1]

The global prevalence of OCD is estimated to range between 1% and 3% in adults[4-3] and between 2% and 3% in adolescents.[5-6] In Brazil, the prevalence of OCD in adolescents is estimated at 3%.[5] Although the prevalence among adolescents is similar to the prevalence in adults, the occurrence of underdiagnosis of OCD in children and adolescents is known mainly due to the low capacity of insight of this population, and difficulty in verbally expressing symptoms, thoughts, and feelings.[4-7-5] In addition, parents have difficulty recognizing common behaviors of the age group and what can characterize a mental disorder.[8]

During adolescence, OCD usually causes significant changes in the routine of personal and social life, and it is common for adolescents with OCD to perceive differences in their behavior. It is not uncommon for adolescents with compulsive symptoms to feel ashamed of their thoughts and behaviors.[4-9] In addition, adolescents with OCD often have other comorbidities, such as anxiety and depression disorders.[4-9-10] A network analysis has shown that OCS (obsessive-compulsive symptoms) are also associated with guilt, sadness, and concentration problems symptoms, mutually influencing and reinforcing OCD and depression.[10]

Due to its prevalence and damage to physical and mental health, OCD is considered a public health problem, and the development of effective psychotherapeutic interventions is recommended, especially in developing countries.[4] Although both individual cognitive-behavioral therapy (ICBT) and group cognitive-behavioral therapy (GCBT) show efficacy in treating OCD in adults[10-11-12-13] and adolescents[14-15-16], some authors suggest that GCBT should be more used to reduce the waiting lists and increase the population's access to mental health services.[12-13]

This need to reduce the waiting time to receive treatment is necessary since evidence suggests that early treatment increases the chances of lifelong remission of symptoms.[15-17] The recommendation is that adolescents receive an appropriate diagnosis and treatment as early as possible.[17] Although the use of GCBT to reduce the waiting lines in public health services is

recommended in Brazil, mainly due to its lower cost,[18] this practice is not usually performed. A possible explanation was provided by a systematic review with meta-analysis, which aimed to assess the effectiveness of existing GCBT manuals for OCD in adolescents. The authors located six GCBT manuals used for the treatment of OCD in adolescents from different countries. Although all manuals showed evidence of efficacy, none of them are available for use in Brazil.[19]

This finding highlights the need for a GCBT manual (or protocol), with evidence of validity and efficacy, for the treatment of adolescents with OCD in Brazil. Thus, aiming to reduce the waiting lines and providing early treatment to the largest possible number of adolescents with OCD in Brazil, this study aims to present the process of construction and evidence of content validity of a group cognitive-behavioral therapy manual for Brazilians adolescents with obsessive-compulsive disorder, entitled “CAMALEO TOC”.

Method

The method of this study uses a quantitative and qualitative approach, as suggested by international guidelines for the development and adaptation of instruments in the health area.[20-21-22] The elaboration of the GCBT CAMALEO TOC manual was performed in six stages: 1) Systematic review in search of manuals with scientific evidence (Bortoncello et al., 2022); 2) Appreciation of existing manuals; 3) Preparation of the new manual; 4) Expert assessment; 5); Assessment of the manual by adolescents; 6) Appreciation of the assessments. Figure 1 illustrates the flowchart of procedures followed to prepare the CAMALEO TOC Manual.

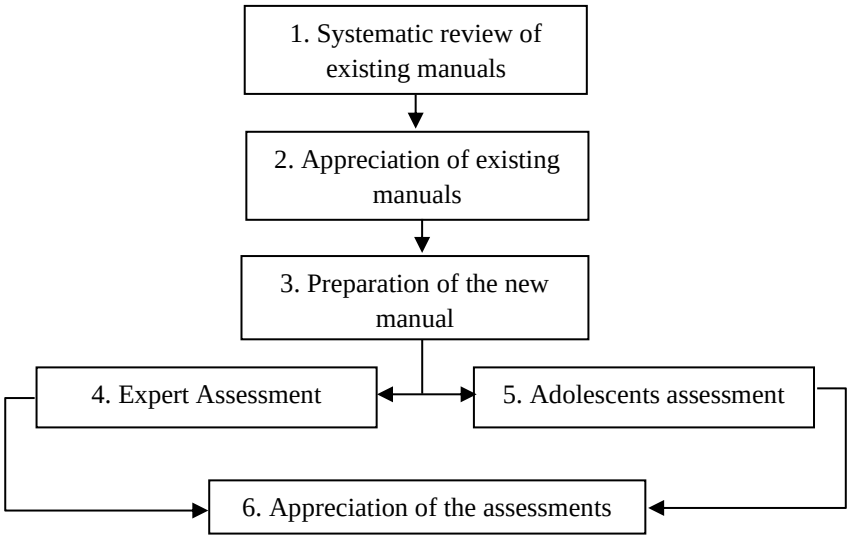

Figure 1. *Procedures for prepare the CAMALEO TOC Manual*

Stage 1 - Systematic Review in search of manuals with scientific evidence

Initially, a systematic review with meta-analysis was performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses - PRISMA model.[23] The review aimed to locate and evaluate evidence of the effectiveness of GCBT manuals used in the treatment of adolescents with OCD. For this, five databases were consulted and 713 studies were retrieved. After applying the inclusion and exclusion criteria, 13 articles remained for qualitative analysis and eight for quantitative analysis (meta-analysis). The results of the systematic review indicated the existence of six manuals and the meta-analysis showed that GCBT is effective in reducing OCD symptoms in adolescents (*d* = -1.32). However, none of the manuals are available for use in Brazil.[19]

2. Appreciation of existing manuals

Based on these results, the six manuals identified in the systematic review were acquired and their contents were extensively reviewed by a psychologist expert in childhood and adolescence with OCD (Cristiane Flôres Bortoncello). Data from these manuals were used as a basis for the preparation of the manual CAMALEO TOC. For example, the average total duration of treatments, number of weekly sessions and duration of each session, type of family participation during the consultations, structure, and topics covered in each session.[19]

Nessa etapa, somente uma psicóloga especialista em TOC na infância e adolescência (Cristiane Flores Bortoncello) realizou a leitura dos manuais. Isso ocorreu devido ao tamanho dos manuais/protocolos (alguns apresentavam 300 páginas), que tornou inviável a participação não remunerada de outros especialistas em TOC na infância e adolescência. At this stage, only a psychologist specializing in childhood and adolescence OCD (Cristiane Flores Bortoncello) read the manuals. This was due to the size of the manuals/protocols (some had 300 pages), which made the unpaid participation of other specialists in OCD in childhood and adolescence unfeasible.

3. Preparation of the new manual

The CAMALEO TOC manual was prepared by an expert psychologist in childhood and adolescence OCD (Cristiane Flôres Bortoncello), aiming to provide quality group psychotherapy treatment for Brazilian adolescents with OCD between 10 and 19 years of age. The manual consists of 130 pages and is divided into 12 sections, as shown in Chart 1.

Chart 1. Structure of the CAMALEO TOC Manual

Session 1 - Do you have obsessive compulsive disorder (OCD)? Psychoeducation on obsessions, compulsions, mental compulsions, sensory phenomena, avoidances, and symptom list.
Session 2 – Do you know how this happened to you? Psychoeducation on the causes of OCD, cognitive model of OCD, sensory phenomenon, family accommodation, and tasks.
Session 3 – How do I overcome OCD? Information on treatment with Cognitive-Behavioral Therapy, exposure and ritual prevention, habituation, and medication.
Session 4 – Coping with symptoms related to contamination, disgust, cleaning rituals, excessive washing, and bathing. Psychoeducation about excessive worry, normal hygiene habits, beliefs, CBT and Ritual Exposure and Prevention (REP) tasks.
Session 5 – Facing the symptoms related to doubts, checks, doing, and redoing. Psychoeducation on beliefs related to the need to check and tasks.
Session 6 – Facing symptoms related to symmetry, ordering, counting, and organization. Psychoeducation on perfectionism, insight, cognitive rigidity, and tasks.
Session 7 – Facing symptoms related to superstition (lucky or unlucky numbers, colors with special meaning), and natural disasters. Psychoeducation and beliefs about magical or superstitious thoughts, and related tasks.
Session 8 – Facing obsessive rumination symptoms related to aggression, violence, sex, and religion. Psychoeducation and beliefs about intrusive thoughts, thought power, thought control, and related tasks.
Session 9 – Facing the hoard. Psychoeducation and beliefs about hoarding, pathological hoarding, and related tasks.
Session 10 – What have I learned so far and how do I protect myself so OCD doesn't come back? Psychoeducation about lapses, relapses, and related tasks.
Session 11 – Preparing for Graduation. Relapse prevention, reinforcement session, and related tasks.
Session 12 – Graduation. Last session to clarify possible doubts, confraternization, and evaluate the treatment.

Sessions 1 and 2 occur with the simultaneous presence of adolescents and their guardians (2:00 hours each), to provide important information about the entire treatment and verify family accommodation.

Sessions 3 to 12 are divided into two parts:

1st Part: session with adolescents (1:30 hours) to ensure confidentiality and freedom to talk about the adolescents' symptoms throughout the treatment.

2nd Part: session with adolescents and guardians (30 minutes remaining) to observe the severity of symptoms, family accommodation, and provide adequate support for adolescents throughout the treatment.

During treatment, both adolescents with OCD and their guardians have access to information that allows them to obtain a better understanding of OCD and the suffering generated by it. Participants also receive suggestions to improve interpersonal and family relationships, which contribute to the effectiveness of treatment.[24]

During the preparation of the manual, the semantic, idiomatic and conceptual equivalence of terms adapted from the six international manuals were considered. In addition, simple language was used instead of scientific in order to simplify the understanding of the manual by adolescents of different ages and types of schooling (*i.e.,* public or private). Furthermore, another GCBT manual for the treatment of adults with OCD developed by a Brazilian researcher and therapist, with extensive experience in the field of OCD,[25] was used to support the adaptation of certain cultural and language (*i.e.,* expressions and metaphors) aspects.

The name of the manual CAMALEO TOC was chosen from a character, which was designed by an illustrator to represent the dimensions of OCD symptoms. It is a chameleon mix with OCD, by the acronym in Portuguese “TOC” (*Transtorno obsessivo-compulsivo*). The chameleon is an animal that camouflages itself (changes color) to hide and stay alive, as well as OCD, which tends to change the dimensions of symptoms and intensity throughout life as a strategy for survival and maintenance of the disorder, remaining strong and thereby harming the adolescent.

The character was created as a possibility for adolescents to look from the outside (in concrete) at their symptoms, verify the intensity and the damage caused, be able to think from the outside the most effective strategies for exposure, and at the same time “try to play” with the disorder and make it lighter. Figure 2 presents the manual character cover logo.

Figure 2. *CAMALEO TOC manual character cover logo*

The character appears in session 3 exemplifying each dimension of OCD symptoms, and at the end of the manual in a smaller size, showing that coping through exposure can reduce or eliminate symptoms. Figure 3 presents the character from session 7 related to superstitions (lucky and unlucky numbers, colors with special meaning) and natural disasters.

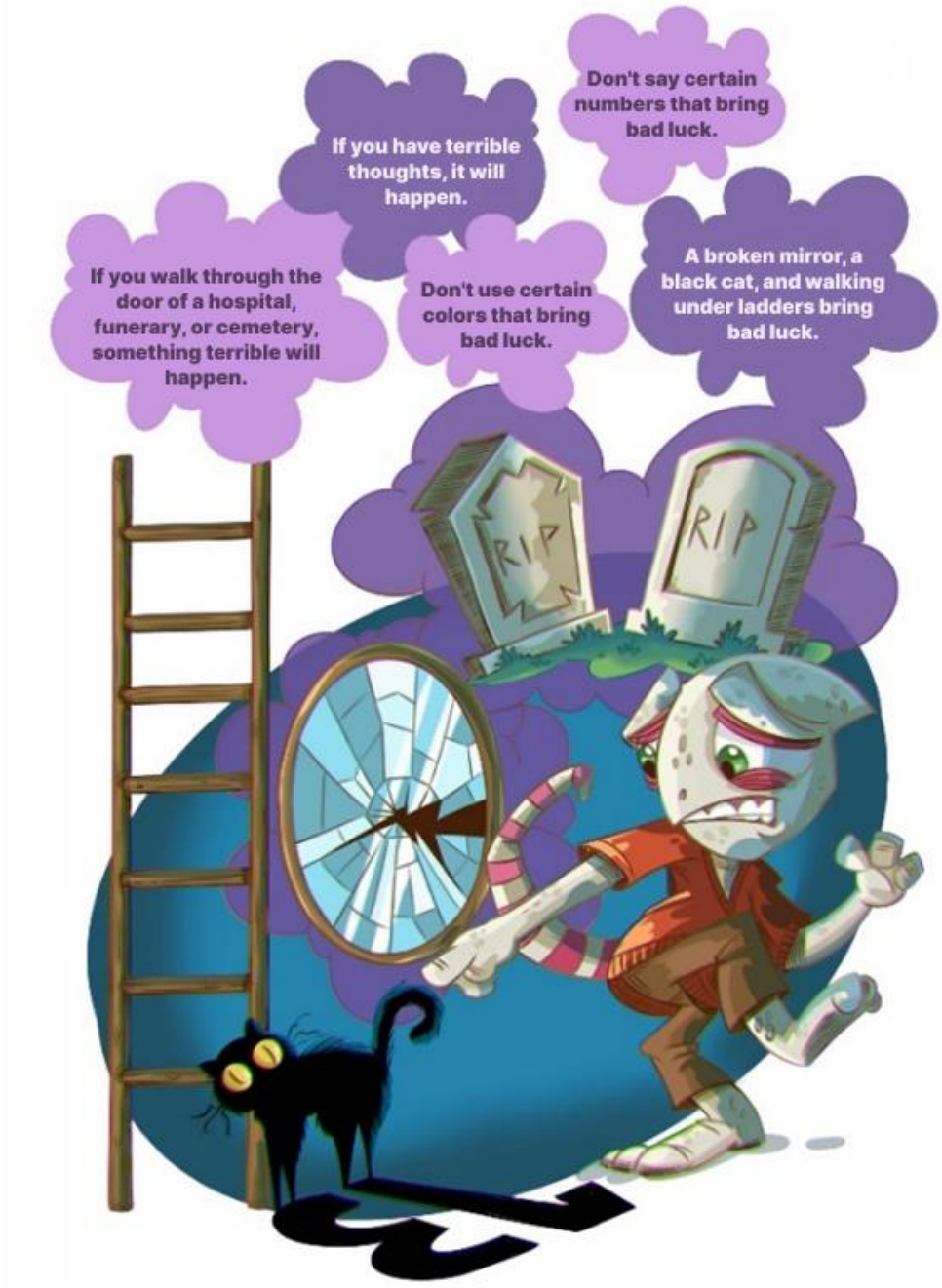

Figure 3. *Example of the CAMALEO TOC character used in section 7 of the manual*

It was decided to develop a new manual, instead of adapting the existing ones, considering that the international manuals used were mostly childish versions (*i.e*., infantilized figures), adult versions adapted for adolescents, or extensive versions (*i.e.,* 298 pages), which

can lead to low adherence by adolescents. In the international manuals, there was also no space reserved for the adolescent to perform the tasks of the GCBT sessions, serving as support during the treatment. Furthermore, these manuals did not describe the sensory phenomenon, which is usually very prevalent in adolescents.

4. Expert assessment

The initial version of the manual was sent for consideration by four psychologists and one psychiatrist experts in childhood and adolescent OCD. These professionals were invited to perform the content validity[26-27] through a critical and detailed analysis. For each session of the manual, experts assessed face relevance/validity (*i.e.,* degree to which the session is appropriate for treating OCD) and adequacy (*i.e.,* Is it a common situation and can be easily understood by adolescents with OCD?) through two closed-ended questions in a Likert type scale (*i.e*., 0 Not at all adequate/relevant and 04 Totally adequate/relevant) and two other dichotomic questions with two response option (Yes/No).

The questions were presented in the following format: 1) Is the language of the information clear and appropriate for the adolescent audience? (adequacy); 2) Does the session use CBT assumptions and is it suitable for use in treating adolescents with OCD? (relevance); 3) The text is too long and/or could be summarized (Yes/No?); 4) Are any words or phrases unclear to you? (Yes No?). If the option “Yes” was selected, in the semi-structured questions, the expert was invited to specify which word or phrase was not clear and to suggest an alternative to improve the indicated passage.

5. Assessment of the manual by adolescents

To assess the clarity of the manual's presentation format and language (*i.e.,* content validity/adequacy),[27] seven healthy adolescents (without a psychiatric diagnosis) who had never undergone psychotherapy were invited to answer a quantitative question (Likert-type scale 0-4) and two dichotomic. The questions presented to the adolescents were the same as those answered in the previous stage by the expert group, except for question 2, which was removed since adolescents were not expected to have technical knowledge about CBT and/or scientific methods. Table 1 presents the sociodemographic profile of adolescents and Table 2 the main observations of experts and adolescents.

Table 1

Sociodemographic profile of adolescents

Sociodemographic variables			
Sex	**Age** (mean = 16.1; SD = 2.1)	**Study/Studied at school**	**Grade/Semester**
Male	15	Private	9th Grade
Female	14	Private	8th Grade
Female	19	Private	4th Semester*
Female	19	Private	2nd Semester*
Female	17	Public	10th Grade
Female	15	Public	9th Grade
Female	14	Public	9th Grade

*Note: ** Higher education

6. Appreciation of the assessments and adjustment of the manual

The qualitative responses from the experts and the adolescents were assessed by a psychologist expert in OCD (Cristiane Flores Bortoncello). All suggestions for modifying words/phrases have been addressed, except some suggestions for reducing the amount of text, as some information is important and cannot be removed from the structure of each session and/or the manual. Quantitative assessments were conducted by a psychologist expert in psychometrics (Nicolas de Oliveira Cardoso). Considering that there were few suggestions for modifications and that the adequacy and relevance scores of the sessions were (≥ 3.5), there was no need to resubmit the manual, after modifications, for reassessment by experts and/or target audience.

Ethical and data collection procedures

The GCBT CAMALEO TOC manual was sent via email to the experts and hand-delivered to the adolescents. In both cases, a link was made available on Google Forms to evaluate the content of the manual. Adolescents were selected by convenience and snowball sampling. The study was approved by the Research Ethics Committee of the Federal University of Health Sciences of Porto Alegre (CAAE: 30918720.9.0000.5345).

Data analysis

Evidence of content validity of the GCBT CAMALEO TOC manual was obtained considering the relevance and adequacy of each session of the manual, through the assessment of expert judges and adolescents (target audience). All analyzes were performed in version 4.1.2 of the R software.[28] The reliability index between experts and participants in the pilot study was measured using the Finn coefficient,[29] which was developed for the analysis of agreement when there is low variability in responses. For this, the data package Various Coefficients of Interrater Reliability and Agreement – IRR[30] was used. Reliability analyzes considered the listwise method for the treatment of missing values.

Results

Assessment of experts and adolescents

The GCBT CAMALEO TOC manual showed a great index of reliability among experts in the adequacy (Finn = 0.98) and relevance (Finn = 0.99 - Appendix A) assessments. Most (*n* = 11) of the sessions analyzed by the experts had Finn ≥ 0.90 (mean session score = 4.0; range 3.6-4.0) in the adequacy and relevance criteria, which indicates almost absolute agreement between the quantitative assessments. However, even in sessions with an average score ≥ 3.6, modifications of some sentences/excerpts were suggested (*i.e.,* qualitative analysis). Table 2 presents a summary of the excerpts from the sessions that underwent reformulations based on the suggestions by the experts.

Table 2

GCBT CAMALEO TOC manual sessions reworked based on experts suggestions

	Excerpts from the sessions (*CAMALEO TOC*)	
Sessions (Finn)	**Before the expert review** (Average of the evaluations of the sessions)	**After expert analysis**
Session 1 (1.0R; 0.90A)	Title Session 1: DO YOU HAVE OBSESSIVE COMPULSIVE DISORDER (OCD)?	What is OCD? (It was placed as a subtitle)*
	If I believe that going under the stairs will bring bad luck to my family, I feel the need to cross the street.	...I feel the need to stay away from stairs*
Session 2 (0.85R; 0.85A)	Be kind and polite and if he doesn't listen, remember that you are on this journey together.	Be kind and polite! It is very difficult for him to deal with the symptoms, so remind him that you are on this journey together**
Session 3 (1.0R; 1.0A)	Remember that anxiety rises and then falls.	Remember that anxiety, fear or discomfort you will feel during the exposure is temporary, you are able to bear it, but if it is too difficult, you can ask someone you trust for help*
	Change or remove the example "don't take your shoes off to enter the house". With the pandemic, it became a welcome habit. It can generate confusion.	Removed*
Session 4 (1.0R; 1.0A)	30 seconds is the maximum time for hand washing. Shampoo or soap no more than twice Not washing dishes and cutlery before meals.	30 seconds is adequate time for...* Shampooing or soap once is considered sufficient* Do not wash dishes and cutlery before meals, when they are already clean*
	I suggest reviewing all examples of coping with "normal hygiene" habits. With the pandemic, it is no longer correct to drink	These and other examples that could generate doubts have been removed or clarified*

	from the same glass, share food, pull over a railing...	
	Avoid social interaction (for example: not to feel anxiety if you have to share the bathroom, not to run the risk of touching someone you think is contaminated, etc.);	Avoid social interaction, outside the pandemic period...*
	Avoid touching toilets, faucets, doorknobs, handrails, sick people for fear of contaminating yourself, etc.	Avoid touching toilets, faucets, doorknobs and handrails in your own home for fear of contaminating yourself (outside the pandemic period)*
	Touching stair, mall, or bus handrails.	Touching stair, mall, or bus handrails and not washing hands immediately*
Session 5 (1.0R; 1.0A)	-	-
Session 6 (1.0R; 1.0A)	-	-
Session 7 (1.0R; 1.0A)	-	-
Session 8 (1.0R; 1.0A)	-	-
Session 9 (1.0R; 1.0A)	-	-
Session 10 (1.0R; 1.0A)	-	-
Session 11 (1.0R; 1.0A)	-	-
Session 12 (1.0R; 1.0A)	-	-

Note: * Modified based on qualitative expert comments; ** Modified based on comments + quantitative analysis (*i.e.,* session Finn < 0.90). **A** – Adequacy; **R** – Relevance.

Although excerpts from some sessions have been reworked, none have undergone significant content or structural reformulations, and few have been removed following expert review. Furthermore, only one session presented Finn < 0.90, some excerpts from four sessions were reformulated based on qualitative analysis and eight sessions did not change. Tree of the five experts suggested modifications of phrases or words in at least one section of the manual. After the experts' analysis, the adolescents performed the reliability analysis of the GCBT CAMALEO TOC manual, with Finn = 0.98 (mean session score = 3.7; range 3.6-3.9) in the adequacy criterion in all analyzed sessions, which indicates almost absolute agreement between quantitative assessments. However, even in sessions with a mean score ≥ 3.6,

changes in terms/words (*i.e.,* qualitative analysis) were suggested. Table 3 presents the synthesis of excerpts from the sessions that underwent reformulations based on the suggestions by the adolescents.

Table 3

GCBT CAMALEO TOC manual sessions reworked based on adolescents' suggestions

Excerpts from the sessions (CAMALEO TOC)		
Sessions (Finn)	**Before adolescents'analysis** (Average of the evaluations of the sessions)	**After adolescents' analysis**
Session 1 (0.93A)	Bad omen Blasphemies Unanimous and Socratic	Bad omen removed Added explanation (insult, outrage)
Session 2 (0.94A)	Unanimous and Socratic	Socratic Questioning (questioning the automatic negative or catastrophic thought that comes to your mind, paying attention, so you don't let fear or distress drive you to do a ritual) Unanimously removed
Session 3 (0.93A)	Unanimous and Socratic	
Session 4 (0.93A)	Unanimous and Socratic	
Session 5 (0.93A)	Unanimous and Socratic	
Session 6 (0.93A)	Unanimous and Socratic	
Session 7 (0.96A)	Obsessive rumination	Word removed
Session 8 (0.96A)	Obsessive rumination	
Session 9 (0.94A)	Obsessive rumination	
Session 10 (0.94A)	Obsessive rumination	
Session 11 (0.94A)	-	
Session 12 (0.94A)	-	

Note: ***** Modified based on qualitative expert comments; A – Adequacy.

Differently from the analysis of the experts, in the analysis of the adolescents only modifications of some specific terms/words of 10 sessions were recommended. None of the sessions underwent significant content or structural reformulations and/or had excerpts removed after the analysis of the adolescents. Differently from what happened in the analysis by experts, none of the sessions presented Finn < 0.90, that is, the changes made in the 10 sessions were based only on the qualitative analysis. Three of the seven adolescents suggested modifications to some word or phrase in the manual. Although two of the five experts and five of the seven adolescents reported that the GCBT CAMALEO TOC manual was too extensive, it was not possible to reduce the size of the sessions/manual due to the need to present specific/necessary contents for the treatment of adolescents involving psychoeducation performed in sessions 1 and 2.

Comparison of the structure of the CAMALEO TOC manual with other GCBT manuals for OCD in adolescents

Table 4 presents the structure data of the CAMALEO TOC manual and the comparison with similar manuals identified in our systematic review.[19] It is noteworthy that, although there is an international GCBT manual for adolescents with OCD that was adapted and tested in Brazil,[31-18] this manual did not perform the translation and adaptation stage recommended by Boateng et al.,[20] and by the International Test Commission,[21-22] as a literature review and language assessment by the target audience (adolescents). Furthermore, no evidence of psychometric and/or cross-cultural adaptation process of the manual has been published and the manual is not available for use by health professionals, whether paid or free.

Table 4

Structure of the CAMALEO TOC manual and comparison with similar manuals

Reference	Manual/protocol	Number of sessions*	Duration of sessions	Family participation (how many/ which sessions)	Number of manual pages
Brazil (present study)	CAMALEO OCD	12	2h	2 sessions with parents and 10 sessions with parents in last 15 min	130
USA (Fischer et al.)[36]	A standardized behavioral group treatment program for obsessive-compulsive disorder[1]	7	1.5h	Optional in all sessions	NR
(Martin et al.)[37]	How I ran OCD off My Land[b]	14	1.5h	Two simultaneous groups: 60 min children (G1) 60 min parents (G2). At the end of each session, the groups got together for 30 min	298
USA (Thienemann et al.)[38]		14	2h	Last 15 min of each session + 1 session with the participation of parents	
Brazil (Asbahr et al.)[31]		12	1.5h		
Brazil (Fatori et al.)[18]		14	1.7h	Last 5 min of each session, they received a summary of what was discussed and were instructed not to reinforce obsessive behaviors	
Iran (Shabani et al.)[16]		12	1h		
USA (Himle et al.)[39]	Group behavioral therapy for adolescents with obsessive compulsive disorder[a]	7	1.5h	1 optional weekly session with patients and family	NR
Australia (Barret et al.)[40]	Freedom From Obsessions and Compulsions Using Cognitive-Behavioral Strategies (FOCUS)	17	1.5h	10 min parents + children and parents 30 min (skills training)	NR
Australia (Farrel et al.)[41]	OCD Busters	16	1.5h	Last 15 min of each session + 3 group sessions with parents (1h) and two individual sessions with each family (1h)	NR
Canada (Selles et al.)[7]	OCD is Not the Boss of Me	12	1.5h	Parents participated in a Parent Group and in the final 15-30 min of each session they join their children to answer questions	252

Note: *All manuals hold one session per week;[a] Protocol originally developed by Krone et al.[b] for the treatment of OCD in adults; [2] Protocol originally developed by March and Mulle[32] for the treatment of OCD in children and adolescents. NR – Not reported.

Regarding the number and duration of sessions, studies with other protocols have an average of 13 sessions (SD = 3) lasting 1.52 hours (SD = 0.24). Thus, CAMALEO TOC is within the average number and duration of sessions of other manuals. In addition, one of the most used GCBT manuals for the treatment of OCD in children internationally[32] is usually adapted in different formats, with variations in the number and duration of sessions.

Regarding the presence of family members, the CAMALEO TOC is one of the manuals with the longest participation of family members during treatment. This decision was made by the creator of the manual since the involvement of parents can be useful to maximize the effectiveness of the treatment.[33]

Regarding the number of pages, although some experts and adolescents have mentioned that the CAMALEO TOC was very extensive and could be summarized, this manual is half the size of other international manuals.[32-7]

Discussion

This study aimed to present the stages of construction of the CAMALEO TOC manual and verify its evidence of content validity. The results of the experts' assessment of the relevance of the content of the manual (Finn = 0.99) and the adequacy of the experts and adolescents (Finn = 0.98) suggest that the structure of the CAMALEO TOC presents excellent preliminary evidence of content validity for use in Brazilian adolescents.

Although there is no minimum number of psychometric evidence for a given instrument to be considered valid, it is known that the greater the number of evidence, the greater its reliability.[20] Therefore, considering that this article presents a type of validity evidence, other studies that include a larger number of participants and perform other analyzes (*e.g.,* intervention/manual effectiveness) should be conducted. In addition to the small sample size, this study also has as a limitation the use of a sample composed almost exclusively of girls aged ≥ 14.

Therefore, before testing the effectiveness of the GCBT CAMALEO TOC manual, future studies are recommended to verify the content validity of the manual in adolescents between 10 and 13 years old, with equal numbers of boys and girls in the sample. Especially considering the existence of Brazilian population data[5] that indicate that OCD symptoms usually appear at an average age of 10 years (SD = 2.4), therefore, it is important to verify the adequacy of the language of the CAMALEO TOC for this age group. Despite these limitations, CAMALEO TOC has some advantages compared to other manuals available for OCD treatment. As far as is known, the CAMALEO TOC is the only instrument that rigorously followed the stages suggested for the development of instruments in the health area, such as conducting a systematic review and content validation by experts and target audience.[20-21-22] In this sense, the evidence of content validity of the CAMALEO TOC contributes to a better understanding of the manual by

adolescents, which may imply greater effectiveness of the intervention since a manual or evaluation instrument with inadequate/invalid content may erroneously indicate the occurrence or no clinically significant effects during treatment.[26]

Furthermore, the CAMALEO TOC is one of the manuals with the longest participation of parents/family members during the sessions, which can also contribute to the greater effectiveness of the intervention. Especially considering the existence of evidence suggesting that family involvement in sessions significantly influences the effect size of ICBT and GCBT interventions with adolescents.[33] Thus, family accommodation is present in relatives of patients with obsessive compulsive disorder, regardless of the type of obsessive-compulsive symptom[34] and the family plays an important role in the development and maintenance of OCD.[35]

We hope that this study will bring contributions to the fields of psychology and clinical psychiatry. In particular, in the development of a GCBT manual for Brazilian adolescents that can be used by the public health network to reduce waiting lines. This recommendation was also indicated by other Brazilian researchers.[18] In addition, an efficacy and validation study of the manual presented in this article is being conducted by the manual's developer and will be published as soon as possible.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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Appendix A
Code used to obtain the agreement index (content validity) between experts and adolescents in Software R

```
### Concordance Experts (Finn)

library(irr)
Experts<-read.csv(file.choose(),sep=";")
View(Experts)

# Session1 (Adequacy) Finn = 0.9
finn(Experts[c(1),c(2:6)],5,"oneway")

# Session1 (Relevance) Finn = 1.0
finn(Experts[c(2),c(2:6)],5,"oneway")

# TOTAL Considering the 12 sessions (Relevance) Finn = 0.99
finn(Experts[c(2,4,6,8,10,12,14,16,18,20,22,24),c(2:6)],5,"twoway")

# TOTAL Considering the 12 sessions (Adequacy) Finn = 0.98
finn(Experts[-c(2,4,6,8,10,12,14,16,18,20,22,24),c(2:6)],5,"twoway")

### Concordance Adolescents (Finn)

library(irr)
Adolescents<-read.csv(file.choose(),sep=";")
View(Adolescents)

# Session1 (Adequacy) Finn = 0.93
finn(Adolescents[c(1),c(2:8)],7,"oneway")

# TOTAL Considering the 12 sessions (Adequacy) Finn = 0.98
finn(Adolescents s[c(1:12),c(2:8)],7,"twoway")
```

Note: In the assessments of the content validity of the manual as a whole (*i.e.,* of the 12 sessions) “twoway” was used since it is a set of items/sessions (*e.g.,* number of sessions = c(2,4,6, 8....). On the other hand, the "oneway" was used in the other cases for the individual assessment of each session (*e.g.,* session 1 = c(1)). Session 1 was used to exemplify the code used, the same format was used in the other 11 sessions with replacement of the number of rows and columns of the database.

8 DIREÇÕES FUTURAS

8.1. Pandemia e terceiro estudo

A pandemia causada pela SARS COVID-19 impactou de forma negativa o andamento desta tese. Tivemos que fazer muitas adaptações e mudanças importantes foram necessárias para que pudéssemos seguir o nosso trabalho. Inicialmente era prevista a realização de três estudos. O terceiro estudo (ainda em andamento), refere-se à aplicação do manual de tratamento elaborado pela autora com o intuito de avaliar e apresentar as primeiras evidências de eficácia do Camaleo TOC em um estudo clínico quase-experimental (pré/pos teste) com 20 adolescentes com idades entre 10 e 19 anos.

Devido a COVID-19 esse estudo, que ocorreria de forma presencial em uma sala de um hospital de Porto Alegre, foi passado para modalidade on-line, sendo necessários novos tramites burocráticos. Para nos adaptarmos a nova realidade imposta pela pandemia, foi necessário que todos os documentos aprovados anteriormente fossem alterados e solicitado a plataforma Brasil (anexo 2) que autorizasse essa nova dinâmica e que o projeto pudesse seguir em frente com essa nova formatação (avaliações, testagens, entrevistas, tratamento e reavaliações on-line).

As mudanças na forma de coletar as informações com os adolescentes e seus pais e no formato da intervenção, trouxe baixa adesão por parte dos adolescentes e suas famílias que seguiam com medo da COVID-19. Outra questão imprevista que também ocorreu durante a pandemia foi que alguns auxiliares do grupo de pesquisa que estavam responsáveis por fazer a primeira avaliação adoeceram e outros declinaram, ocasionando redução na equipe de pesquisa, com isto tivemos de fazer novo treinamento de avaliadores das medidas pré e pós-intervenção, para garantir o cegamento do ensaio clínico. Embora tais situações tenham atrasado o projeto, um novo grupo de ajudantes foi selecionado e treinado para dar seguimento ao estudo após a defesa desta tese.

9 CONCLUSÃO E PERSPECTIVAS

Este estudo teve o objetivo de elaborar um manual de tratamento em grupo para adolescentes com TOC utilizando a Terapia Cognitivo-Comportamental como base, fundamentada por uma revisão sistemática com metanálise realizada no início desta tese (Bortoncello et al., 2022). Embora a pandemia ocasionada pela SARS COVID-19

tenha impedido que o projeto tenha sido realizado de forma plena, daremos seguimento ao estudo utilizando o manual elaborado pela autora para tratar os adolescentes de 10 a 19 anos acometidos pelo TOC. Estamos muito confiantes quanto as perspectivas futuras, pois acreditamos que após o tratamento dos adolescentes com TOC através do manual elaborado pela autora, teremos como resultado: evidência satisfatória de eficácia, redução nos escores dos sintomas de TOC destes adolescentes, aumento nos escores de qualidade de vida dos adolescentes com TOC, redução nos escores de sintomas de ansiedade e depressão dos adolescentes com TOC e redução nos escores de acomodação familiar dos familiares dos adolescentes com TOC.

10. ENVOLVIMENTO DA ALUNA COM O TEMA E LINHA DE PESQUISA

Durante o período do doutorado a aluna esteve envolvida em várias linhas de trabalho acadêmico relacionados ao tema de estudo. Participação em reuniões de pesquisas que acontecem no Brasil e na América latina, grupos de pesquisa conectados ao tema, sendo treinada para ser avaliadora de pesquisa em coleta de dados clínicos (padrão “ouro”). O envolvimento acadêmico da aluna também ocorreu por meio da participação de dois capítulos de livro, um livro de perguntas e respostas sobre TOC, diversas palestras, participação e organização de eventos on-line relacionados a TOC, aulas, lives e reportagens.

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APÊNDICES

APÊNDICE A - Termo de consentimento Livre e esclarecido (TCLE)

Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA)

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

O Transtorno Obsessivo-Compulsivo (TOC) é um transtorno psiquiátrico caracterizado pela presença de pensamentos intrusivos (obsessões), que aumentam a ansiedade das pessoas, causam muito desconforto e podem aparecer acompanhados pela necessidade de realizar atos ritualizados (compulsões), que estão associados à diminuição da ansiedade. Trata-se de uma doença mental grave, muito comum na infância e muito frequente na adolescência. Por se tratar de um transtorno que acarreta muito sofrimento, é importante que o diagnóstico e o tratamento aconteçam o mais breve possível, para tentar impedir o agravamento dos sintomas e aumentar as chances de uma remissão completa dos sintomas. Para isso é fundamental que a família participe do tratamento do TOC para que a acomodação familiar (AF) seja diminuída. A AF é muito comum e acontece quando os familiares acabem participando dos rituais ou evitando situações/locais que possam gerar algum desconforto no familiar com TOC, acreditando que estas medidas irão reduzir os sintomas.

O objetivo deste estudo é desenvolver, avaliar e apresentar as primeiras evidências de validade de um manual de terapia cognitivo comportamental em grupo (TCCG) para o tratamento de adolescentes brasileiros com TOC. Para atingir esse objetivo, os adolescentes irão avaliar a compreensão da linguagem do manual de TCCG, além disso, será oferecido tratamento em grupo para os adolescentes com TOC, com idades entre 10 a 19 anos, através do manual de TCCG elaborado para este estudo. Por fim, será avaliada a acomodação familiar nos pais ou responsáveis que residem com os adolescentes com TOC.

Você e seu filho(a) estão sendo convidados para participar da pesquisa intitulada “Manual de Terapia Cognitivo-Comportamental em Grupo para adolescentes com Transtorno Obsessivo-Compulsivo”. Sua participação não é obrigatória e, mesmo que aceite participar, a qualquer momento poderá desistir e retirar o seu consentimento. A participação de seu filho(a) nessa pesquisa consistirá no preenchimento de questionários relacionados a sintomas psicológicos e emocionais. O preenchimento dos questionários leva em torno de duas horas. Caso o seu filho tenha o diagnóstico de TOC e nunca tenha realizado psicoterapia com a abordagem Cognitivo-Comportamental, ele será convidado a participar de uma intervenção em grupo para o tratamento de TOC. A intervenção ocorrerá ao longo de 12 encontros com frequência semanal e duração de 2 horas no total, onde os adolescentes irão participar das primeiras 1 hora e 30 minutos e os pais nos 30 minutos restantes. No final, o adolescente será convidado a fazer uma reavaliação para a confirmação da ausência de sintomatologia, que levará em torno de 1 hora. Caso ele já tenha sido tratado com abordagem Cognitivo-Comportamental, ele será encaminhado para tratamento no CAPS de referência da região em que vocês residem. Mesmo que seu filho não seja selecionado para participar da pesquisa, caso seja identificada a presença de sintomatologia clínica indicativa de transtorno mental ou comportamentos de risco (por exemplo, automutilação, uso excessivo de álcool ou drogas) ele também será encaminhado ao CAPS mais próximo de sua residência.

Caso o seu filho seja selecionado para participar da intervenção com o manual, você será convidado para participar dos 30 minutos finais de todos os encontros em conjunto com o seu filho. Além da participação nos encontros, a participação dos

responsáveis dos adolescentes com TOC também consistirá no preenchimento de questionários relacionados a história de vida do filho e uma escala de acomodação familiar relacionado ao comportamento dos pais. O preenchimento dos questionários levará em torno de 30 minutos. No final do tratamento de seu filho, você também será convidado a fazer uma reavaliação dos comportamentos relacionados a acomodação familiar, que levará em torno de 30 minutos.

Apesar dos procedimentos não envolverem riscos diretos, é possível que aconteçam desconfortos relacionados à fadiga, devido à duração da pesquisa e à possibilidade de algumas das questões presentes nos questionários despertarem emoções desagradáveis. Caso isso ocorra, você ou seu filho(a) poderão interromper o preenchimento dos questionários e solicitar que um profissional da equipe (psiquiatra ou psicólogo) converse com vocês sobre esses sentimentos negativos. Além disso, caso seja observada necessidade, o profissional que prestou atendimento poderá realizar encaminhamento para o CAPS de referência de sua região, para que você e/ou seu filho(a) possam seguir com acompanhamento psicológico e/ou psiquiátrico. Destaca-se que esta pesquisa pode contribuir com a sociedade por meio do aprimoramento do conhecimento da população geral sobre TOC, seus sintomas e prejuízos associados, além do adolescente receber o tratamento gratuitamente.

As informações obtidas através desse estudo serão mantidas em lugar seguro, codificadas, e a identificação só poderá ser realizada pelo pessoal envolvido diretamente com o projeto, mantendo o sigilo. Caso os dados coletados venham a ser utilizados para publicação científica ou atividades didáticas, não serão utilizados nomes que possam vir a identificar seu filho(a).

Fui informado, que tenho direito ao ressarcimento de quaisquer despesas relacionadas a minha participação na pesquisa, por exemplo, posso solicitar ressarcimento das despesas com passagem de transporte público (ônibus e trem). Também fui informado que tenho direito a uma indenização diante de eventuais danos decorrentes da pesquisa.

Este projeto foi aprovado pelo Comitê de Ética em Pesquisa (CEP) sob número: **30918720.9.0000.5345** e quaisquer dúvidas relativas à pesquisa poderão ser esclarecidas pelo pesquisador responsável: Dr. Ygor Arzeno Ferrão - tel: (51) 3346-1077 ou pela pesquisadora: Cristiane Flôres Bortoncello - tel: (51) 3199-6300 ou (51) 997398544.

Caso você tenha qualquer dúvida quanto aos seus direitos como participante de pesquisa, entre em contato com Comitê de Ética em Pesquisa da Universidade Federal de Ciências da Saúde de Porto Alegre (CEP-UFCSPA) em (51) 3303-8804, Rua Sarmento Leite, 245, CEP: 90050-170, Porto Alegre – RS, e-mail: cep@ufcspa.edu.br. O Comitê de Ética é um órgão independente constituído de profissionais das diferentes áreas do conhecimento e membros da comunidade. Sua responsabilidade é garantir a proteção dos direitos, a segurança e o bem-estar dos participantes por meio da revisão e da aprovação do estudo, entre outras ações.

Após a leitura e recebimento de uma cópia (via) deste documento, informo que concordo que o meu filho(a) _____ participe desta pesquisa.

Porto Alegre, RS, ...de.....de.....

_____	_____
Assinatura do pai/mãe ou responsável	Assinatura do pesquisador
Nome:	Nome: Cristiane Flôres Bortoncello

_____

Assinatura do pesquisador

APÊNDICE B – Termo de Assentimento (TA)

Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA)

TERMO DE ASSENTIMENTO

Eu,_____, entendi o objetivo do estudo, que é o de avaliar a compreensão da linguagem do manual de Terapia Cognitivo-Comportamental em Grupo para adolescentes com TOC e oferecer tratamento para os adolescentes com TOC, com idades entre 10 a 19 anos.

Também entendi que antes de fazer o tratamento farei uma entrevista que levará o tempo de duas horas e caso eu tenha TOC e nunca tenha recebido tratamento através da abordagem Cognitivo-Comportamental, poderei participar de uma intervenção em grupo para o tratamento desta doença que ocorrerá semanalmente com duração estimada de 12 encontros de 2 horas cada. Também compreendi que no final do tratamento farei uma reavaliação para ver se os sintomas diminuíram ou sumiram e isso levará em torno de 1 hora. Entendi que apesar dos procedimentos não envolverem risco direto a minha saúde, é possível que aconteçam desconfortos relacionados ao tempo de duração da pesquisa e à possibilidade de algumas das questões presentes nos questionários despertarem emoções ruins.

Entendi que posso dizer "sim" e participar, mas que, a qualquer momento posso dizer "não" e desistir que ninguém vai ficar brabo comigo. Os pesquisadores tiraram minhas dúvidas e conversaram com os meus responsáveis. Recebi uma cópia deste documento, li e concordo em participar da pesquisa.

Porto Alegre, RS, ...de.....de.....

_____ _____

Assinatura do adolescente Assinatura do pesquisador

Nome: Nome: Cristiane Flôres Bortoncello

_____

Assinatura do aplicador

ANEXOS

ANEXO 1 - Autorização da Plataforma Brasil parecer nº 4.098.340

UNIVERSIDADE FEDERAL DE CIÊNCIAS DA SAÚDE DE PORTO ALEGRE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Manual de terapia Cognitivo-Comportamental em Grupo para adolescentes com Transtorno Obsessivo-Compulsivo

Pesquisador: Ygor Arzeno Ferrão

Área Temática:

Versão: 2

CAAE: 30918720.9.0000.5345

Instituição Proponente: Universidade Federal de Ciências da Saúde de Porto Alegre

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.098.340

Apresentação do Projeto:

O transtorno obsessivo-compulsivo (TOC) é uma doença mental grave, muito comum na infância e adolescência, com prevalência entre 2 a 3% nesta faixa etária, seu curso é crônico e, caso não seja tratado, se mantém por toda a vida, raramente desaparecendo por completo. Por se tratar de um transtorno que acarreta muito sofrimento, é importante que o diagnóstico e o tratamento aconteçam o mais breve possível. A Terapia Cognitivo-Comportamental (TCC) é considerada a primeira escolha de tratamento em crianças e adolescentes que apresentam sintomas leves e moderados e associada à farmacoterapia nos casos de sintomas de intensidade moderada à grave. O estudo dois apresenta as etapas de confecção do manual: I) Leitura dos manuais de TCCG mais eficazes para o tratamento de TOC em adolescentes localizados na revisão sistemática e utilização de dados estatísticos obtidos na metanálise; II) redação do manual tendo como base os resultados da etapa I e utilizando linguagem acessível aos
adolescentes e III) avaliação do manual por especialistas. No estudo três será realizado um estudo piloto utilizando o manual confeccionado para verificar possíveis dificuldades de entendimento da linguagem para os adolescentes e possível redução dos sintomas dos adolescentes com TOC. A amostra será composta por 44 adolescentes
(entre 10 e 19 anos) sendo 22 com TOC e 22 sem o diagnóstico. O grupo dos adolescentes com TOC (GTOC) receberá tratamento com o manual confeccionado durante 3 meses (12 sessões) por

Endereço: Rua Sarmento Leite ,245
Bairro: Sarmento **CEP:** 90.050-170
UF: RS **Município:** PORTO ALEGRE
Telefone: (51)3303-8804 **E-mail:** cep@ufcspa.edu.br

um terapeuta e um co-terapeuta, (ambos psicólogos com especialização em TCC) e devidamente treinados para tratar TOC através do manual elaborado. As sessões acontecerão semanalmente por 1 hora e 30 minutos com os adolescentes, mais 30 minutos com os pais/responsáveis. O grupo de adolescentes sem TOC (GSTOC) não receberá intervenção e posteriormente terá seus escores de TOC comparados com o GTOC no pré e pós-teste. Para aumentar a confiabilidade dos resultados, o terapeuta e o co-terapeuta não aplicarão nenhum dos instrumentos de rastreio de sintomas e nem participarão das entrevistas de seleção de participantes no pré e pós-teste. Tais mediadas visam evitar os vieses de desempenho e detecção.

Objetivo da Pesquisa:

Desenvolver, avaliar e apresentar as primeiras evidências de validade de um manual de TCCG para o tratamento de adolescentes brasileiros com TOC

Avaliação dos Riscos e Benefícios:

Riscos:

De acordo com a classificação didática de projetos de pesquisa por risco e benefício (Goldim, 2000), este trabalho, por suas características, pode ser considerado com risco mínimo para os pacientes avaliados, pois, apesar dos procedimentos não envolverem riscos diretos, é possível que aconteçam desconfortos relacionados à fadiga, devido à duração da pesquisa e à possibilidade de algumas das questões presentes nos questionários despertarem emoções desagradáveis. Caso o participante sinta qualquer desconforto durante a aplicação dos questionários ele poderá optar por suspender a sua participação, assim como por receber atendimento psicológico/psiquiátrico de um membro da equipe de pesquisa e caso necessário, encaminhamento para o CAPS para a realização de tratamento psicológico e /ou psiquiátrico.

Benefícios:

O potencial benefício para a sociedade é que este estudo pode incrementar o conhecimento sobre este transtorno, os sintomas e prejuízos associados, além de prestar atendimento gratuito aos adolescentes com TOC.

Comentários e Considerações sobre a Pesquisa:

A pesquisa está bem fundamentada, os objetivos claros e definidos, bem como toda metodologia a ser empregada, além disso, os participantes e os critérios estão bem delimitados.

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Considerações sobre os Termos de apresentação obrigatória:

Todos os termos de apresentação obrigatórios foram submetidos e aceitos.

Recomendações:

Iniciar coleta de dados somente após a aprovação do projeto junto ao CEP.

Conclusões ou Pendências e Lista de Inadequações:

Para início da pesquisa e coleta de dados, utilizar a última versão aprovada do TCLE. O projeto está adequado para ser desenvolvido,tendo seu término previsto para 12/2021.

Considerações Finais a critério do CEP:

de acordo com o parecer do Relator.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1392908.pdf	20/05/2020 09:33:27		Aceito
Outros	Convite.pptx	20/05/2020 09:23:26	CRISTIANE FLORES BORTONCELLO	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEMODIFICADO.doc	20/05/2020 09:21:51	CRISTIANE FLORES BORTONCELLO	Aceito
Outros	RELATORIOPARCIALEFINAL080420.pdf	08/04/2020 09:30:57	CRISTIANE FLORES BORTONCELLO	Aceito
Outros	DESCRICAOEQUIPE.doc	07/02/2020 09:39:12	CRISTIANE FLORES BORTONCELLO	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TERMODEASSENTIMENTO.doc	07/02/2020 09:22:03	CRISTIANE FLORES BORTONCELLO	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.doc	07/02/2020 09:21:18	CRISTIANE FLORES BORTONCELLO	Aceito
Projeto Detalhado / Brochura Investigador	PROJETODETALHADO.doc	07/02/2020 09:20:36	CRISTIANE FLORES BORTONCELLO	Aceito
Orçamento	ORCAMENTO.doc	07/02/2020 09:16:11	CRISTIANE FLORES BORTONCELLO	Aceito
Declaração de Instituição e Infraestrutura	AUTORIZACAOHMIPV.pdf	07/02/2020 09:14:20	CRISTIANE FLORES BORTONCELLO	Aceito

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Cronograma	CRONOGRAMA.doc	07/02/2020 08:58:35	CRISTIANE FLORES BORTONCELLO	Aceito
Folha de Rosto	FOLHADEROSTOASSINADA.pdf	07/02/2020 08:41:52	CRISTIANE FLORES BORTONCELLO	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PORTO ALEGRE, 19 de Junho de 2020

Assinado por:
EDI CÁRMEN PULROLNIK
(Coordenador(a))

Endereço: Rua Sarmento Leite ,245
Bairro: Sarmento **CEP:** 90.050-170
UF: RS **Município:** PORTO ALEGRE
Telefone: (51)3303-8804 **E-mail:** cep@ufcspa.edu.br

ANEXO 2 - Ementa do projeto com relação ao covid

HOSPITAL MATERNO INFANTIL PRESIDENTE VARGAS UNIVERSIDADE FEDERAL DAS CIÊNCIAS DA SAÚDE DE PORTO ALEGRE

Emenda ao Projeto de Pesquisa:

Projeto: Manual de Terapia Cognitivo Comportamental para adolescentes com Transtorno Obsessivo-Compulsivo.

Instituição proponente: Universidade Federal das Ciências da Saúde de Porto Alegre (UFCSPA).

Instituição coparticipante: Hospital Materno Infantil Presidente Vargas.

Orientador: Dr. Ygor Arzeno Ferrão.
Responsável pela condução da pesquisa: Cristiane Bortoncello

Encaminhamos este ofício às Instituições proponente e coparticipante conforme submetido na Plataforma Brasil.

Através desta Emenda, solicitamos avaliação e autorização para mudanças e adaptações em nosso projeto de pesquisa original. O referido projeto já havia sido aprovado pelo CEP da UFCSPA. No entanto, um dos ajustes que solicitamos é que o projeto seja aprovado também pelo CEP do HMIPV como (coparticipante). Reiteramos que marcamos a UFCSPA como Instituição proponente e o HMIPV como coparticipe, mas a Plataforma Brasil não permite novas mudanças no momento em relação a este tópico. Acreditamos que se trata de uma alteração provocada pelo próprio *software* da Plataforma Brasil, uma vez que não é possível marcar a mesma Instituição como proponente e coparticipante conforme ocorreu.

Valendo-nos desta emenda, solicitamos autorização para mudanças em nosso projeto original já aprovado previamente pelo CEP da UFCSPA. Em função do recente agravamento da pandemia por COVID 19 no Estado do Rio Grande do Sul e na cidade de Porto Alegre, propomos realizar os

questionários, instrumentos previstos neste projeto e o tratamento no formato *online,* reduzindo assim o risco de exposição ao coronavírus - tanto para pesquisadores quanto para os participantes. Planejamos realizar a mudança para o formato *online* utilizando duas plataformas: o REDCAP e o *Google Meet*. O REDCAP é um *software* acessível pela UFCSPA em que questionários autoaplicáveis podem ser anexados de forma segura. Os participantes podem responder estes instrumentos através de um *link* fornecido pelos pesquisadores. Nesta plataforma será anexado o TCLE para que os participantes concordem ou não e também todos os instrumentos autoaplicáveis previstos no projeto de pesquisa. Somente se os participantes marcarem que leram e concordam com o TCLE, a plataforma do REDCAP imediatamente abrirá os questionários autoaplicáveis, para que os participantes o respondam.

Os seguintes questionários serão autoaplicáveis via REDCAP: 1) Questionário sociodemográfico e de Saúde; 2) Inventário de Beck para depressão (BDI); 3) Inventario de depressão Infantil (CDI); 4) Inventário de Beck para Ansiedade (BAI); 5) Escala de Ansiedade Infantil Revisada: "o que penso e sinto" (RCMAS); 6) Escala multidimensional de satisfação de vida para crianças – Versão Reduzida (MSLSS); 7) Escala de Qualidade de Vida da Organização Mundial da Saúde – Versão abreviada (WHOQOL-BREF); 8) Escala de acomodação familiar para o TOC (FAS-IR).

Já o *Google Meet* é um *site* que permite vídeo chamadas de forma sigilosa e que apenas quem tiver acesso ao *link* pode participar da sessão. Nas vídeo chamadas podem ser realizados questionários que dependem do entrevistador, que é o caso de alguns dos instrumentos de nosso projeto – 1) Escala Dimensional para Avaliação de Presença e Gravidade de Sintomas Obsessivo-Compulsivos - DY-BOCS, 2) Escala Yale-Brown de Obsessões e Compulsões – versão para crianças (CY-BOCS); 3) Escala Yale-Brown de Obsessões e Compulsões (Y-BOCS) e 4) Escala de fenômenos sensoriais da USP (USP-SPS); 5) Escala de Transtornos Afetivos e Esquizofrenia para Crianças em Idade Escolar / Versão Atual e ao Longo da Vida (K-SADS-PL); 6) Entrevista Clínica Estruturada para os Transtornos do DSM-5 – Versão Clínica (SCID-5-CV). Apenas estes instrumentos serão aplicados nas vídeo-chamadas.

Inicialmente, propomos realizar um convite aos participantes através de contato telefônico ou via e-mail. Para aqueles que demonstrarem interesse em participar da pesquisa, encaminharemos um *link* de acesso para a plataforma do REDCAP, que abrirá automaticamente o Termo de Consentimento Livre e Esclarecido (TCLE). Esse *link* para o acesso ao REDCAP será encaminhado via *e-mail* apenas para o participante. Os participantes só poderão iniciar a participação na pesquisa se lerem e concordarem com o TCLE *versão online* que estará anexado no *link* da plataforma REDCAP. Uma via do TCLE ficará disponível para *download* de forma acessível na mesma plataforma para os participantes. Dividiremos as entrevistas em dois momentos:

Primeiro, os participantes responderão parte dos instrumentos (autoaplicáveis) através da Plataforma *REDCAP*,

No segundo momento, realizaremos a vídeo chamada através da plataforma *Google Meet*, quando iremos aplicar os instrumentos que não podem ser autoaplicáveis. O *Google Meet* permite chamadas de vídeo com garantia de segurança e sigilo e as entrevistas transcorrerão apenas com a presença virtual dos membros da equipe de pesquisa e dos participantes. Apenas os pesquisadores poderão estar presentes no ambiente físico em que será realizada a entrevista e o mesmo será solicitado aos participantes, o que pode garantir o sigilo durante as entrevistas.

Somente caso os participantes tenham concluído a primeira parte das entrevistas no REDCAP e assim concordado com o TCLE, encaminharemos o convite e o *link* para a vídeo chamada através de contato telefônico ou e-mail. Apenas os pesquisadores da Equipe serão autorizados a participar das vídeo chamadas com os participantes. As entrevistas não serão gravadas em nenhum momento e apenas os questionários previstos neste projeto serão aplicados na mesma.

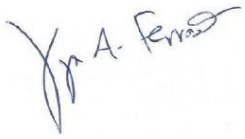
Após o aceite da participação e a assinatura do TCLE pelos adolescentes e pelos pais, iremos realizar o tratamento destes adolescentes com um manual de tratamento (criado pela autora) de Terapia Cognitivo Comportamental para os adolescentes com Transtorno Obsessivo Compulsivo (TOC). Este manual será encaminhado por e-mail e pelo correio para os adolescentes que serão tratados através de plataforma *online* (através do *Google Meet)* q*ue como comentamos anteriormente,* é um *site* que permite vídeo chamadas de forma sigilosa, já que apenas quem tiver acesso ao *link* pode participar da sessão. As chamadas de vídeo serão realizadas uma vez por semana (em dia e horário combinado previamente) por 12 semanas (total do tratamento) com um tempo de duração de duas horas, sendo que os adolescentes participarão das primeiras 1:30 horas e os pais em conjunto nos 30 minutos restantes. Como comentamos anteriormente, o *Google Meet* permite chamadas de vídeo com garantia de segurança e sigilo e o tratamento transcorrerão apenas com a presença virtual dos membros da equipe de pesquisa e dos participantes. Apenas os pesquisadores poderão estar presentes no ambiente físico em que será realizado o tratamento e o mesmo será solicitado aos participantes, o que pode garantir o sigilo durante as entrevistas. Somente caso os participantes tenham concluído a primeira parte das entrevistas no REDCAP e assim concordado com o TCLE, encaminharemos o convite e o *link* para a vídeo chamada através de contato telefônico ou e-mail. Apenas os pesquisadores da Equipe serão autorizados a participar das vídeo chamadas com os participantes. O tratamento não será gravado em nenhum momento.

Uma vez que a pandemia por coronavírus (COVID 19) tem apresentado recrudescimento nos últimos meses em nossa região, acreditamos que no formato *online* iremos colaborar com a redução da exposição das pessoas ao risco de contaminação, sendo que o isolamento é orientado pelas autoridades sanitárias responsáveis neste momento. Dessa forma, propomos

manter o estudo do Manual de Terapia Cognitivo Comportamental para adolescentes com Transtorno Obsessivo-Compulsivo (TOC), usando de métodos criativos neste contexto de adversidade.

Porto Alegre, 15 setembro de 2021.

Atenciosamente,



Dr. Ygor Arzeno Ferrão.