

UNIVERSIDADE DO VALE DO TAQUARI - UNIVATES
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS MÉDICAS

**ESTUDO DE ASSOCIAÇÃO ENTRE ALIANÇA TERAPÊUTICA
E SINTOMAS ANSIOSOS, DEPRESSIVOS E DE IRRITABILIDADE
ATRAVÉS DE TELE-PSICOTERAPIAS
NO CONTEXTO DA PANDEMIA DE COVID-19.**

Luiza Silveira Lucas

Lajeado/RS, março de 2023

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Dissertação apresentada ao Programa de Pós-Graduação em Ciências Médicas da Universidade do Vale do Taquari - Univates, como parte da exigência para a obtenção do título de Mestre em Ciências Médicas na área de concentração Ciências do Comportamento.

Orientador: Prof. Dr. Flávio Milman Shansis

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A Banca examinadora abaixo aprova a Dissertação apresentada ao Programa de Pós-Graduação em Ciências Médicas da Universidade do Vale do Taquari - Univates como parte da exigência para obtenção do título de Mestre em Ciências Médicas, na área de concentração de Ciências do Comportamento.

Prof. Dr. Flávio Milman Shansis - Orientador
Universidade do Vale do Taquari

Prof. Dr. Cláudio Laks Eizirik
Universidade Federal do Rio Grande do Sul

Prof. Dra. Daiane Heidrich
Universidade do Vale do Taquari

Prof. Dr. Guilherme Liberato da Silva
Universidade do Vale do Taquari

Lajeado/RS, 24 de março de 2023

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RESUMO

As tele-psicoterapias por videoconferência, como a tele-psicoterapia cognitivo-comportamental (tele-TCC) e a tele-psicoterapia interpessoal (tele-TIP), estão sendo cada vez mais utilizadas para tratar pessoas com ansiedade, depressão e irritabilidade. Embora a eficácia desses tratamentos tenha evidências que estão progressivamente sendo demonstradas, outros fatores associados aos seus resultados ainda precisam ser melhor explorados. A aliança terapêutica (AT) refere-se aos aspectos colaborativos da relação terapeuta-paciente e é um importante fator associado aos resultados em psicoterapias presenciais; até o momento, contudo, existem poucos estudos abordando especificamente a AT em tele-psicoterapia. Os objetivos deste estudo são entender: (a) Quão forte é a TA em tele-TCC e tele-TIP; (b) Se existe alguma diferença nos níveis de AT entre tele-TCC e tele-TIP e (c) Se existe uma correlação entre AT e resultados clínicos de tele-TCC e tele-TIP. No presente estudo, foi realizada uma análise secundária por protocolo a partir de um ensaio clínico randomizado (ECR), realizado pelo nosso grupo, formado por dois braços paralelos comparando tele-TCC e tele-TIP. As principais medidas de desfecho foram o PHQ-9 para sintomas depressivos, GAD-7 para sintomas de ansiedade e ARI para irritabilidade. Os níveis de AT foram medidos utilizando o *Working Alliance Inventory* - versão curta para pacientes (WAI-s). A correlação dos resultados com a AT foi analisada através do coeficiente de correlação de Pearson. Sessenta e nove indivíduos (tele-TCC n=30; tele-TIP n=39) foram incluídos. A pontuação total do WAI-s na amostra de tele-TCC foi de 74,5 ($\pm$ 8,3) e na amostra de tele-TIP foi de 76,3 ($\pm$ 7,4); portanto, ao se comparar os níveis de TA entre tele-TCC e tele-TIP, não houve diferença estatisticamente significativa ($p=0.852$). Foi encontrada uma correlação significativa entre os níveis de AT e a redução da ansiedade na amostra completa ($p=0.032$). Por outro lado, não foi encontrada correlação entre os níveis de AT e níveis de ansiedade quando as amostras foram analisadas separadamente (t-CBT $p=0.311$; t-IPT $p=0.063$), assim como não houve correlação entre os níveis de AT e níveis de depressão ou irritabilidade ($p>0.05$). O presente estudo conclui que níveis elevados de TA são formados entre paciente e terapeuta tanto no t-CBT quanto no t-IPT, sem diferença estatisticamente significativa entre estas duas modalidades de tele-psicoterapia. Ainda, os resultados deste estudo demonstram que a AT esteve associada à redução nos níveis de ansiedade, mas não houve associação entre os níveis de AT e os desfechos depressão ou irritabilidade.

Palavras-chave: Aliança terapêutica, Ansiedade, Depressão, Ensaio clínico randomizado, Pesquisa em psicoterapia, Psicoterapia, Tratamento via Internet

ABSTRACT

Tele psychotherapies via videoconference, such as tele-Cognitive Behavioral Psychotherapy (t-CBT) and tele-Interpersonal Psychotherapy (t-IPT) are increasingly being used to treat people with anxiety, depression and irritability. Although the effectiveness of these treatments has evidence that is progressively being demonstrated, other factors associated with their results still need to be better explored. Therapeutic alliance (TA) refers to the collaborative aspects of the therapist-patient relationship and is an important factor associated with outcomes in in-person psychotherapies; to date, however, there are few studies specifically addressing TA in tele-psychotherapy. The aims of this study are to address: (a) How strong is TA in t-CBT and t-IPT; (b) Whether there is a difference in TA levels between t-CBT and t-IPT; (c) Whether there is a correlation between TA and clinical outcomes of t-CBT and t-IPT. In the present study, a secondary analysis per protocol was performed based on a randomized clinical trial (RCT), carried out by our group, formed by two parallel arms comparing t-CBT and t-IPT. The main outcome measures were PHQ-9 for depressive symptoms, GAD-7 for anxiety symptoms and ARI for irritability. TA levels were measured using Working Alliance Inventory- short version for patients (WAI-s). The correlation of main outcomes with TA was analyzed using Pearson's correlation coefficient. Sixty-nine subjects (t-CBT $n=30$; t-IPT $n=39$) were included. The total WAI-s score in the t-CBT sample was 74.5 (± 8.3) and in the t-IPT sample was 76.3 (± 7.4), therefore, when comparing the levels of TA between tele-TCC and tele-TIP, there was no significant difference ($p=0.852$). A significant correlation was found between TA levels and anxiety reduction in the complete sample ($p=0.032$). On the other hand, no correlation was found between TA levels and anxiety levels when the samples were analyzed separately (t-CBT $p=0.311$; t-IPT $p=0.063$), as well as no correlation between TA levels and levels of depression or irritability ($p>0.05$). The present study concludes that high levels of TA are formed between patient and therapist both in t-CBT and in t-IPT, with no statistically significant difference between them. Furthermore, the results of this study demonstrate that TA was associated with a reduction in anxiety levels, but there was no association between TA levels and depression or irritability outcomes.

Keywords: Anxiety, Depression, Internet-based treatment, Psychotherapy, Psychotherapy research, Randomized clinical trial, Therapeutic Alliance

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LISTA DE ABREVIATURAS E SIGLAS

- ARI** – Affective Reactivity Index – Índice de Reatividade Afetiva
- AT** – Aliança Terapêutica
- ANCOVA** – *Analysis of Covariance* – Análise de Covariância
- CBT** – *Cognitive Behavioral Therapy* – Psicoterapia Cognitivo-Comportamental
- Covid-19** – *Corona virus disease* – Doença do Coronavírus
- CFP** – Conselho Federal de Psicologia
- COEP** – Comitê de Ética em Pesquisa da Universidade do Vale do Taquari
- CONSORT** – *Consolidated Standards of Reporting Trials* – Padrões consolidados de reporte de Ensaios
- DSM-5** – *Diagnostic and Statistical Manual of Mental Disorders* – Manual Diagnóstico e Estatístico de Transtornos Mentais 5.^a edição
- ECR** – Ensaio Clínico Randomizado
- GAD** – *Generalized Anxiety Disorder* – Transtorno de Ansiedade Generalizada
- GAD-7** – *Generalized Anxiety Disorder based on 7 questions (questionnaire)* – Questionário de Transtorno de Ansiedade Generalizada baseado em 7 perguntas
- GEE** – *Generalized Estimating Equations test* – teste estatístico de Equações de estimativas generalizadas
- H0** – Hipótese nula
- H1** – Hipótese alternativa
- HCPA** – Hospital de Clínicas de Porto Alegre
- ICF** – *Informed Consent Form* – Termo de Consentimento Livre e Esclarecido
- IPT** – *Interpersonal psychotherapy* – Psicoterapia Interpessoal
- ITT** – *intention-to-treat analysis* – análise por intenção de tratar
- LSD** – *Least Significant Difference* (LSD) test – Teste estatístico de "diferença menos significativa"
- MDD** – *Major Depressive Disorder* – Transtorno Depressivo Maior
- PHQ-9** – Patient Health Questionnaire (for depressive symptoms) based on 9 questions – Questionário de Saúde do Paciente (para sintomas depressivos) baseado em 9 perguntas
- RCT** – *Randomized controlled trial* – Ensaio clínico randomizado
- SCID-5** – *Structured Clinical Interview based on DSM-5* – Entrevista Clínica Estruturada baseada no DSM-5
- SD** – *standard deviation* – desvio padrão
- SICT** – Secretaria de Inovação, Ciência e Tecnologia do Estado do Rio Grande do Sul
- SUS** – Sistema Único de Saúde
- TA** – Therapeutic alliance
- t-CBT** – *tele- Cognitive Behavioral Therapy* – Tele-psicoterapia Cognitivo-Comportamental
- t-IPT** – *tele- Interpersonal Therapy* – Tele-psicoterapia Interpessoal

TCC – Psicoterapia Cognitivo-Comportamental

TCLE – Termo de Consentimento Livre e Esclarecido

TelePSI – projeto de Atenção em Saúde Mental por Teleatendimento para Profissionais de Saúde no Contexto da Covid-19

Tele-TCC – Tele-psicoterapia Cognitivo-Comportamental

Tele-TIP – Tele-psicoterapia Interpessoal

TIP – Psicoterapia Interpessoal

UFRGS – Universidade Federal do Rio Grande do Sul

UNIVATES – Universidade do Vale do Taquari

UERGS – Universidade Estadual do Rio Grande do Sul

UNISC – Universidade de Santa Cruz do Sul

VC – *videoconference* – videoconferência

WAI – *Working Alliance Inventory* – Inventário de Aliança Terapêutica

WAI-s – *Working Alliance Inventory short version for patient* – Inventário de Aliança Terapêutica versão curta para paciente

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1. Introdução

1.1. Impacto da pandemia de Covid-19 na saúde mental dos indivíduos

A pandemia de Covid-19, causada pelo vírus Sars-CoV-2, identificado pela primeira vez em dezembro de 2019, trouxe enormes consequências para toda a população mundial. Além dos graves efeitos sobre os Sistemas de Saúde dos países do mundo todo, dos efeitos sobre a saúde física dos indivíduos em particular, do impacto sobre a economia global e sobre problemas sociais, a pandemia acarretou distanciamento físico, medo e mudança nos hábitos de vida. Essas questões acabaram por afetar de forma significativa a saúde mental das pessoas. Indivíduos que não apresentavam histórico psiquiátrico anterior passaram a desenvolver sintomas emocionais e, aqueles que já os apresentavam, experimentaram agravamento dos sintomas (PAN et al, 2021; PIERCE et al, 2020).

1.2 Psicoterapias

As psicoterapias são tratamentos psicológicos que utilizam a comunicação verbal e não verbal como forma de "aliviar um desconforto ou sofrimento psíquico, eliminar sintomas de um transtorno definido, resolver problemas pessoais de natureza emocional ou psicológica ou estimular o desenvolvimento pessoal" (CORDIOLI et al, 2019).

As psicoterapias são fundamentadas em racionais ou teorias que oferecem explanação para os sintomas e embasam técnicas para seu tratamento (CORDIOLI et al, 2019). Dentre as psicoterapias, cita-se os principais tipos: psicanálise, psicoterapia de orientação analítica, psicoterapia breve dinâmica, psicoterapia baseada na mentalização, psicoterapia de apoio, psicoterapia interpessoal (TIP), terapia cognitiva, terapia comportamental, psicoterapia cognitivo comportamental (TCC), terapia racional-emotiva, terapia dos esquemas, terapias contextuais comportamentais (*mindfulness*, aceitação e compromisso, comportamental dialética, metacognitiva, focada na compaixão), psicoterapia motivacional, terapia de dessensibilização e reprocessamento por movimentos oculares, hipnose (CORDIOLI et al, 2019). Dentre essas modalidades, aqui se destacam dois tipos específicos de psicoterapia que têm sido bastante estudadas: a Psicoterapia Cognitivo-Comportamental (TCC) e a Psicoterapia Interpessoal (TIP).

A TCC é uma abordagem psicoterapêutica estruturada, diretiva, ativa, de prazo limitado, que se fundamenta na racionalidade teórica subjacente de que a emoção - forma como o indivíduo se sente- e o comportamento - o que o indivíduo faz - são em grande parte determinados pelo modo como ele interpreta o mundo. (BECK, 2013). "A noção de que são interpretações - e não os fatos em si- que trazem sofrimento ao indivíduo é central para compreender a psicopatologia" (CORDIOLI et al, 2019). A partir desse entendimento, o terapeuta em TCC procura produzir, de várias formas, uma mudança cognitiva – modificação no pensamento e

no sistema de crenças do paciente – com objetivo de gerar então uma mudança emocional e comportamental duradoura (BECK, 2013).

A TIP é uma forma de psicoterapia breve desenvolvida por Gerald Klerman e Myrna Weissman, que busca entender o contexto interpessoal e social nos quais os sintomas do indivíduo surgiram e como essas variáveis se relacionam. A TIP parte do princípio de que problemas interpessoais e os sintomas estão intimamente associados e que se influenciam mutuamente (problemas interpessoais podem levar aos sintomas e os sintomas podem levar a problemas interpessoais). Desenvolvida originalmente para tratar depressão, a TIP passou a ser utilizada na prática clínica também para outros transtornos, como transtornos de ansiedade, relacionados ao trauma e desregulação emocional. O objetivo da TIP é obter alívio dos sintomas pela abordagem de problemas interpessoais que possam estar contribuindo para a origem ou manutenção dos sintomas. A TIP tenta intervir no efeito dos sintomas no ajustamento social e nas relações interpessoais, focando os problemas atuais conscientes e pré-conscientes (WEISSMAN et al, 2000).

A TCC e a TIP foram testadas em estudos com amostras de pacientes com sintomas depressivos e demonstraram efetividade no alívio desta sintomatologia. (PARIKH et al, 2016). Em relação aos sintomas ansiosos, a TCC mostrou bons resultados em diversos estudos (KATZMAN et al, 2014). Por outro lado, a TIP tem sido, ainda, pouco estudada em transtornos ansiosos. Alguns estudos investigaram a efetividade da TIP no Transtornos de Ansiedade Social, Transtorno de Estresse Pós-traumático e no Transtorno do Pânico, com resultados promissores (MARKOWITZ et al, 2014). Até o momento, não há estudos comparando a eficácia da TIP e da TCC para os Transtornos de Ansiedade.

1.3 . Tele-psicoterapias

Durante a pandemia da Covid-19, a redução do contato social entre as pessoas, em função do necessário afastamento físico, foi preconizada pela Organização Mundial de Saúde visando à diminuição da propagação do vírus. Como consequência, uma série de atividades, antes realizadas de forma presencial, passaram a ser, quando possível e de acordo com a possibilidade, realizadas de forma remota através do uso de diferentes plataformas na internet (ANTONELLO et al, 2020). Dentre as inúmeras atividades que foram afetadas, os atendimentos na área da saúde sofreram importante impacto.

A mudança dos atendimentos presenciais em medicina para atendimentos remotos, recebeu diversas denominações, dentre eles Telemedicina. Atendimentos por Telemedicina já eram utilizados muito antes da pandemia da Covid-19, sendo que há relatos de sua utilização desde a descoberta da telefonia no final do século XIX. Embora a Telemedicina já estivesse se consolidando nos âmbitos nacional e internacional e determinando a quebra de paradigmas nos sistemas de saúde, foi com o surgimento da Covid-19 que o mundo teve suas estruturas de funcionamento abaladas, tendo adequar, em um período muito breve de tempo, às novas

tecnologias, em especial a esse tipo de atendimento remoto em saúde (SCHMITZ et al., 2020).

Especificamente na área das psicoterapias, houve uma implementação de algo que, antes, era ainda incipiente: as psicoterapias realizadas de forma remota, também chamadas de tele-psicoterapias. O modelo da tele-psicoterapia, antes exaustivamente debatido quanto a sua eficácia e a outras questões inerentes à própria técnica psicoterápica (SFOGGIA et al, 2014), passou a ser imediatamente utilizado, desde o início da pandemia, de forma ampla em diferentes países (MARKOWITZ, 2021; SAMMONS et al, 2020).

No Brasil, esse fenômeno não foi diferente. Diversos profissionais e pacientes aderiram ao modelo da telemedicina, reconhecido pelo Conselho Federal de Medicina e pelo Governo Federal na Lei Nº 13.989, de 15 de abril de 2020 (Brasil, 2020), o que abrangeu o atendimento em Saúde Mental. Na mesma direção, o Conselho Federal de Psicologia (CFP), por meio da Resolução CFP nº 04/2020, dispõe sobre regulamentação de serviços psicológicos prestados por meio de Tecnologia da Informação e da Comunicação durante a pandemia do Covid-19.

No campo da pesquisa acadêmica, em colaboração com o Ministério da Saúde do Brasil, ainda na gestão do Ministro Luiz Henrique Mandetta, cabe ressaltar a elaboração de um protocolo de pesquisa e de atendimento realizado por pesquisadores vinculados ao Hospital de Clínicas de Porto Alegre, ao Departamento de Psiquiatria e Medicina Legal da Universidade Federal do Rio Grande do Sul (UFRGS) e a várias outras Instituições acadêmicas e não acadêmicas do país, como a Associação de Psiquiatria do Rio Grande do Sul. Este protocolo, coordenado pelo Professor Giovanni Salum da UFRGS, recebeu o nome de TelePSI e foi elaborado com o objetivo de ofertar tele-atendimentos em saúde mental especificamente para profissionais de saúde durante a pandemia, uma vez que, assim como no resto do mundo, foi observada importante incidência de casos de esgotamento (*burnout*) em trabalhadores da área da saúde, em especial naqueles que trabalhavam na linha de frente com pacientes com Covid-19. Além de ofertar atendimentos, o TelePSI ofereceu treinamento para os profissionais de saúde mental que iriam realizar os teleatendimentos. As modalidades de tele-psicoterapia ofertadas pelo TelePSI incluíram a Tele-psicoterapia Cognitivo-comportamental breve (Tele-TCC) e a Tele-psicoterapia Interpessoal breve (Tele-TIP) voltadas para o atendimento de profissionais da área da saúde (SALUM et al, 2020).

Em relação às evidências científicas das Tele-psicoterapias, uma revisão recente de 24 estudos, que avaliou as evidências de intervenções de tele-psicoterapia síncrona para depressão, ansiedade, transtorno de estresse pós-traumático e transtorno de ajustamento, concluiu que as evidências são suficientes para apoiar esses tratamentos (VARKER et al, 2019). Cabe ressaltar que a maioria das intervenções incluídas nesta revisão foram baseadas em tele-TCC. Outra meta-análise comparando a eficácia das tele-psicoterapias por videoconferência às psicoterapias presenciais mostrou eficácia equivalente entre

elas, entretanto a tele-TCC demonstrou eficácia superior em comparação com outras tele-psicoterapias de linhas teóricas diferentes, tais como psicodinâmica ou psicoeducação (FERNANDEZ et al, 2021). Nenhum estudo baseado em tele-TIP foi incluído nesta segunda meta-análise. Uma terceira meta-análise recente de ensaios clínicos randomizados, baseada em 20 estudos que incluíram apenas intervenções cognitivo comportamentais, como a tele-TCC, mostrou que a tele-psicoterapia síncrona (por videoconferência ou por telefone) é tão eficaz quanto a psicoterapia presencial (LIN et al, 2022). Esses são resultados animadores, que embasam o uso da tele-TCC. Entretanto, nenhum dos estudos citados na estudou a tele-TIP. De fato, em amplas buscas na literatura científica, não foi encontrado nenhum estudo sobre tele-TIP.

1.4. Aliança Terapêutica

As psicoterapias possuem fatores específicos e inespecíficos dentro daquilo que se estabeleceu como o seu modelo conceitual, independentemente do tipo de psicoterapia utilizado. Dentre os vários fatores que contribuem para uma melhor efetividade do tratamento psicoterápico, a Aliança Terapêutica (AT) possui um papel bastante importante (GOMES, 2015; FLÜCKIGER et al, 2018).

A AT designa "a capacidade do paciente de estabelecer uma ligação de trabalho com o terapeuta" (EIZIRIK et al, 2008). Embora as definições de AT tenham origem na psicanálise, ela é hoje entendida como um construto universal às diversas abordagens teóricas em psicoterapia. A AT é composta por três elementos essenciais: 1- o desenvolvimento de vínculo pessoal composto por sentimentos positivos recíprocos; 2- o acordo sobre os objetivos do tratamento; e 3- o acordo sobre as tarefas que cabem ao terapeuta ao paciente no processo psicoterapêutico (BORDIN, 1979).

Uma síntese meta-analítica de 295 estudos independentes sobre psicoterapia mostrou uma correlação moderada, mas robusta, entre AT e o resultado em psicoterapias presenciais tradicionais, sendo semelhante entre os diferentes tipos de psicoterapias presenciais (FLÜCKIGER et al., 2018).

Ainda é bastante incipiente, no entanto, a literatura a respeito da AT nas tele-psicoterapias. Embora existam estudos que mostram que a AT se desenvolve nas tele-psicoterapias, como um estudo de revisão e outra revisão sistemática e metanálise que demonstraram que os níveis de AT são moderados a fortes nessa modalidade de tratamento à distância (SIMPSON et al, 2014; NORWOOD et al, 2018), cabe ressaltar que a maioria dos estudos incluídos nessas revisões tiveram como intervenção apenas a tele-TCC. Nenhum estudo foi encontrado na literatura investigando a AT em tele-TIP. Outro aspecto importante a ressaltar é de que não se sabe se a AT se correlaciona ou não com os resultados das tele-psicoterapias.

1.5. Por que os Vales do Taquari e do Rio Pardo?

As regiões do Vale do Taquari e do Vale do Rio Pardo são as regiões com mais altos índices de suicídio no Brasil, com taxas três vezes maior que a taxa brasileira (que é de 6,0 suicídios por 100.000 habitantes), com 17,2 suicídios por 100.000 habitantes (Secretaria de Saúde do Estado do Rio Grande do Sul, 2018). Desta forma, é razoável se pensar que essas regiões poderiam ser atingidas por um mais suicídios durante e após a pandemia, uma vez que dados têm demonstrado consistentemente que os períodos pós-catástrofes são momentos sensíveis para o aumento de taxas de suicídio (GUNNEL et al, 2020). Como o espectro do comportamento suicida está relacionado, em especial, aos diagnósticos de Transtorno Bipolar e de Transtorno Depressivo Maior, e estes, por sua vez, apresentam sintomas depressivos, ansiosos e de irritabilidade, supõe-se que auxiliar no manejo de tais sintomas, através de técnicas psicoterápicas realizadas de forma remota, no contexto da pandemia, poderia auxiliar a prevenir futuros comportamentos suicidas em uma região com altos índices.

Desta forma, nosso grupo criou o projeto intitulado "Ensaio Clínico Randomizado com tele-psicoterapia Breve Cognitivo-comportamental e tele-psicoterapia Breve Interpessoal em uma amostra populacional com Transtornos do Afeto Negativo e Comportamento Suicida leve na região dos Vales do Taquari e do Rio Pardo durante e após a pandemia da Covid-19", através de uma parceria entre as Universidades UNIVATES, UNISC e UERGS. Esse projeto recebeu financiamento através do Edital de Chamamento Público número 001/2020, vinculado às ações do Programa INOVA - RS de apoio ao enfrentamento da Covid-19" da Secretaria de Inovação, Ciência e Tecnologia (SICT) do estado do Rio Grande do Sul.

Esse projeto objetivou criar uma ferramenta e um protocolo de tele-atendimentos em saúde mental durante e após a pandemia da Covid-19. O nome fantasia do projeto, pelo qual a comunidade local passou a conhecê-lo, foi "Vale a Vida", em referência à Região dos Vales do Taquari e do Rio Pardo. Este programa visou oferecer tratamento na modalidade tele-psicoterapias de forma gratuita para moradores dessas regiões através de protocolo de pesquisa. No ANEXO 1, verifica-se como foi apresentado o "Vale a Vida" à população.

1.6. Objetivos

O presente estudo busca analisar a associação entre a Aliança Terapêutica e os desfechos de sintomas depressivos, ansiosos e de irritabilidade quando utilizadas duas técnicas distintas de tele-psicoterapia (Tele-TCC e Tele-TIP) em uma amostra de residentes nos Vales do Taquari e Rio Pardo, durante e após a pandemia da Covid-19.

Objetivo geral:

Estudar a associação entre AT e sintomas ansiosos, depressivos e de irritabilidade no contexto da utilização de dois tipos de tele-terapias: Tele-TCC e Tele-TIP.

Objetivos específicos:

- 1- Examinar como a AT se associa aos sintomas ansiosos no contexto da utilização de dois tipos de tele-terapias: Tele-TCC e Tele-TIP;
- 2- Examinar como a AT se associa aos sintomas depressivos no contexto da utilização de dois tipos de tele-terapias: Tele-TCC e Tele-TIP;
- 3- Examinar como a AT se associa aos sintomas de irritabilidade no contexto da utilização de dois tipos de tele-terapias: Tele-TCC e Tele-TIP, e ,
- 4- Comparar a AT na Tele-TCC e na Tele-TIP.

1.7 Hipóteses

A hipótese alternativa (H1) do presente estudo é que a AT se associa com maior resposta às tele-terapias Tele-TCC e Tele-TIP.

A hipótese nula é (H0) é de que a AT não se associa com maior resposta às tele-terapias Tele-TCC e Tele-TIP.

Para os objetivos específicos, as hipóteses secundárias são:

- 1-A AT se associa a melhora de sintomas ansiosos nas tele-terapias (H1); A AT não se associa a melhora de sintomas ansiosos nas tele-terapias (H0);
- 2-A AT se associa a melhora de sintomas depressivos nas tele-terapias (H1); A AT não se associa a melhora de sintomas depressivos nas tele-terapias (H0);
- 3-A AT se associa a melhora de sintomas de irritabilidade nas tele-terapias (H1); A AT não se associa a melhora de sintomas de irritabilidade nas tele-terapias (H0) , e,
- 4-A AT na Tele-TCC é diferente à AT na Tele-TIP (H1); A AT na Tele-TIP não é diferente da AT na Tele-TCC (H0).

2. Materiais e métodos

2.1 Desenho do estudo

O "Vale a Vida" foi um ensaio clínico não-farmacológico randomizado e controlado (ECR). O estudo foi coordenado pelo Professor Flávio Milman Shansis da UNIVATES, através do seu programa de Pós-Graduação em Ciências Médicas e do Tecnovates, e contou com a colaboração da Universidade de Santa Cruz do Sul

(UNISC) e Universidade Estadual do Rio Grande do Sul (UERGS), e apoio das empresas de tecnologia Tummi e Tekann.

O ensaio clínico foi realizado em uma plataforma digital criada especificamente para o estudo, com desenvolvimento colaborativo com as empresas de tecnologia Tummi e Tekann. Essa plataforma esteve hospedada em um website (www.valeavida.com.br).

A divulgação para recrutamento de participantes se deu através de meios de comunicação (rádio, jornal e televisão) e da mídia social (Facebook e Instagram), entre março e novembro de 2021.

Os sujeitos acessaram a plataforma por meio do website, no qual constava a explicação do projeto. Os indivíduos acessaram também pelo website o Termo de Consentimento Livre e Esclarecido (TCLE), e, após o aceite do mesmo, preenchiam seus dados sócio-demográficos, histórico de problemas de saúde física e mental e instrumentos que avaliavam sintomas depressivos, ansiosos e de irritabilidade, além de desesperança e ideação suicida.

Após essa parte inicial, a gerente de projetos contatava os participantes e agendava a tele-consulta psiquiátrica, que funcionava como triagem. As teleconsultas psiquiátricas foram realizadas por uma médica psiquiatra através da plataforma criada para o presente estudo. Na tele-consulta, foi utilizada como base uma entrevista psiquiátrica semi-estruturada orientada pelo protocolo do TelePSI e foi aplicada a Entrevista Clínica Estruturada, denominada SCID-5, que é um guia de entrevista para a realização do diagnóstico dos transtornos psiquiátricos pelo Manual Diagnóstico e Estatístico de Transtornos Mentais 5.^a edição, DSM-5 (First et al, 2015; American Psychiatric Association, 2013). A médica verificava se o paciente preenchia os critérios de inclusão, conforme descritos no item 2.2 deste documento, realizava o diagnóstico psiquiátrico e estratificava o risco de suicídio pela escala de Columbia em três níveis: nenhum risco, baixo, moderado e alto risco (POSNER et al, 2011). Indivíduos com moderado e alto risco de suicídio não foram incluídos no estudo em função de questões éticas, sendo esses encaminhados para atendimento de emergência presencial, e aqueles encaminhados a atendimentos médicos com brevidade.

Os indivíduos que preenchiam os critérios para participar do estudo e que assinaram o TCLE, eram designados para o ECR, sendo então randomizados para receber uma das duas intervenções: Tele-TIP ou Tele-TCC. As sessões de Tele-TIP e Tele-TCC foram realizadas por psicólogas treinadas e certificadas nas técnicas psicoterápicas através de Cursos com provas finais realizados pelo TelePSI do HCPA/UFRGS.

Ambas as intervenções são manualizadas, e consistem em quatro sessões de tele-psicoterapia realizadas, de forma online, através da plataforma “Vale a Vida” (www.valeavida.com.br). As quatro sessões ocorriam em frequência semanal, com duração de 45 a 50 minutos cada. Entre as sessões, os participantes recebiam vídeos que instruíam técnicas terapêuticas associadas à intervenção que estavam

recebendo. Os vídeos enviados faziam parte dos manuais de Tele-TIP e Tele-TCC do TelePSI do HCPA/UFRGS, e estavam hospedados na plataforma Youtube do TelePSI. Esses vídeos podem ser conferidos em <https://www.youtube.com/playlist?list=PLS1eD60Nooag8rhTBuWu8ejlZkyesLvUD>.

Antes do início da intervenção, entre cada uma das quatro sessões, e ao final da intervenção, os indivíduos dos dois grupos recebiam instrumentos auto-aplicáveis. Os sintomas ansiosos, depressivos e de irritabilidade eram avaliados antes da intervenção (na semana 0) e após a intervenção (na semana 4), e seguem, ainda hoje, sendo avaliados na fase de acompanhamento (*follow-up*), em 3, 6 e 9 meses após o final da intervenção. A AT foi avaliada entre a terceira e a quarta sessão da intervenção. Um resumo esquemático da metodologia do estudo pode ser encontrado no ANEXO 2.

2.2 Critérios de inclusão e exclusão

Os critérios de inclusão foram: 1- indivíduos adultos (maiores de 18 anos); 2- moradores do Vale do Taquari ou Vale do Rio Pardo; 3- que apresentassem sintomas depressivos, ansiosos, de irritabilidade, estresse e esgotamento emocional; 4- com nenhum ou com baixo risco de suicídio.

Foram excluídas pessoas que não preencheram os critérios de inclusão ou que estavam em outro tratamento psicoterápico. Participantes excluídos por terem médio e alto risco de suicídio foram encaminhados para atendimentos presenciais na rede básica de saúde do Sistema Único de Saúde (SUS), sendo que os com risco moderado foram orientados a buscar atendimento presencial com brevidade, e aqueles com risco alto foram orientados a serviços de emergência médica em locais de referência.

2.3 Instrumentos de avaliação

A AT foi avaliada pelo instrumento Inventário de Aliança Terapêutica - versão reduzida para paciente, com 12 questões, a WAI-s, do inglês *WAI, Working Alliance Inventory*. A WAI-s foi desenvolvida por Horvath e Greenberg em 1989, e é um instrumento para avaliação da aliança terapêutica em diferentes contextos clínicos, possuindo versões para paciente e para terapeuta (HORVARTH et al, 1989). As versões originais para paciente e terapeutas são compostas por 36 itens cada e as versões reduzidas são compostas por 12 itens cada. No presente estudo, foi utilizada a versão reduzida para paciente, preenchida pelo participante entre a terceira e a quarta sessão da intervenção. Optou-se por não utilizar a versão da escala para terapeuta, pois diversos estudos já demonstraram que a versão para paciente tem boa validade e confiabilidade e, em estudos que avaliaram a associação entre AT e desfecho clínico, não houve diferença estatística entre a AT quando avaliada por paciente ou por terapeuta (FLÜCKIGER et al, 2018). A WAI-s é organizada em três subescalas: vínculo, objetivo e tarefa, cada uma com 4 questões, que são respondidas por meio de uma escala *likert* de sete pontos (1 =

nunca a 7 = sempre). Importante ressaltar que se trata de um inventário não vinculado a nenhuma escola teórica específica em psicoterapia, tem sido bastante utilizado no campo da pesquisa em psicoterapia e já teve seu uso validado para o Português brasileiro (MAIA et al, 2017; SERRALTA et al, 2020) A escala WAI-s está no ANEXO 3 deste documento.

Os sintomas ansiosos foram avaliados pela escala GAD-7, que é um instrumento auto-aplicável breve para avaliação de sintomas ansiosos. É composta por sete itens, dispostos em uma escala de quatro pontos: 0 (nenhuma vez) a 3 (quase todos os dias), com pontuação que varia de 0 a 21, e mede frequência de sinais e sintomas de ansiedade relativa às duas semanas anteriores ao preenchimento do instrumento. Considera-se indicador positivo de sinais e sintomas de transtornos de ansiedade quando a pontuação é igual ou maior que 10 (SPITZER et al, 2006). A GAD-7 já possui versão validada para o Português brasileiro (MORENO et al, 2016). A escala GAD-7 está no ANEXO 4 deste documento.

Os sintomas depressivos foram avaliados pela escala PHQ-9, que é um instrumento auto-aplicável breve para avaliação de sintomas depressivos (SPITZER, 1999). O instrumento contém nove itens, dispostos em uma escala de quatro pontos: 0 (nenhuma vez) a 3 (quase todos os dias), com pontuação que varia de 0 a 27 para avaliar a frequência de sinais e sintomas de depressão nas duas semanas anteriores ao preenchimento. Considera-se indicador positivo de depressão maior quando a pontuação é maior ou igual a 10. A PHQ-9 já foi validada no Brasil para o Português brasileiro (SANTOS et al, 2013). A escala PHQ-9 está no ANEXO 5 deste documento.

Os sintomas de irritabilidade foram avaliados pela escala Índice de Reatividade Afetiva (ARI). Foi desenvolvida inicialmente para aferir sintomas de irritabilidade na infância e adolescência, mas teve sua validade para adultos também comprovada (MULRANEY et al, 2014). O instrumento é composto por seis itens avaliando sentimentos e comportamentos relacionados à irritabilidade e um item que avalia o comprometimento devido a irritabilidade. Os entrevistados avaliam cada item usando uma escala de 3 pontos (0 = falso; 1 = um pouco verdadeiro; 2 = certamente verdadeiro). As pontuações totais do ARI referem-se aos primeiros seis itens e variam de 0 a 12, com pontuações mais altas refletindo níveis mais elevados de irritabilidade. A escala ARI já foi validada para o Português brasileiro (DE SOUZA et al, 2013). A escala ARI está no ANEXO 6 deste documento.

2.4 Análise estatística

O tamanho amostral calculado para o estudo guarda-chuva, que visava comparar as tele-psicoterapias, foi de 270 indivíduos em cada grupo, considerando uma variabilidade do padrão de 0,8 para cada grupo e a diferença nos efeitos entre os testes de 0,1. O cálculo amostral do estudo guarda-chuva foi executado de

acordo com a característica do estudo de comparação dos métodos de psicoterapia, que utilizou testes de equivalência.

Para o presente projeto de pesquisa, considerando um nível de significância de 5%, poder de 80% e um coeficiente de correlação mínimo de 0,25 entre os escores de aliança terapêutica e os sintomas de ansiedade e depressão, obteve-se um total mínimo de 124 pacientes. Esse tamanho amostral foi calculado no programa WinPEPI (*Programs for Epidemiologists for Windows*) versão 11.43 e foi baseado nos estudos de Andersson et al (2012) e FLÜCKIGER et al (2018).

As variáveis quantitativas foram descritas por média e desvio padrão, ou mediana e amplitude interquartílica. As variáveis qualitativas foram descritas por frequências absolutas e relativas. Para comparar os tipos de tele-psicoterapia em relação à aliança terapêutica, o teste *t-student* (dados simétricos) foi utilizado. Para avaliar a associação entre a aliança terapêutica e os sintomas de ansiedade, depressão e irritabilidade, o teste da correlação de Pearson (dados simétricos) foi aplicado. Para controle de fatores confundidores, o modelo de regressão linear multivariado foi aplicado. O nível de significância adotado foi de 5% ($p < 0,05$) e essas análises foram realizadas no programa SPSS versão 21.0.

Foram realizados dois tipos de análises estatísticas. A análise dos desfechos principais do estudo guarda-chuva, que comparou tele-TIP e tele-TCC, se deu por **intenção de tratar** (*intention-to-treat*), ou seja, todos os pacientes que participaram da randomização foram incluídos, mesmo aqueles que abandonaram o estudo ou que realizaram as intervenções mas não preencheram os questionários de acompanhamento. Esses resultados originaram o **artigo 1** da presente Dissertação. Os resultados da segunda análise estatística foi **por protocolo**, ou seja, somente os participantes que concluíram todo o acompanhamento e preencheram completamente os questionários foram incluídos nessa análise. Esses resultados originaram o **artigo 2** da presente Dissertação.

2.5 Aspectos éticos

O presente estudo obedece a todas as recomendações de Ética em Pesquisa. Foi submetido e aprovado pelo Comitê de Ética em Pesquisa da Universidade do Vale do Taquari (COEP), através da Plataforma Brasil, sob o CAAE 40951820.6.0000.5310.

Todos os participantes receberam um Termo de Consentimento Livre e Esclarecido, sendo que a recusa à participação foi livre para todos, assim como a decisão de sair do estudo a qualquer momento, sem prejuízo à continuidade de seu tratamento. Não serão divulgadas informações confidenciais dos participantes ou dados sigilosos sobre os mesmos. Os participantes não foram expostos a riscos desnecessários.

3. Resultados

Os resultados estão aqui apresentados em dois artigos científicos separados, escritos em língua inglesa.

O primeiro artigo, denominado **"Synchronous Tele-Interpersonal Psychotherapy versus Tele-Cognitive Behavioral Therapy for adults: which works better? Results from a Randomized Clinical Trial."**, apresenta os resultados principais de nosso ECR comparando tele-TIP à tele-TCC, em relação à melhora de sintomas depressivos, ansiosos e de irritabilidade. Esse artigo foi submetido à revista *Acta Psychiatrica Scandinavica* em 25 de janeiro de 2023, sob o número *ACP-2023-11327*, e está em processo de revisão por pares. No ANEXO 7 encontra-se o comprovante de submissão.

O segundo artigo, denominado **"Therapeutic Alliance in Brief Tele-psychotherapies in a Randomized Clinical Trial"**, traz os resultados da análise secundária sobre a AT nas duas diferentes tele-psicoterapias utilizadas no presente estudo, com a comparação da AT na tele-TIP e na tele-TCC e a correlação entre AT e os desfechos principais do ECR. Esse artigo está em vias de ser submetido para avaliação em uma Revista científica.

3.1 Primeiro artigo

Synchronous Tele-Interpersonal Psychotherapy versus Tele-Cognitive Behavioral Therapy for adults: which works better? Results from a Randomized Clinical Trial.

Luiza Silveira Lucas^a, Bruno Lo Iacono Borba^a, Bruno Martini de Azevedo^b, Alexandro Cagliari^c, Andreia Rosane de Moura Valim^d, Edna Linhares Garcia^{d,e}, Silvia Virginia Coutinho Areosa^{d,f}, Alessandra Menezes Morelle^g, Marzie Rita Alves Damin^g, Simone Stulp^h, Alana Castro Panzenhagen^{i*}, Flávio Milman Shansis^{a*}

^a Graduate Program in Medical Sciences, Universidade do Vale do Taquari (UNIVATES), Lajeado, Brazil

^b Faculty of Medicine, Universidade do Vale do Taquari (UNIVATES), Lajeado, Brazil

^c Graduate Program in Environmental and Sustainability (Professional Master's), Universidade do Estado do Rio Grande do Sul (UERGS), Santa Cruz do Sul, Brazil

^d Graduate Program in Health Promotion - Universidade de Santa Cruz do Sul (UNISC), Santa Cruz do Sul, Brazil

^e Graduate Program in Psychology (Professional Master's)- Universidade de Santa Cruz do Sul (UNISC), Santa Cruz do Sul, Brazil

^f Graduate Program in Regional Development - Universidade de Santa Cruz do Sul (UNISC), Santa Cruz do Sul, Brazil

^g Thummi, Rio Grande do Sul, Brazil

^h Graduate Program in Environment and Development, Universidade do Vale do Taquari (UNIVATES), Lajeado, Brazil

ⁱ Graduate Program in Biological Sciences: Biochemistry - Universidade Federal do Rio Grande do Sul (UFRGS), Porto Alegre, Brazil

* Shared last co-authorship

Corresponding Author:

Flávio Milman Shansis

Graduate Program in Medical Sciences

Universidade do Vale do Taquari (UNIVATES)

Av. Avelino Talini, 171, Lajeado - Rio Grande do Sul, Postal-code: 95914-014, Brazil

Tel: +55(51)37147035; Email: flavio.shansis@univates.br

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Abstract

Introduction: Remote synchronous Cognitive Behavioral Therapy (t-CBT) is the most studied remote therapy and has evidence for treating depression and anxiety symptoms.

Objective: This research aims to compare the effectiveness of Tele-Interpersonal Psychotherapy (t-IPT) to t-CBT. We hypothesize that t-IPT is as effective as t-CBT.

Methods: We conducted a randomized clinical trial with two parallel arms and equal randomization. The allocation was on a 1:1 ratio based on a computerized randomization sequence of permuted blocks of 50. The interventions and assessments were based on a website designed specifically for the trial. Participants were adults from a community basis with symptoms of anxiety, depression or irritability who received four sessions of t-CBT or t-IPT. The main outcome measures were the Patient Health Questionnaire-9 (PHQ-9) for depressive symptoms, Generalized Anxiety Disorder-7 (GAD-7) for anxiety symptoms and Affective Reactivity Index (ARI) for irritability.

Results: 149 individuals (t-CBT n= 73; t-IPT 76) were randomized (mean age 32.5 years $\pm$ 10.7). 7 participants withdrew from interventions (t-CBT n=4; t-IPT n=3), and 20 finalized the interventions but did not fill out the follow-up questionnaires (t-CBT n=9; t-IPT n=11). We conducted an intention-to-treat analysis. There was an overall decrease in symptoms of depression, anxiety and irritability ($p < 0.001$) in both treatment arms and this improvement was not superior in one type of psychotherapy. The effectiveness analysis showed that interventions were equivalent.

Conclusions: t-IPT is as effective as t-CBT in treating community adults with symptoms of anxiety, depression or irritability.

Introduction

Depression and anxiety are the two most disabling mental disorders, ranking in the top 25 leading disease burdens worldwide in the Global Burden of Disease Study 2019 [1, 2]. The Covid-19 pandemic worsened it, resulting in an estimated 25% increase in the global prevalence of anxiety and depressive disorders [3, 4]. Since the beginning of the pandemic, the United Nations has called for action to minimize the mental health consequences of Covid-19, investing in mental health interventions that could be delivered remotely [5].

Remote synchronous cognitive behavioral therapy is the most studied remote therapy and has evidence of treating depressive and anxiety symptoms [6, 7, 8]. Despite the lack of evidence, other in-person psychotherapies were rapidly switched to remote-delivered psychotherapy during the pandemic [9]. Therefore, it is important to investigate and compare the effectiveness of different remote psychotherapies for these conditions.

Interpersonal psychotherapy (IPT) focuses on helping the patient to improve their social functioning and interpersonal relationships [10, 11]. IPT has consistent supportive evidence for treating depression when delivered in person [12] and has similar effectiveness to in-person CBT in reducing depressive symptoms [13]. Nevertheless, the evidence for treating anxiety disorders with in-person IPT is conflicting and scarce [14]. Only two studies investigated the efficacy of remote synchronous IPT for depressive symptoms, to our knowledge, but both were telephone-delivered and on specific populations [15, 16]. No study has investigated the effectiveness of remote synchronous video-delivered IPT (t-IPT) for symptoms of anxiety or depression.

This study aims to compare the efficacy of synchronous video-delivered brief Tele-Cognitive Behavioral Therapy (t-CBT) *versus* synchronous video-delivered brief Tele-Interpersonal Psychotherapy (t-IPT) for adults with symptoms of depression, anxiety and irritability. We hypothesize that t-IPT is equally effective and non-inferior to t-CBT. This work is, to the best of our knowledge, the first Randomized Clinical Trial (RCT) comparing synchronous video-delivered t-CBT *versus* t-IPT.

Materials and Methods

Trial design

We conducted a RCT with two parallel arms and equal randomization to compare synchronous t-IPT with t-CBT. The Research Ethics Committee of *Universidade do Vale do Taquari*, through the Brazil Platform of Ethics (*Plataforma*

Brasil), approved the research protocol under the Certificate of Presentation of Ethical Appreciation number 40951820.6.0000.5310.

Participants were eligible if they were: (a) feeling depressed, anxious, irritable, stressed or emotionally exhausted; (b) aged 18 and over; (c) able to understand self-administered questionnaires; (d) not currently on psychotherapy. Only participants residing in the region of *Vale do Taquari or Rio Pardo* in the State of Rio Grande do Sul, Brazil, were included. People presenting a moderate or high risk of suicide or with psychotic and delusional symptoms were excluded from the study.

Participants were recruited through advertisement via local radio, newspaper and social media. Information regarding the study was given in these advertisements, including the address of the study website (www.valeavida.com.br), which provided general information and instructions on how to proceed for participation in the study. All individuals who were interested in participating could register directly at the website. After registration, the subjects signed an online Informed Consent Form (ICF). On the website, participants were instructed to fill in socio-demographic data and baseline self-administered questionnaires that assessed symptoms of depression, anxiety, irritability, hopelessness, and suicidal ideation.

Afterward, a teleconsultation with a psychiatrist was scheduled. This teleconsultation was an interview conducted on the research website. It was based on the Telepsychiatry for the general population of TelePSI, a project funded by the Brazilian government with the collaboration of several academic institutions aiming to reduce the impact of Covid-19-related distress (Salum et al., 2020). The medical doctor assessed individuals for eligibility, checking the inclusion and exclusion criteria and applying the Columbia Suicide Risk Assessment Scale (C-SSRS) in order to stratify the risk of suicide as low, moderate, high or no risk [17]. Those who met the inclusion criteria were assigned to the clinical trial and underwent randomization. The research protocol is described in Figure 1.

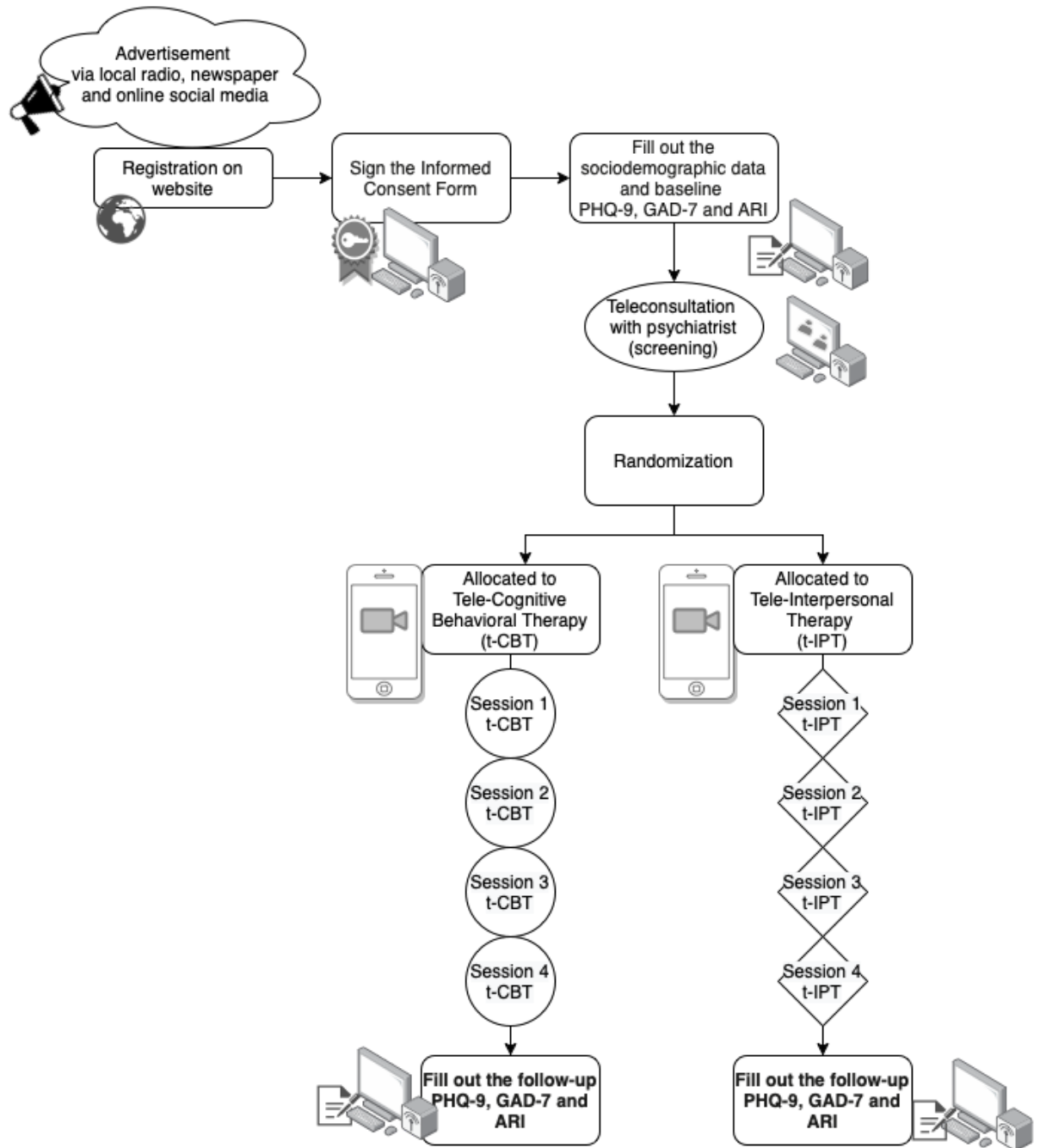


Fig. 1. Scheme of the research protocol

t-CBT, Tele-Cognitive Behavioral Therapy; *t-IPT*, Tele-Interpersonal Psychotherapy; *PHQ-9*, Patient Health Questionnaire-9; *GAD-7*, Generalized Anxiety Disorder-7; *ARI*, Affective Reactivity Index;

Interventions

The included participants received four sessions of either t-CBT or t-IPT. These sessions were conducted by three clinical psychologists who received training and certification on both t-CBT and t-IPT through the TelePSI prior to this study [18].

One group received four sessions of t-CBT, with a weekly interval between sessions, while the other group received four sessions of t-IPT, with the same weekly interval. The t-CBT and t-IPT sessions were performed according to the TelePSI manuals, and the content of each session is described elsewhere [19]. Each psychotherapy session lasted approximately 50 minutes and took place on a web platform designed specifically for the study.

A weekly group supervision was conducted by an experienced supervisor (E.L.G) throughout the course of this study. During these supervisions, the three therapists and supervisor met for two hours and the treatment was emphasized.

Outcomes

The outcome variables were defined a priori. The principal outcome measures were Patient Health Questionnaire-9 (PHQ-9) for depressive symptoms, Generalized Anxiety Disorder-7 (GAD-7) for anxiety symptoms and Affective Reactivity Index (ARI) for irritability symptoms.

PHQ-9 is a brief self-administered instrument for the assessment of depressive symptoms. The instrument contains nine items, arranged on a four-point scale: 0 (never) to 3 (almost every day), with a score ranging from 0 to 27 to assess the frequency of signs and symptoms of depression in the previous two weeks. A positive presence of major depression is considered when the score is greater than or equal to 10. Regarding severity, PHQ-9 comprises five categories, where a cut-off point of 0 to 4 indicates no depressive symptoms, 5 to 9 indicates mild depressive symptoms, 10 to 14 indicates moderate depressive symptoms, 15 to 19 indicates moderately-severe depressive symptoms, and 20 to 27 indicates severe depressive symptoms [20, 21, 22, 23]. The PHQ-9 has already been validated in Brazil for Brazilian Portuguese [24].

GAD-7 is a brief self-administered instrument for the assessment of anxiety symptoms. It consists of seven items, arranged on a four-point scale: 0 (never) to 3 (almost every day), with a score ranging from 0 to 21. It measures the frequency of signs and symptoms of anxiety in the previous two weeks. A positive presence of generalized anxiety disorder is considered when the score is equal to or greater than 10. The cut-off points for mild, moderate and severe levels of anxiety on GAD-7 are 5 to 9, 10 to 14, and greater than 15, respectively [25, 26]. The GAD-7 has already been validated for Brazilian Portuguese [27].

ARI is a brief self-administered instrument for the assessment of symptoms of irritability. The instrument consists of six items assessing feelings and behaviors related to irritability and one item assessing impairment due to irritability. Respondents rate each item using a 3-point scale (0 = false; 1 = somewhat true; 2 = certainly true). Total ARI scores refer to the first six items and range from 0 to 12, with higher scores reflecting higher levels of irritability. There are no cut-off points.

The ARI scale was initially developed to be used in childhood and adolescence, but later its validity for adults was proven [28]. The ARI scale has already been validated for Brazilian Portuguese [29].

Patients were assessed by filling out these self-administered questionnaires at baseline and follow-up, which occurred when the intervention was finished.

Sample Size

A sample size of 170 subjects (85 subjects in each group) was calculated, considering a power of 90% and a significance level of 5%. The sample size calculation was performed according to the characteristic of the study comparing psychotherapy methods, which will use equivalence tests.

Randomization

Participants were randomized to two groups, one of t-CBT and the other of t-IPT. The allocation was on a 1:1 ratio based on a computerized randomization sequence of permuted blocks of 50. The random allocation sequence was generated by a researcher who was not directly involved in the intervention (B.L.I.B.).

Statistical analyses

Data were analyzed using descriptive and inferential statistics. Statistical analyzes were performed using the Statistical Package for the Social Sciences, version 28.0 (IBM Corp. Released, 2021), using a significance level of 5% ($p \leq 0.05$).

The continuous variables were expressed as mean $\pm$ standard deviation (SD), and the categorical variables as absolute and relative frequencies in the descriptive analysis. The distribution of numerical variables was evaluated using the Kolmogorov-Smirnov test. T-student test was applied for the comparison of means. Pearson's chi-square test was used in comparing proportions.

To compare the scores of the PHQ-9, GAD-7 and ARI scales over time according to the groups, the Generalized Estimating Equations (GEE) model complemented by the Least Significant Difference (LSD) test was applied. Due to the asymmetry of the scales, the gamma model was used in the analyses. The effect size of the type of therapy was evaluated by Cohen, where values below 0.5 represent a weak effect, between 0.5 and 0.8, a medium effect, and above 0.8, a strong effect size [30].

The McNemar test was used to compare the pre and post-intervention levels of anxiety and depression in each type of therapy.

The analysis was conducted as intention-to-treat (ITT), which includes in statistics all the participants taking part in a trial, even participants who dropped out or did not finish the assessments, based on the group they were initially randomly allocated. ITT analysis assesses clinical effectiveness [31].

We performed post-hoc sub analyses to test whether t-IPT is still as effective as t-CBT in participants who met criteria for Generalized Anxiety Disorder (GAD-7 greater than or equal to 10; sub analysis #1) and in participants who met criteria for Major Depressive Disorder (PHQ-9 greater than or equal to 10; sub analysis #2).

Results

Characteristics of the study sample

A summary diagram based on Consolidated Standards of Reporting Trials (CONSORT) [32] is presented in Figure 2. Between March and November 2021, 495 individuals registered on the website and signed the ICF. Of these, 229 individuals underwent teleconsultation with the psychiatrist in order to assess eligibility. Finally, 149 individuals were included in the research and randomized. Of these, 73 were randomly assigned to t-CBT (49%) and 76 to t-IPT (51%). The data collection ended in January 2022.

Seven participants withdrew from interventions, four of these from the t-CBT arm and three from the t-IPT arm. Of these, five individuals had completed one session (four from t-CBT and one from t-IPT), one individual from the t-IPT arm had completed two sessions, and one individual from the t-IPT arm had completed three sessions before the withdrawal. Twenty participants finalized the interventions but did not complete the follow-up questionnaires - nine from the t-CBT arm and eleven from the t-IPT arm. Nevertheless, all participants who commenced the interventions were included in the statistical analysis (ITT).

The characterization of these groups of patients is shown in Table 1. The mean age was 32.5 years (± 10.7), and there was a female predominance (73.8%). Most of the participants were single, without children and with incomplete graduation. A small part of the participants were taking psychotropic medication (less than 20%), which is similar in both arms. No statistically significant differences were observed between the two intervention arms (t-CBT and t-IPT).

Outcomes measures

Table 2 shows results on the outcome measures, including change scores with 95% confidence intervals, and comparison between t-CBT and t-IPT.

GEE analysis of PHQ-9, GAD-7 and ARI showed an overall decrease in symptoms of depression, anxiety and irritability, respectively ($p < 0.001$), in both treatment arms. This improvement was not superior in one type of psychotherapy, being similar between t-CBT and t-IPT. The baseline assessment was filled out on average 18 days before the interventions commenced, and the follow-up assessment was filled out on average seven days after completion of the intervention.

Comparative Effectiveness

Observing the effect size of therapy, according to Cohen (2013) [30], there is a variation from -0.19 to 0.24, indicating that the type of psychotherapy has a weak effect on the results (Table 2). This suggests that t-CBT is equivalent to t-IPT in lowering anxiety, depression and irritability symptoms.

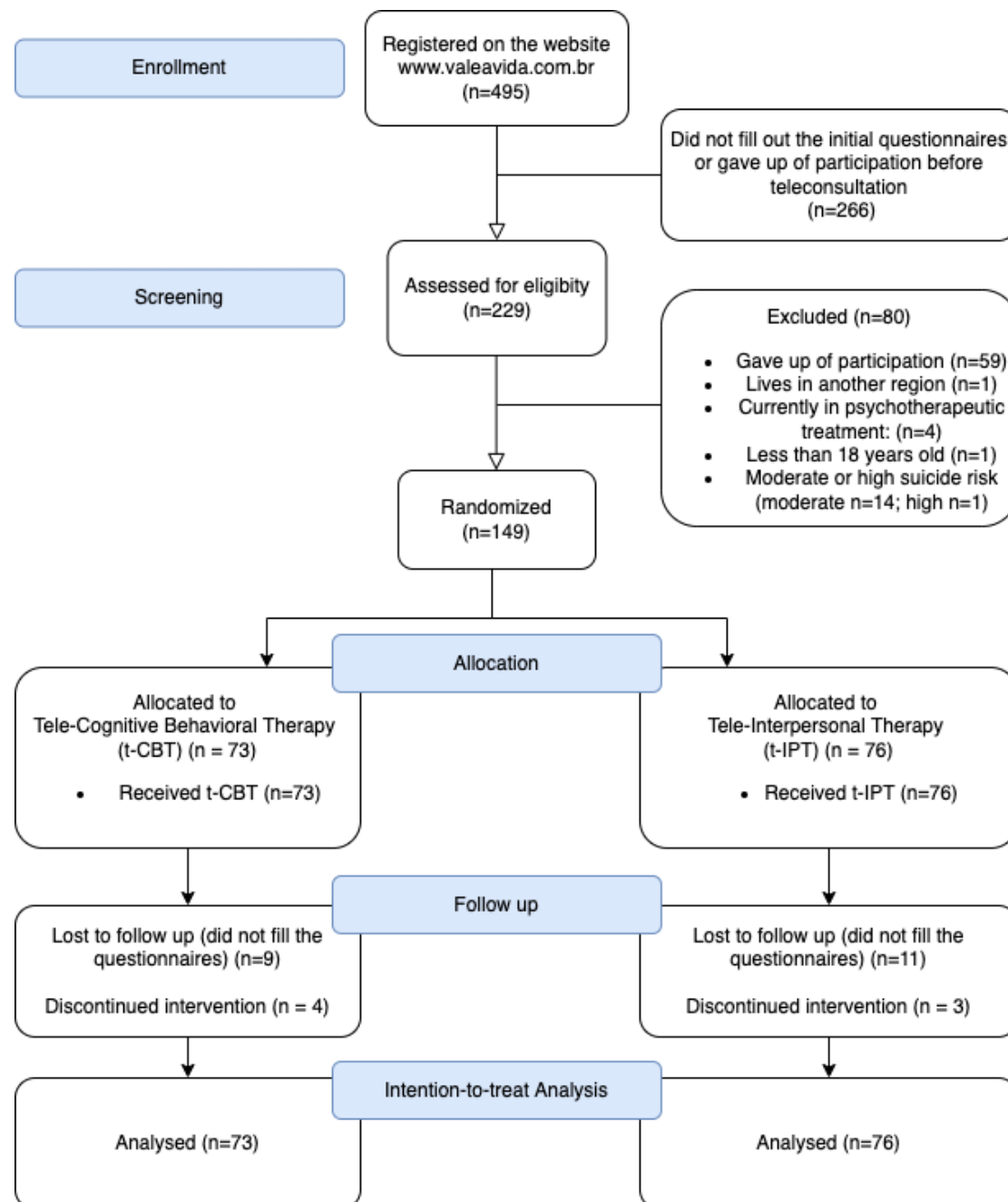


Fig. 2. CONSORT flow diagram.

t-CBT, Tele-Cognitive Behavioral Therapy; *t-IPT*, Tele-Interpersonal Psychotherapy; *PHQ-9*, Patient Health Questionnaire-9; *GAD-7*, Generalized Anxiety Disorder-7; *ARI*, Affective Reactivity Index.

Table 1: Sample Characterization.

Variables	t-CBT (n=73)	t-IPT (n=76)	p value
Mean age, years (SD)	32.7 ± 10.6	32.4 ± 10.9	0.854 ^a
Female sex	55 (75.3)	55 (72.4)	0.821 ^b
Self-defined ethnicity			0.170 ^b
White	59 (80.8)	70 (92.1)	
Black	13 (17.7)	6 (7.8)	
Asian	1 (1.4)	0 (0.0)	
Marital status			0.354 ^b
Single	51 (69.9)	52 (68.4)	
Married	20 (27.4)	18 (23.7)	
Divorced	2 (2.7)	3 (3.9)	
Widower	0 (0.0)	3 (3.9)	
Sons			0.635 ^b
No children	49 (67.1)	49 (64.5)	
With children	24 (32.9)	27 (35.5)	
Level of education			0.262 ^b
Elementary school	3 (4.1)	0 (0.0)	
Incomplete high school	4 (5.5)	2 (2.6)	
Completed high school	10 (13.7)	10 (13.2)	
Incomplete graduation	24 (32.9)	30 (39.5)	
Complete graduation	14 (19.2)	21 (27.6)	
Postgraduate	18 (24.7)	13 (17.1)	
Psychotropics			0.727 ^b
Yes	10 (13.7)	13 (17.1)	
No	63 (86.3)	63 (82.9)	
Finished intervention			0.278 ^b
Yes. finished intervention	69 (94.5)	73 (96.1)	
Dropout after first session	4 (5.5)	1 (1.3)	
Dropout after second session	0 (0.0)	1 (1.3)	
Dropout after third session	0 (0.0)	1 (1.3)	

Values express n (%), unless otherwise indicated; *t*-CBT, Tele-Cognitive Behavioral Therapy;
t-IPT, Tele-Interpersonal Psychotherapy;

^a Estimated by T-student test; ^b Estimated by Pearson's chi-square test;

Table 2: Outcome measures (p*) and comparison between t-CBT and t-IPT (P*).

Outcome	t-CBT (n=73)	t-IPT (n=76)	P**	Cohen (CI 95%)
	Mean ± SD	Mean ± SD		
Anxiety symptoms				
GAD-7				
Baseline	12.6 ± 4.8	12.2 ± 4.9	0.594	0.09 (-0.24 to 0.41)
Follow up	9.3 ± 5.4	8.2 ± 4.9	0.251	0.21 (-0.15 to 0.57)
Change in scores	-3.34	-4.00	0.512	0.17 (-0.19 to 0.53)
(CI 95%)	(-4.86 to -1.82)	(-5.24 to -2.76)		
p*	<0.001	<0.001		
Depressive symptoms				
PHQ-9				
Baseline	13.4 ± 6.5	13.5 ± 5.9	0.982	-0.00 (-0.33 to 0.32)
Follow up	9.7 ± 6.3	8.2 ± 5.5	0.186	0.24 (-0.12 to 0.59)
Change in scores	-3.77	-5.21	0.168	0.22 (-0.14 to 0.57)
(CI 95%)	(-5.21 to -2.34)	(-6.65 to -3.76)		
p*	<0.001	<0.001		
Irritability				
ARI				
Baseline	7.2 ± 4.5	7.1 ± 4.1	0.875	0.03 (-0.29 to 0.35)
Follow up	4.0 ± 4.1	4.7 ± 4.1	0.275	-0.18 (-0.50 to 0.15)
Change in scores	-3.21	-2.6	0.244	-0.19 (-0.51 to 0.13)
(CI 95%)	(-4.27 to -2.14)	(-3.30 to -1.42)		
p*	<0.001	<0.001		

t-CBT, Tele-Cognitive Behavioral Therapy; t-IPT, Tele-Interpersonal Psychotherapy; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7; ARI, Affective Reactivity Index. Results obtained from *Least Significant Difference* (LSD) test using the Generalized Estimating Equations (GEE) model with gamma distribution of dependent variables; p* stands for change in scores from baseline to follow-up; P** stands for the difference between t-CBT and t-IPT.

Post-hoc Subanalysis: Effectiveness in GAD and MDD

Subanalysis #1 comprised the 106 participants who met the criteria for Generalized Anxiety Disorder (GAD). The mean age was 31.3 years (± 10.2), with a predominance of females (77.4%). Of these, 50 were randomly assigned to t-CBT (47.2%) and 56 to t-IPT (52.8%). The groups were homogeneous regarding age, sex, marital status, education level, number of children, use of psychotropic drugs and completion of interventions. As shown in Table 3, both interventions effectively reduced anxiety, with no difference between the two types of therapy. Observing the effect size of therapy, according to Cohen, there is a variation from -0.26 to 0.36, indicating a weak effect of the type of therapy, which demonstrates an equivalence between them in the treatment of GAD.

Subanalysis #2 comprised the 104 participants who met the criteria for Major Depressive Disorder (MDD). The mean age was 32.1 years (± 10.8), with a

predominance of females (76%). Of these, 47 were randomly assigned to t-CBT (45.2%) and 57 to t-IPT (54.8%). The groups were homogeneous regarding age, sex, marital status, education level, number of children, use of psychotropic drugs and completion of interventions. As shown in Table 4, both interventions effectively reduced depressive symptoms, with no difference between the two types of therapy. Observing the effect size of therapy, according to Cohen, there is a variation from -0.14 to 0.42, indicating a weak effect of the type of therapy, which demonstrates an equivalence between them.

Table 3. Outcome measures (p*) and comparison between t-CBT and t-IPT (P*) in participants with Generalized Anxiety Disorder (n=106).

Outcome	t-CBT (n=50)	t-IPT (n=56)	P**	Cohen (CI 95%)
	Mean ± SD	Mean ± SD		
GAD-7				
Baseline	15.2 ± 3.3	14.4 ± 3.2	0.224	0.24 (-0.15 to 0.62)
Follow up	10.1 ± 5.1	9.5 ± 5.0	0.570	0.12 (-0.31 to 0.56)
Change in scores (CI 95%)	-5.10 (-6.78 to -3.41)	-4.95 (-6.47 to -3.44)	0.899	0.02 (-0.43 to 0.43)
p*	<0.001	<0.001		

t-CBT, Tele-Cognitive Behavioral Therapy; t-IPT, Tele-Interpersonal Psychotherapy; GAD-7, Generalized Anxiety Disorder-7.

Results obtained from *Least Significant Difference* (LSD) test using the Generalized Estimating Equations (GEE) model with gamma distribution of dependent variables; p* stands for change in scores from baseline to follow-up; P** stands for the difference between t-CBT and t-IPT.

Table 4. Outcome measures (p*) and comparison between t-CBT and t-IPT (P*) in participants with Major Depressive Disorder (n=104).

Outcome	t-CBT (n=47)	t-IPT (n=57)	P**	Cohen (CI 95%)
	Mean ± SD	Mean ± SD		
PHQ-9				
Baseline	17.2 ± 4.7	15.8 ± 4.8	0.117	0.31 (-0.08 a 0.69)
Follow up	11.9 ± 6.2	9.4 ± 5.5	0.075	0.42 (-0.01 a 0.85)
Change in scores (CI 95%)	-5.39 (-7.14 a -3.64)	-6.17 (-7.87 a -4.47)	0.268	0.16 (-0.27 a 0.58)
p*	<0.001	<0.001		

t-CBT, Tele-Cognitive Behavioral Therapy; t-IPT, Tele-Interpersonal Psychotherapy; GAD-7, Generalized Anxiety Disorder-7.

Results obtained from *Least Significant Difference* (LSD) test using the Generalized Estimating Equations (GEE) model with gamma distribution of dependent variables; p* stands for change in scores from baseline to follow-up; P** stands for the difference between t-CBT and t-IPT.

Discussion and Conclusion

Our results showed the equal effectiveness of two different types of tele-psychotherapies (t-CBT and t-IPT) performed synchronously. At the end of the trial, both t-CBT and t-IPT effectively reduced symptoms of anxiety, depression and irritability ($p < 0.001$) in a community sample formed by adults, predominantly female, white, single and without children. We observed non-inferiority in the intention-to-treat analysis.

Telepsychotherapy is defined as the administration of psychotherapy using remote technologies and can be delivered synchronously or asynchronously [33]. It has many advantages over in-person treatments, such as convenience (fewer time constraints), accessibility (no need for transportation, no geographic barrier), less perceived stigma [8], and especially in pandemics like the Covid-19, reducing the spread of the disease [9].

In synchronous telepsychotherapy, the patient and therapist interaction happens in real time by telephone or videoconference [8]. Our study compares two synchronous videoconference-delivered psychotherapies, t-CBT and t-IPT.

Our findings are of great relevance because, as far as we know, this study is the first to investigate and prove the effectiveness of remote synchronous video-delivered IPT (t-IPT) for symptoms of anxiety, depression and irritability, when compared to the gold-standard t-CBT. The effectiveness of t-CBT demonstrated in our results is consistent with previous reviews and meta-analyses. A recent review of 24 studies, which assessed the evidence for synchronous telepsychology interventions for depression, anxiety, posttraumatic stress disorder (PTSD), and adjustment disorder, concluded that the evidence is sufficient to support videoconference and telephone-delivered intervention [6]. The majority of interventions included in this review were CBT, but they also included behavioral, behavioral-activation, exposure, cognitive-processing, supportive and problem-solving therapies [6]. Another meta-analysis comparing the effectiveness of video-delivered psychotherapy to in-person treatments showed that the improvement was most pronounced when CBT is used and when anxiety, depression or PTSD is the target [7]. A third recent meta-analysis of RCTs based on Behavioral activation, CBT, cognitive-processing therapy and problem-solving therapy for multiple psychiatric diagnoses showed that synchronous telepsychotherapy is as effective as in-person psychotherapy [8]. Lin and colleagues [8] included videoconference-delivered treatments, but unlike Fernandez and colleagues [7], they also included telephone-delivered psychotherapy studies. None of these studies included video or telephone-delivered IPT. Only two studies investigated the efficacy of synchronous remote IPT, but both focused only on depressive symptoms, in specific populations and were telephone-delivered [15, 16].

In the last 30 years, many studies have investigated asynchronous telepsychotherapy, which are computer or internet-delivered treatments in which the patient assesses the intervention material on a platform and the contact with a therapist is variable: some have a therapist support (named "guided"), occurring by chatbot or e-mail, others are completely self-help, as described by Andersson et al [34]. Asynchronous psychotherapy should not be confused with synchronous psychotherapy. Asynchronous CBT is extensively studied, and is shown to be effective in anxiety and depressive disorders [35].

Nevertheless, a recent network meta-analysis including 155 trials with more than fifteen thousand depressed patients, designed to compare the effectiveness and acceptability of CBT delivery formats showed that guided self-help CBT may be less acceptable and have higher dropout rates for patients than in-person individual, in-person group, or telephone psychotherapy formats [36]. Cuijpers and colleagues showed also that the synchronous telephone CBT for depression had the highest ranking for acceptability when compared to others [36]. However, they did not include synchronous videoconference-delivered studies.

A recently published article showed that asynchronous internet self-help CBT intervention reduced worry in the general population during Covid-19, when compared to mental health advice [37]. Secondary outcomes of their intervention reduced anxiety and depression symptoms, a similar finding to ours. It is important to note that the major difference between this to ours is that they used asynchronous intervention. Their dropout rate in the self-help CBT arm was high; only 37.7% of the 175 participants allocated finished the 10-session intervention, while in our study, only 5.5% of participants quit in the t-CBT and 3.9% in the t-IPT groups. We highlight this is consistent with the low acceptability of self-help internet interventions [36].

When comparing asynchronous remote IPT and asynchronous remote CBT, only two studies were published. Dagöö et al showed that both self-help guided CBT and self-help guided IPT can improve social anxiety disorder [38]. Donker et al. compared asynchronous remote CBT with asynchronous remote IPT in a "3-arm, fully self-guided, online noninferiority trial" over 4 weeks in the general population [39]. In Donker's study, one arm received a new protocol of self-guided CBT, the second received self-guided IPT and a third received an active control, which was a self-guided treatment based on CBT (named MoodGYM). A significant reduction in depressive symptoms was seen in all arms, with noninferiority [39]. Although the result of this study is interesting, the dropout rate of this study was 70%, which is again consistent with the low acceptability of asynchronous interventions [36] and contrasts with the low dropout rate evidenced in our study.

Our study has several aspects of strength. It is the first study to assess t-IPT in adults on a community basis with symptoms of depression, anxiety or irritability. This study has an adequate sample size and an active comparison group (t-CBT).

Despite that, several limitations and possible sources of imprecision need to be discussed. First, as our sample was not clinical but from a community, our data should be interpreted carefully concerning generalization. The protocol was conceived during the Covid-19 pandemic scenario, where people were isolated, in lockdown, and without access to any other mental health treatment. Then, our inclusion criteria comprised self-reporting symptoms of depression, anxiety, irritability, stress and emotional exhaustion. We did not exclude participants who did not meet the criteria for Major Depressive Disorder (PHQ-9 $\geq$ 10) or Generalized Anxiety Disorder (GAD-7 $\geq$ 10). This was in order to facilitate access to the intervention for all interested individuals of the general population. We did not focus initially on psychopathology diagnostics, aiming to mimic a universal prevention approach. Similar broad inclusion criteria were used in another mental health RCT designed during the pandemic [37]. To reduce the effect of a possible selection bias and enable the extrapolation of results to clinical samples, we performed two subanalyses which included only participants who met criteria for the referred psychiatric diagnoses, using the cutoff points defined in the PHQ-9 and GAD-7 scales as a threshold. Even when we look at these subanalyses, t-IPT remains equivalent to t-CBT in reducing the target symptoms.

Second, our protocol included only an active group control, the t-CBT, which we considered the current standard treatment. We did not include a passive control group, such as "wait list" (WL) or "treatment as usual" (TAU). Although this can be a limitation, we argue that both TAU and a WL would be inadequate control groups. This is in line with the conclusions of two meta-analyses on this subject. Munder and colleagues focused on the inexistence of a single TAU and analyzed the impact of the intensity of TAU in the effects of face-to-face and internet-based psychotherapy [40]. Furukawa and colleagues showed that "wait list" may be a placebo condition in psychotherapy trials because its effect size is often smaller than no treatment [41].

Third, both of our interventions were based on brief treatments of only four sessions, which differs from the standard protocols of in-person CBT and IPT, which comprise at least 12 sessions [42, 11]. Despite that, there was a positive result of our interventions in reducing anxiety, depressive and irritability symptoms. This is consistent with a recent systematic review investigating the dose-response in psychological therapies [43]. Dose-response is "the relationship between the dose (e.g., length, frequency) of treatment and the subsequent probability of improvement." Robinson et al found that the optimal doses of psychotherapy range between 4 to 26 sessions [43]. They also found that weekly therapy, which was the frequency used in our study, "seems to accelerate the rate of improvement compared to less frequent schedules" [43].

Finally, the dropout rate was similarly low in both tele psychotherapy groups, with 5.5% dropouts in the t-CBT and 3.9% in the t-IPT group. There are also similar missing follow-up data, 12.3% in t-CBT and 14.4% in t-IPT. We have no information

on the reasons for dropout or loss to follow up, but there is some chance that these participants have worsened their symptoms, which could be a bias. As these rates did not differ between intervention arms, we believe this potential bias does not greatly influence the validity of the results. Moreover, all analyses were in the intention-to-treat format to reduce biases.

Future research is needed to replicate our findings of t-IPT noninferiority to t-CBT in different samples and to examine whether these interventions are as effective as in-person psychotherapies. Cost-effectiveness studies for synchronous online psychotherapies could also help to determine where this type of treatment is helpful for implementation in public health systems.

Statements

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Statement of Ethics

All participants gave signed an online informed consent before entering the study, which was approved by the Ethics Committee of Universidade do Vale do Taquari through Brazil Platform of Ethics (*Plataforma Brasil*), approved the research protocol under the Certificate of Presentation of Ethical Appreciation number 40951820.6.0000.5310.

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Conflict of Interest Statement

The authors declare that the research was conducted in absence of any commercial or financial relationship that could be constructed as a potential conflict of interest. L.S.L. receives master's scholarship ("PROSUC Modalidade II") from Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), Brazil. B.M.A received scholarship from Fundação de Amparo à Pesquisa do Estado do Rio Grande do Sul (FAPERGS), Brazil. A.E.C.P. receives a doctoral 's scholarship from CAPES, Brazil, and a scholarship from *Deutscher Akademischer Austauschdienst*, Deutschland. A.M.M is cofounder of *Thummi* in Brazil.

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Author Contributions

L.S.L. and B.L.I.B: concept and design of the trial, coordinated the randomization and allocation procedure, acquisition, analysis and interpretation of data, and wrote the paper. B.M.A.: acquisition of the data and writing the paper. A.C., A.R.M.V, and S.S.: concept and design of the trial and paper revision. A.M.M and M.R.A.D.: concept and design of the trial, coordinated the development and provided

support of the website where the intervention took place and paper revision. E.L.G and S.V.C.A.: concept and design of the trial, supervision of interventions, paper revision. A.C.P.: concept and the trial's design, coordinated trial management, analysis and interpretation of data, provided methodological and statistical support and critical revision. F.M.S.: concept and the design of the trial, obtained funding and ethics approval for the study, coordinated trial management, analysis and interpretation of data, and critical revision. All authors read and approved the final version.

Data Availability Statement

The data that support the findings of this study are not publicly available due to containing information that could compromise the privacy of research participants but are available from the corresponding author (F.M.S.) upon reasonable request.

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3.2 Segundo artigo

Therapeutic Alliance in Brief Tele-psychotherapies in a Randomized Clinical Trial

Luiza Silveira Lucas^a, Alana Castro Panzenhagen^b, Flávio Milman Shansis^a

^a Graduate Program in Medical Sciences, *Universidade do Vale do Taquari (UNIVATES)*, Brazil

^b Graduate Program in Biological Sciences: Biochemistry - *Universidade Federal do Rio Grande do Sul (UFRGS)*, Brazil

Corresponding author:

Flávio Milman Shansis

Graduate Program in Medical Sciences, *Universidade do Vale do Taquari (UNIVATES)*, Brazil

Address: Av. Avelino Talini, no 171 , Bairro Universitário, Lajeado - Rio Grande do Sul, Postal-code: 95914-014, Brazil

Tel: +55-51- 37147035

Email: flavio.shansis@univates.br

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Abstract

Introduction: Tele psychotherapies via videoconference, such as tele- Cognitive Behavioral Psychotherapy (t-CBT) and tele-Interpersonal Psychotherapy (t-IPT) are increasingly being used to treat people with mental health issues such as anxiety, depression and irritability. Although the effectiveness of these treatments is clear, other factors associated with its outcomes still need to be further explored. Therapeutic alliance (TA) refers to the collaborative aspects of the therapist-patient relationship and is an important factor associated with outcomes in in-person psychotherapies, but until now there were few studies addressing TA in tele psychotherapies.

Objective: The aims of our study are to address (a) How strong is TA in t-CBT and t-IPT? (b) Is there any difference in TA levels between t-CBT and t-IPT? (c) Is there a correlation between TA and clinical outcomes of t-CBT and t-IPT?

Methods: We conducted a secondary analysis per protocol of a randomized controlled trial (RCT) with two parallel arms and equal randomization comparing t-IPT to t-CBT. The main outcome measures were Patient Health Questionnaire-9 (PHQ-9) for depressive symptoms, Generalized Anxiety Disorder-7 (GAD-7) for anxiety symptoms and Affective Reactivity Index (ARI) for irritability. TA levels were measured using Working Alliance Inventory- short version for patients (WAI-s). We conducted TA-outcomes correlation using Pearson's correlation coefficient.

Results: 69 individuals (t-CBT n=30; t-IPT n=39) were included. (a) The total WAI-s score in the t-CBT sample was 74.5 ($\pm$ 8.3) and in the t-IPT sample was 76.3 ($\pm$ 7.4). (b) When comparing TA levels between t-CBT and t-IPT, no differences were obtained. (c) There is a significant correlation between TA level and anxiety reduction in the complete sample. We found no correlation between TA levels and changes in anxiety when samples were analyzed separately, as well as no correlation between TA levels and change in depression or irritability.

Conclusions: High levels of TA are formed between patient and therapist both in t-CBT and t-IPT, with no difference between them. TA was associated with reduction in anxiety levels, but there was no association between TA levels and change in depression or irritability.

Introduction

Tele-psychotherapies are psychological treatments offered via telephone or videoconference (VC) that have developed rapidly over the last few decades, being as effective as in-person psychotherapies (Fernandez et al, 2021). Some of the benefits of tele-psychotherapy are bringing mental health to people who live in rural areas or areas with difficult access, with physical or psychological disabilities, in a state of incarceration, caring responsibilities, financial difficulties, work responsibilities and anxieties associated with the stigma of attending mental health appointments (Simpson and Reid, 2014). Since the beginning of the Covid-19 pandemic, this type of remote treatment has been instrumental in minimizing the mental health consequences of the pandemics (Abraham et al., 2021; Markowitz et al., 2021, United Nations, 2020). Despite that, there are some scientific questions that are still unanswered regarding tele psychotherapies.

Therapeutic alliance (TA), also known as working or helping alliance, refers to the collaborative aspects of the therapist-patient relationship (Flückiger et al, 2018). Bordin (1979) proposed a pantheoretical version of the alliance based on Greenson's ideas (1965), which included three features: 1- the development of bond composed of reciprocal positive feelings; 2- the agreement on the treatment goals; 3- the agreement on the tasks that belong to the therapist and the patient in the psychotherapeutic process (BORDIN, 1979). One review and another systematic review and meta analysis have shown that TA levels rates moderate to strong in VC psychotherapy (Simpson and Reid, 2014; Norwood, 2018). In most of the studies included in these reviews the intervention was synchronous VC tele-cognitive behavioral therapy (t-CBT). None studied TA in tele-interpersonal psychotherapy (t-IPT).

A meta-analytic synthesis of 295 independent psychotherapy studies showed a moderate but robust correlation between TA and outcome on traditional in-person psychotherapies, being similar over different types of in-person treatments (Flückiger et al., 2018). Eighteen "e-mental health" studies were separately analyzed in two meta-analyses which concluded that TA-outcome correlation has a moderate effect size (Flückiger et al., 2018; Probst et al., 2019). Unfortunately, between included studies, 16 were based in asynchronous interventions, and the only 2 using synchronous tele psychotherapy were VC anger management for post traumatic stress disorder and cognitive behavioral therapy by phone to psychosis (Greene et al., 2010; Mulligan et al., 2014). More recently, Norwood et al. published a secondary analysis of a randomized controlled trial (RCT) of t-CBT for health anxiety, including 46 participants, and demonstrated a significant correlation between TA and outcome (2021). No other research presenting data about the TA-outcome correlation in tele psychotherapies were found in the scientific literature.

In this paper, we therefore present a secondary analysis based on data of a RCT comparing 4 sessions of t-IPT to 4 sessions of t-CBT (Lucas et al., 2023). This

RCT demonstrated the equal effectiveness of t-IPT and t-CBT. We conducted this secondary analysis aiming to understand: (a) How strong is TA in these brief tele-psychotherapies? (b) Is there any difference in TA levels between t-CBT and t-IPT? (c) Is there a correlation between TA and clinical outcomes of t-CBT and t-IPT?. This is the first study investigating TA in t-CBT and t-IPT for anxiety, depressive and irritability symptoms.

Materials and Methods

Trial design and participants

We performed a RCT with two parallel arms and equal randomization to compare synchronous t-IPT with t-CBT.

The Research Ethics Committee of *Universidade do Vale do Taquari*, through the Brazil Platform of Ethics (*Plataforma Brasil*), approved the research protocol under the Certificate of Presentation of Ethical Appreciation number 40951820.6.0000.5310.

Participants were eligible if they were: (a) feeling depressed, anxious, irritable, stressful and/or emotionally exhausted; (b) aged 18 and over; (c) able to understand self-administered questionnaires; (d) not currently on psychotherapy. Only participants living in the region of *Vale do Taquari* or *Rio Pardo* in the State of Rio Grande do Sul, Brazil, were included due to funding issues. People evaluated as moderate or high risk of suicide or with psychotic and delusional symptoms were excluded from the study.

Participants were recruited through advertisement via local radio, newspaper and social media. Information regarding the study was given in these advertisements, including the address of a website (www.valeavida.com.br) that provided general information and instructions on how to proceed for participation in the study. All individuals who were interested in participating could register at this website. After registration, the subjects signed online the Informed Consent Form (ICF). On the website, participants were instructed to fill socio-demographic data and baseline self-administred questionnaires that assess symptoms of depression, anxiety, irritability, hopelessness, and suicidal ideation.

Afterward, a teleconsultation with a psychiatrist was scheduled. This teleconsultation was an interview conducted on the research website and was based on the Telepsychiatry for the general population of TelePSI, which was a project funded by the Brazilian government with the collaboration of several academic institutions aiming to reduce the impact of Covid-19 related distress (Salum et al., 2020). The medical doctor assessed individuals for eligibility, checking the inclusion and exclusion criteria and applying the Columbia Suicide Risk Assessment Scale (C-SSRS) in order to stratify the risk of suicide as low, moderate, high or no risk (Posner et al., 2011). Those who met the inclusion criteria were assigned to the

clinical trial and underwent randomization. The research protocol is described on Figure 1.

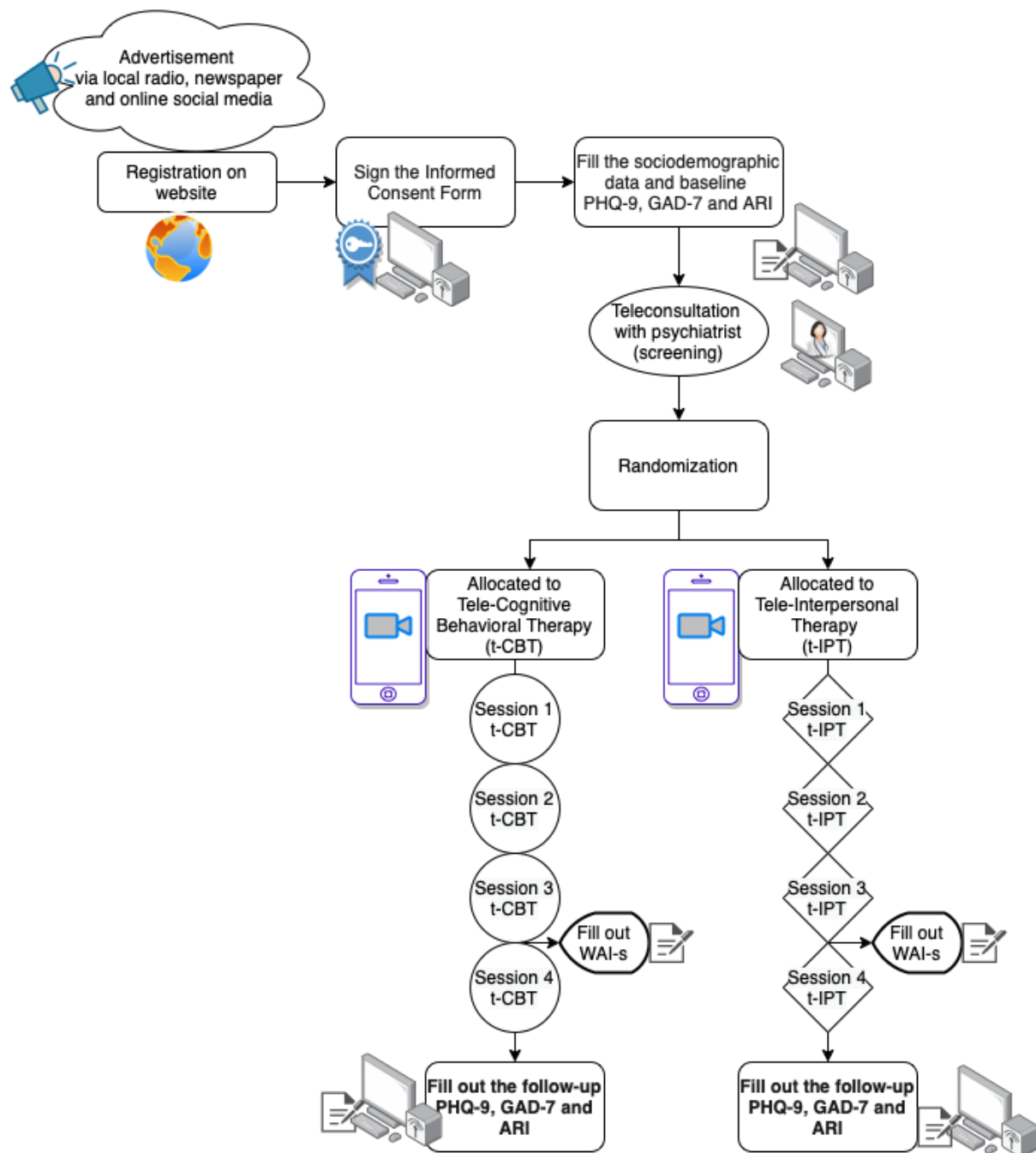


Figure 1. Scheme of the research protocol

t-CBT, Tele-Cognitive Behavioral Therapy; *t-IPT*, Tele-Interpersonal Psychotherapy; *PHQ-9*, Patient Health Questionnaire-9; *GAD-7*, Generalized Anxiety Disorder-7; *ARI*, Affective Reactivity Index; *WAI-s*, Working Alliance Inventory- short version for patient.

Interventions

The included participants received four sessions of either t-CBT or t-IPT. These sessions were conducted by three clinical psychologists who received training and certification on both t-CBT and t-IPT through the TelePSI prior to this study (Salum et al., 2020).

One group received four sessions of t-CBT, with a weekly interval between each session, while the other group received four sessions of t-IPT, with the same weekly interval. The t-CBT and t-IPT sessions were performed according to the TelePSI manuals and content of each session is described elsewhere (*TelePSI*, 2020). Each psychotherapy session lasted approximately 50 minutes and took place on a web platform designed specifically for the study.

A weekly group supervision was conducted by an experienced supervisor throughout the course of this study. During these supervisions, the three therapists and supervisor met for two hours and the treatment was emphasized.

Outcome measures

The outcome variables were defined a priori. The principal outcome measures were Patient Health Questionnaire-9 (PHQ-9) for depressive symptoms, Generalized Anxiety Disorder-7 (GAD-7) for anxiety symptoms and Affective Reactivity Index (ARI) for irritability symptoms. These self-administered questionnaires were obtained at baseline and at follow-up, that occurred when intervention was finished.

PHQ-9 is a brief self-administered instrument for the assessment of depressive symptoms. The instrument contains nine items, arranged on a four-point scale: 0 (never) to 3 (almost every day), with a score ranging from 0 to 27 to assess the frequency of signs and symptoms of depression in the previous two weeks. A positive presence of major depression is considered when the score is greater than or equal to 10 (Costantini et al., 2021; Negeri et al., 2021; Spitzer, 1999). The PHQ-9 has already been validated in Brazil for Brazilian Portuguese (Santos et al., 2013).

GAD-7 is a brief self-administered instrument for the assessment of anxiety symptoms. It consists of seven items, arranged on a four-point scale: 0 (never) to 3 (almost every day), with a score ranging from 0 to 21. It measures the frequency of signs and symptoms of anxiety in the previous two weeks (Toussaint et al., 2020; Spitzer et al., 2006). The GAD-7 has already been validated for Brazilian Portuguese (Moreno et al., 2016).

ARI is a brief self-administered instrument for the assessment of symptoms of irritability. The instrument consists of six items assessing feelings and behaviors related to irritability and one item assessing impairment due to irritability. Respondents rate each item using a 3-point scale (0 = false; 1 = somewhat true; 2 = certainly true). Total ARI scores refer to the first six items and range from 0 to 12, with higher scores reflecting higher levels of irritability. There are no cut-off points. The ARI scale was initially developed to be used in childhood and adolescence, but

later its validity for adults has been proven (Mulraney et al., 2014). The ARI scale has already been validated for Brazilian Portuguese (De Sousa et al., 2013).

TA measure

Therapeutic alliance was evaluated by the patient between the third and fourth session of the intervention using Working Alliance Inventory (WAI), short version with 12 questions for patients (WAI-s). WAI was developed by Horvath and Greenberg, being an instrument for evaluating the TA in different clinical contexts, not linked to any theoretical school (1989). The original versions for patients and therapists are composed of 36 items each and the short versions are composed of 12 items each. In this study, we used the short version for the patient, here called WAI-s. WAI-s is organized into three subscales: Bond, Goal and Task, each with 4 questions, which are answered using a seven-point likert scale (1 = never to 7 = always), so the minimum score would be 7 and the maximum score would be 84 (Tracey & Kokotovic, 1989).

Randomization

Participants were randomized to two groups, one of t-CBT and other of t-IPT. The allocation was on a 1:1 ratio based on a computerized randomization sequence of permeated blocks of 50. The random allocation sequence was generated by a person who was not directly involved in the intervention.

Statistical analysis

Data were analyzed using descriptive and inferential statistics. Statistical analyzes were performed using the Statistical Package for the Social Sciences, version 28.0 (IBM Corp. Released, 2021), using a significance level of 5% ($p \leq 0.05$).

The continuous variables were expressed as mean $\pm$ standard deviation (SD) and categorical variables as absolute and relative frequencies in the descriptive analysis. The distribution of numeric variables was evaluated using the Shapiro-Wilk test. T-student test was applied for the comparison of means. Pearson's chi-square test was used in comparing proportions. To adjust for possible confounding factors, the Analysis of Covariance (ANCOVA) was applied.

To compare the scores of the PHQ-9, GAD-7 and ARI scales over time according to the groups, the Generalized Estimating Equations (GEE) model complemented by the Least Significant Difference (LSD) test was applied. Due to the asymmetry of the scales, the gamma model was used in the analyses. The McNemar test was used to compare the pre and post-intervention levels of anxiety, depression and irritability in each type of therapy. The effect size of the type of therapy was evaluated by Cohen, where values below 0.5 represent weak effect, between 0.5 and 0.8 medium effect and above 0.8 strong effect size (Cohen, 2013).

The correlation between the TA and changes in PHQ-9, GAD-7 and ARI after the intervention were assessed using Pearson's correlation coefficient. We

conducted a per protocol analysis, which includes in statistics only the participants who completed the interventions and completed the questionnaires.

Results

Characteristics of the study sample

A summary diagram based on Consolidated Standards of Reporting Trials (CONSORT) is presented in Figure 2.

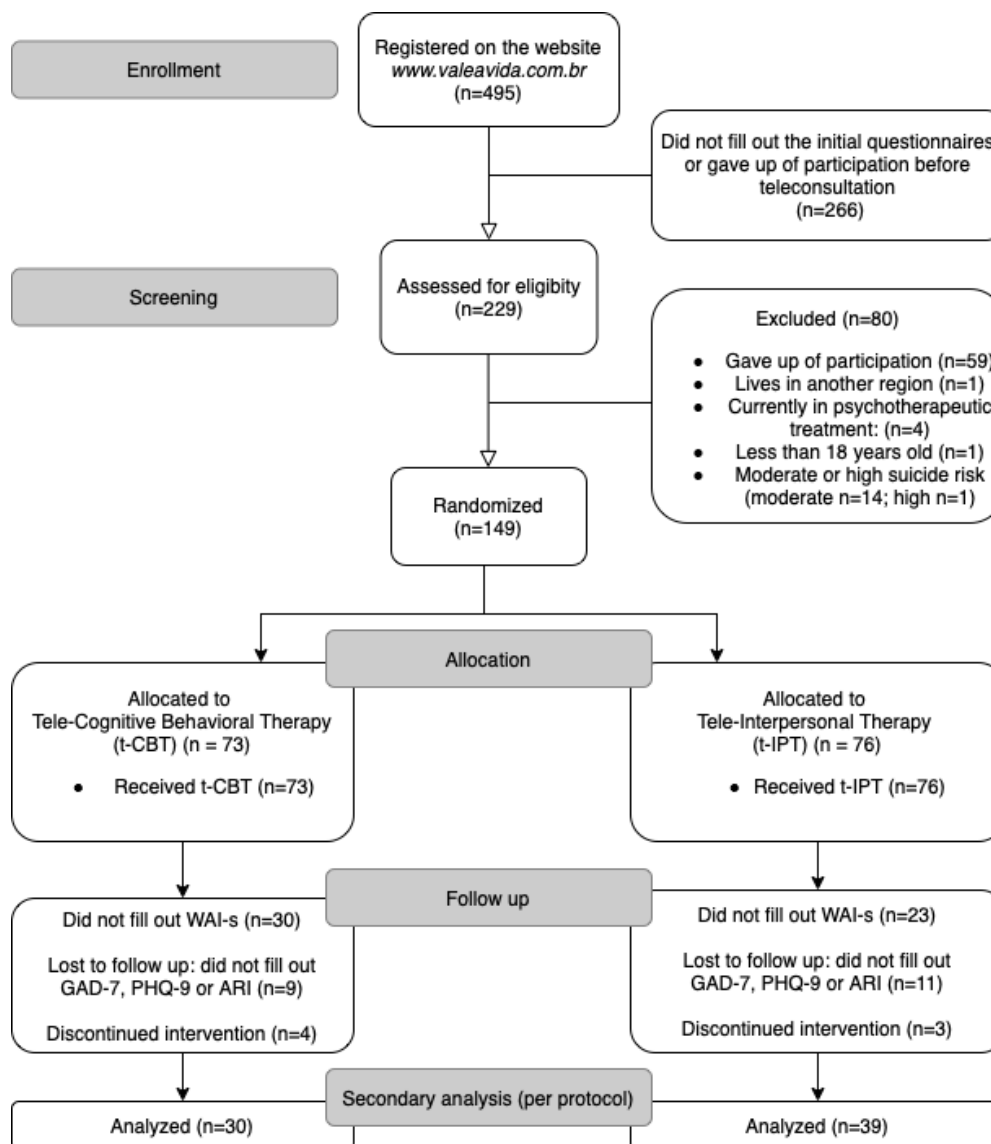


Figure 2. CONSORT flow diagram

t-CBT, Tele-Cognitive Behavioral Therapy; *t-IPT*, Tele-Interpersonal Psychotherapy; *PHQ-9*, Patient Health Questionnaire-9; *GAD-7*, Generalized Anxiety Disorder-7; *ARI*, Affective Reactivity Index; *WAI-s*, Working Alliance Inventory- short version for patient.

Between March and November 2021, 495 individuals registered on the website and signed the ICF. Of these, 229 individuals were submitted to the teleconsultation with the psychiatrist in order to assess eligibility. 149 individuals were included in the research and randomized (73 t-CBT; 76 t-IPT). Of these, we analyzed data from 69 individuals who finalized the protocols and filled out the questionnaires (30 t-CBT; 39 t-IPT). The characterization of these 69 participants is shown in Table 1.

Table 1 – Sample Characterization

Variables	t-CBT (n=30)	t-IPT (n=39)	<i>p</i> value
	n (%)	n (%)	
Mean age, years (SD)	34.9 ± 10.9	32.1 ± 10	0.272 ^a
Female sex	22 (73.8)	26 (66.7)	0.739 ^b
Self-defined ethnicity			0.018^b
White	23 (76.7)	39 (100)	
Brown	4 (13.3)	0 (0)	
Black	2 (6.7)	0 (0)	
Asian	1 (3.3)	0 (0)	
Marital status			0.300 ^b
Single	19 (63.3)	28 (71.8)	
Married	9 (30)	10 (25.6)	
Divorced	2 (6.7)	0 (0)	
Widower	0 (0)	1 (2.6)	
Sons			0.591 ^b
No children	18 (60)	26 (66.7)	
With children	12 (40)	13 (33.3)	
Level of education			0.863 ^b
Incomplete high school	1 (3.3)	1 (2.6)	
High school	4 (13.3)	6 (15.4)	
Incomplete graduation	6 (20)	12 (30.8)	
Graduated	11 (36.7)	12 (30.8)	
Postgraduate	8 (26.7)	8 (20.5)	
Psychotropics			0.168 ^c
No	28 (93.3)	31 (79.5)	

Values express n (%), unless otherwise indicated.

^a T-student test; ^b Pearson's chi-square test; ^c Fisher's exact test;

Outcomes measures

Table 2 shows results on the outcome measures, including change scores with 95% confidence intervals, and comparison between t-CBT and t-IPT.

There was an overall decrease in symptoms of depression and anxiety ($p < 0.001$), in both treatment arms. This improvement was not superior in one type of psychotherapy, being similar between t-CBT and t-IPT. As for the symptoms of irritability, the improvement was significant only in the t-CBT group ($p = 0.020$), being borderline in the t-IPT group ($p = 0.054$). However, the improvement was not superior in one type of therapy, being similar between t-CBT and t-IPT (Table 2).

Observing the effect size of therapy according to Cohen (2013), there is a variation from -0.42 to 0.21, indicating that the type of psychotherapy has a weak effect on the results (Table 2). This suggests that t-CBT is equivalent to t-IPT on change in anxiety, depressive and irritability symptoms.

Table 2. Outcome measures (p^*) and comparison between t-CBT and t-IPT (P^*).

Outcome	t-CBT (n=30)	t-IPT (n=39)	P**	Cohen (CI 95%)
	Mean ± SD	Mean ± SD		
Anxiety symptoms				
GAD-7				
Baseline	11.7 ± 4.6	11.8 ± 4.6	0.670	-0.02 (-0.50 a 0.46)
Follow up	8.8 ± 5.6	7.8 ± 4.1	0.622	0.21 (-0.27 a 0.69)
Change in scores (CI 95%)	-2.93 (-4.80 a -1.06)	-4.03 (-5.64 a -2.41)	0.369	0.21 (-0.27 a 0.68)
p*	0.002	<0.001		
Depressive symptoms				
PHQ-9				
Baseline	13.0 ± 6.1	12.5 ± 5.5	0.824	-0.08 (-0.39 a 0.56)
Follow up	9.1 ± 6.9	8.7 ± 5.4	0.867	0.06 (-0.41 a 0.54)
Change in scores (CI 95%)	-3.87 (-5.71 a -2.02)	-3.77 (-5.68 a -1.85)	0.987	-0.02 (-0.49 a 0.56)
p*	<0.001	<0.001		
Irritability				
ARI				
Baseline	5.7 ± 4.2	6.7 ± 4.0	0.308	-0.26 (-0.73 a 0.22)
Follow up	4.2 ± 4.2	5.9 ± 3.9	0.116	-0.42 (-0.89 a 0.06)
Change in scores (CI 95%)	-1.50 (-2.72 a -0.28)	-0.85 (-1.80 a 0.02)	0.264	-0.22 (-0.69 a 0.26)
p*	0.020	0.054		

t-CBT, Tele-Cognitive Behavioral Therapy; t-IPT, Tele-Interpersonal Psychotherapy; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7; ARI, Affective Reactivity Index.

Results obtained from *Least Significant Difference* (LSD) test using the Generalized Estimating Equations (GEE) model with gamma distribution of dependent variables; p^* stands for change in scores from baseline to follow up; P^{**} stands for the difference between t-CBT and t-IPT.

Therapeutic alliance

Therapeutic alliance data (WAI-s) are shown in Table 3. The total WAI-s score in the t-CBT sample was 74.5 (± 8.3) and in the t-IPT sample was 76.3 (± 7.4). When comparing TA between t-CBT and t-IPT, no differences were obtained in terms of total scores ($P^{**}=0.852$) and goal ($P^{**}=0.443$), task ($P^{**}=0.816$) and bond ($P^{**}=0.509$) subscales.

Table 3: WAI-s compared between t-CBT and t-IPT.

Therapeutic alliance WAI-s	t-CBT (n=30)	t-IPT (n=39)	P*	P**
	Mean $\pm$ SD	Mean $\pm$ SD		
Total	74.5 $\pm$ 8.3	76.3 $\pm$ 7.4	0.329	0.852
Goal	25.8 $\pm$ 2.7	25.7 $\pm$ 2.4	0.936	0.443
Task	25.4 $\pm$ 3.2	26.0 $\pm$ 2.6	0.416	0.816
Bond	23.3 $\pm$ 4.6	24.6 $\pm$ 3.6	0.176	0.509

* Teste t-student; ** Adjusted for skin color using Analysis of Covariance (ANCOVA). WAI-s, Working Alliance

Inventory short version for patient; t-CBT, Tele-Cognitive Behavioral Therapy; t-IPT, Tele-Interpersonal Psychotherapy.

The associations between TA (WAI-s) and the changes in anxiety (GAD-7), depression (PHQ-9) and irritability (ARI) is presented in Table 4. In the complete sample, a significant inverse correlation was observed between the change in anxiety (GAD-7) with the WAI-s total ($rs=-0.258$; $p=0.032$). There was also a significant inverse association in the total sample between the change in the anxiety score (GAD-7) and the WAI-s Goal ($rs=0.267$; $p=0.026$). This association between WAI-s goal and change in anxiety subscale was observed in the t-IPT sample ($rs=-0.332$; $p=0.039$), but not in the t-CBT sample ($rs=-0.200$; $p=0.288$). We did not find an association between TA levels and changes in anxiety symptoms when we investigate t-CBT and t-IPT samples independently. No association was found between TA levels and changes in depressive or irritability symptoms.

Table 4: Association between changes obtained in anxiety (GAD-7), depression (PHQ-9) and irritability (ARI) scores with the therapeutic alliance in the total sample and by type of tele-psychotherapy.

Associations	Complete sample (n=69)	t-CBT (n=30)	t-IPT (n=39)
	Pearson's correlation coefficient	Pearson's correlation coefficient	Pearson's correlation coefficient
Anxiety symptoms			
Δ GAD-7			
WAI-s Total	-0.258 (p=0.032)	-0.191 (p=0.311)	-0.300 (p=0.063)
WAI-s Goal	-0.267 (p=0.026)	-0.200 (p=0.288)	-0.332 (p=0.039)
WAI-s Tasks	-0.192 (p=0.113)	-0.073 (p=0.702)	-0.293 (p=0.070)
WAI-s Bond	-0.197 (p=0.105)	-0.178 (p=0.346)	-0.191 (p=0.245)

Table 4 (continued)

Associations	Complete sample (n=69)	t-CBT (n=30)	t-IPT (n=39)
	Pearson's correlation coefficient	Pearson's correlation coefficient	Pearson's correlation coefficient
Depressive symptoms			
Δ PHQ-9			
WAI-s Total	-0.108 (p=0.377)	0.020 (p=0.917)	-0.207 (p=0.207)
WAI-s Goal	-0.125 (p=0.305)	0.160 (p=0.222)	-0.134 (p=0.415)
WAI-s Tasks	-0.174 (p=0.152)	-0.135 (p=0.475)	-0.214 (p=0.190)
WAI-s Bond	-0.009 (p=0.942)	0.195 (p=0.301)	-0.185 (p=0.260)
Irritability symptoms			
Δ ARI			
WAI-s Total	0.085 (p=0.489)	0.042 (p=0.827)	0.108 (p=0.511)
WAI-s Goal	0.027 (p=0.827)	-0.110 (p=0.564)	0.185 (p=0.259)
WAI-s Tasks	-0.052 (p=0.673)	-0.098 (p=0.606)	-0.019 (p=0.906)
WAI-s Bond	0.181 (p=0.136)	0.205 (p=0.277)	0.116 (p=0.482)

Δ=difference between the scores obtained after the intervention in relation to baseline scores

Discussion and Conclusion

Tele psychotherapies are increasingly being used to treat people with mental health issues such as anxiety, depression and irritability (Simpson, 2009; Fernandez et al, 2021). Although the effectiveness of these remote treatments is clear, such as we recently showed in our paper comparing t-IPT to t-CBT (Lucas et al., 2023), other factors associated with its outcomes still need to be further explored. Here we study TA, which is an important factor associated with outcomes in in-person psychotherapies, but until now there were few studies addressing TA in synchronous tele psychotherapies. In the current study, we demonstrated that high levels of TA are formed between patient and therapist in two types of brief tele-psychotherapies, t-CBT and t-IPT. We also demonstrated that there was no difference in TA levels between t-CBT and t-IPT. When addressing correlation between TA and clinical outcomes of t-CBT and t-IPT, we found a significant correlation between TA level and anxiety reduction in the complete sample. We found no correlation between TA levels and changes in anxiety when samples were analyzed separately, as well as no correlation between TA levels and change in depression or irritability.

Our first aim was to understand how strong TA between patient and therapist would be in these brief tele-psychotherapies, t-CBT and t-IPT, for which we found high levels of TA: 74.5 ± 8.3 in t-CBT and 76.3 ± 7.4 in t-IPT, considering that the maximum score on WAI-s would be 84. Two reviews previously found high TA levels in synchronous VC psychotherapy. The first was Simpson and Reid's, which included 23 studies and compared TA levels in VC and in-person psychotherapy, with no

difference (Simpson and Reid, 2014). Nine over 23 studies were based on t-CBT, and none were t-IPT. Only 5 of 23 studies were RCTs. The second was Norwood and colleagues' meta-analysis, which also showed that TA between patient and therapist in VC treatments achieved high levels and outcomes were similar when comparing VC to in-person treatments (2018). Despite that, differently from Simpson and Reid's review (2014), Norwood et al. found higher TA levels in in-person treatments when compared to VC psychotherapy. All 10 samples in the second received VC cognitive behavioral therapy performed on an individual basis (not group therapy). None of the cited reviews were not able to analyze the correlation between TA in VC therapy and outcomes.

Our second aim was to understand if there would be any difference in TA levels between t-CBT and t-IPT, for which we understood that levels in both therapies were similar. Our study was the first one to study TA in t-IPT.

The last aim of our research was to understand if there was a TA-outcomes correlation in t-CBT and t-IPT. Addressing the topic of TA in psychotherapy, Flückiger et al. had meta-analytic reviewed over 300 studies, and have shown a positive correlation of the TA and outcomes, being similar over different types of in-person treatments (2018). Between these studies, 295 were in-person psychotherapies, finding an overall TA-outcome association of $r=0.278$ ($p<0.0001$), that is, TA has a positive association with outcomes, with a weak to moderate strength. Unfortunately, Flückiger et al. found only 18 studies addressing TA in "e-mental health", and 16 of them were based on asynchronous treatments, which are usually self-help treatments, in which contact with a therapist varies from none to few contacts via email or chat. The average effect size (ES) of TA in "e-mental health" outcomes found on this meta analysis was $r=0.275$ ($p<0.0001$), quite similar to in-person psychotherapies. Taking into account the important differences between asynchronous therapies and therapies that are performed synchronously, with a therapist connected in real time with the patient, usually through VC (such as t-IPT and t-CBT), we understand that the findings of this meta analysis about TA-outcome correlation could not be extrapolated to synchronous psychotherapies.

The two synchronous tele psychotherapy included in these meta analysis were VC anger management for post traumatic stress disorder and cognitive behavioral therapy by phone to psychosis (Flückiger et al., 2018; Greene et al., 2010; Mulligan et al., 2014), with a ES of $r=0.35$ and $r=0.34$, respectively. Recently, Norwood et al. published a secondary analysis of a RCT of t-CBT for health anxiety, including 46 participants, and demonstrated a significant correlation between TA and reduction in health anxiety measured by Short Health Anxiety Inventory ($r=0.25$) (2021). Similarly, in our RCT, we found a moderate correlation between TA and reduction in anxiety ($r=-0.258$; $p=0.032$) when analyzing our complete sample ($n=69$). It means that the greater the TA, the greater the reduction in anxiety symptoms. We could not find TA-outcome correlation in reducing anxiety symptoms when we separately analyzed t-CBT and t-IPT, which could be explained by the number of

participants in each group of interventions, which could not be large enough to find a statistically significant difference. Even though the two tele-psychotherapy also showed a reduction in the symptoms of depression and irritability, as we show in table 2, no correlation was found between TA and the reduction in depressive symptoms and irritability symptoms.

Regarding the analysis of the WAI-s subscales (bond, task and goal), we found a significant inverse association in the complete sample between the change in the anxiety score (GAD-7) and the WAI-s Goal ($r=0.267$; $p=0.026$). As WAI-s Goal subscale addresses if patient and therapist agree on the goal of the treatment, we understand that the greater the agreement between treatment goals, the greater the reduction in anxiety symptoms. This association between WAI-s goal and change in anxiety subscale was observed in the t-IPT sample ($r=0.33$; $p=0.039$), but not in the t-CBT sample ($r=0.20$; $p=0.288$). This could be potentially explained by the larger number of participants in t-IPT ($n=39$). We could hypothesize that if our t-CBT ($n=30$) group were larger, we could also find a statistically significant TA-outcome on Goal subscale in this group. We cannot affirm that in t-IPT the patient and therapist agreed more about goals of treatment, because as we show in Table 3, in both treatments WAI-s goal subscale levels were similar: 25.8 ± 2.7 in t-CBT and 25.7 ± 2.4 in t-IPT ($p^{**}= 0.443$). WAI-s bond and task subscales had also similar levels between groups, but when we analyze TA-outcomes correlations were found when we analyze bond and task subscales.

Probst et al. published a meta-analysis including the same 18 "e-mental health" studies of Flückinger' meta-analysis (Probst et al., 2019; Flückiger et al., 2018). One of their aims was to analyze TA-outcome correlation using WAI-s subscales, and for this they included data from 9 studies with 13 independent samples, all of them of asynchronous interventions. Interestingly, when this 9 studies investigated this correlation separately, most of them did not find TA-outcome correlation in WAI-s subscales, but when meta analysis was performed correlations between TA and outcomes were found in all three subscales: bond ($r= 0.16$), task ($r=0.28$) and goal ($r=0.22$). Again, this is probably due to the small number of participants in individual studies.

Another hypothesis could be that bond between patient and therapist and agreement on what patient and therapist need to do in therapy (tasks) are less important than the goal in "e-mental health". In Berger's narrative review about TA in internet interventions, the author discusses these hypotheses that, on internet intervention, bond could be less important in asynchronous treatments, as some of them are therapist-guided and others, not (2016). We understand that this assumption cannot be extrapolated to VC synchronous treatments, because of different natures of these treatments. One issue that we must keep in mind, and that could potentially be a limitation of our study, is that we performed only 4 sessions of t-CBT or t-IPT, that is, the therapies were brief. It may be that in brief therapies, only agreement on therapy goals is associated with outcomes, but not bond and task.

Probst et al. also aimed to understand the potential moderators of TA, but none of the investigated categorical moderator variables (amount of therapeutic contact; treatment duration; time of the alliance assessment; disorder-specificity of outcome and average age of participants) significantly accounted for variability of the effect sizes (2019).

Some limitations and possible sources of imprecisions need to be discussed. First, our interventions were brief treatments of 4 sessions. We highlight that even with just 4 sessions, TA between patients and with their therapists were at high levels. Second, we measured WAI-s only once, between the third and fourth week of interventions. It would be interesting if we could have analyzed variation in TA between sessions, but when we designed the study protocol, which ran during Covid-19 pandemics, we believed that including fewer questionnaires would be better for the participants. The decision of including WAI-s between the third and fourth session was based on previous research which showed that a strong AT could be formed between patient and therapist early in therapy, i.e. between the first and fifth session (Flückiger et al., 2018). Third, we chose to use only the patient version of WAI-s, as several studies have already demonstrated that the patient version has good validity and reliability and when the association between TA and clinical outcome was investigated, there was no statistical difference between TA when evaluated by patient or therapist (Flückiger et al., 2018). It could be possible that our results are influenced by a phenomenon known as the halo effect: a trend seeing higher correlations between working alliance and outcome if both are rated by the same person (Horvath et al., 2011). Despite that, the existence of the halo effect was not proven: even if the ES of AT-outcome correlation when rated by the same person is slightly bigger ($r=0.29$) then when rated by a different person ($r=0.24$), this was not statistically significant (Horvath et al., 2011). Fourth, our analysis was *per protocol*, that is, only the data from 69 of total 149 participants of the original work were included. That was because we needed to analyze WAI-s and correlation to outcome (measured by GAD-7, PHQ-9 and ARI), so we could not include in the analysis participants who did not fill out these questionnaires. This can be a source of bias, because it is possible that participants who developed lower TA with therapists choose to not fill the WAI-s.

Despite that, our study has a number of strengths. This is the first study to assess TA in t-IPT, to compare it to TA in t-CBT, correlating with outcomes. Another quality is that our sample and setting are quite similar to real life settings: adults from a community basis with symptoms of depression, anxiety or irritability, and VC therapies performed synchronously by home. Also, we believe that our study has an adequate total sample size. We add that our study is the first in the field of TA in VC psychotherapies that was based outside North America, Europe and Oceania. This is an important strength taking into account that "there is a broad consensus that psychotherapy is embedded in cultural-specific contexts" and "the country in which a

study is conducted might impact the generalizability of the alliance and its relation to outcome across ethnic minorities" (Flückiger et al., 2018).

In conclusion, the data presented in this manuscript demonstrated that great TA is formed between patients and therapists in t-CBT and t-IPT, being equivalent between them. We also show that TA is associated with reducing anxiety levels in these remote psychotherapies. We believe that further research in this field is needed to test if our results will be replicated and to continue enabling the knowledge in this important field to be deepened.

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Statement of Ethics

All participants gave signed an online informed consent before entering the study, which was approved by the Ethics Committee of Universidade do Vale do Taquari through Brazil Platform of Ethics (*Plataforma Brasil*), approved the research protocol under the Certificate of Presentation of Ethical Appreciation number 40951820.6.0000.5310.

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Conflict of Interest Statement

The authors declare that the research was conducted in absence of any commercial or financial relationship that could be constructed as a potential conflict of interest. L.S.L. receives master's scholarship ("PROSUC Modalidade II") from Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), Brazil. A.E.C.P. receives a doctoral 's scholarship from CAPES, Brazil, and a scholarship from *Deutscher Akademischer Austauschdienst*, Deutschland.

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Author Contributions

L.S.L.: concept and design of the trial, coordinated the randomization and allocation procedure, acquisition, analysis and interpretation of data, and wrote the paper. A.E.C.P.: concept and the design of the trial, coordinated trial management,

analysis and interpretation of data, provided methodological and statistical support and critical revision. F.M.S.: concept and the design of the trial, obtained funding and ethics approval for the study, coordinated trial management, analysis and interpretation of data, and critical revision. All authors read and approved the final version.

Data Availability Statement

The data that support the findings of this study are not publicly available due to containing information that could compromise the privacy of research participants but are available from the corresponding author (F.M.S.) upon reasonable request.

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4. Conclusão

As tele-psicoterapias, assim como a telemedicina em geral, estão sendo cada vez mais utilizadas como modalidade de tratamento. No contexto da pandemia da Covid-19, no qual o isolamento físico foi preconizado, as tele-psicoterapias foram fundamentais para auxiliar pessoas em sofrimento psíquico, sendo rapidamente empregadas logo após o início do período pandêmico (MARKOWITZ, 2021, SAMMONS et al, 2020). Embora alguns estudos demonstrassem a eficácia das tele-psicoterapias, especialmente na modalidade tele-TCC (FERNANDEZ et al, 2021; LIN et al, 2022), não havia ainda estudos embasando o uso da tele-TIP. Desta forma, se faziam necessários estudos que avaliassem também a eficácia da tele-TIP.

A presente dissertação apresenta, em seu artigo 1, o primeiro estudo a demonstrar a eficácia equivalente de dois tipos diferentes de tele-psicoterapia breve realizadas de forma síncrona, a tele-TCC e tele-TIP. Ao final do ECR, tanto a tele-TCC quanto a tele-TIP reduziram efetivamente os sintomas de ansiedade, depressão e irritabilidade ($p < 0,001$) em uma amostra comunitária formada por adultos, predominantemente do sexo feminino, brancos, solteiros e sem filhos. Esses resultados positivos acerca da efetividade destas duas modalidades de tele-psicoterapias trazem ainda mais comprovação científica sobre a efetividade da tele-TCC, e são, até onde podemos saber, os primeiros resultados na literatura acerca da eficácia da tele-TIP.

Além disso, dentre os fatores associados com os resultados das psicoterapias, está a aliança terapêutica (AT). Esta é entendida como a capacidade de o paciente estabelecer uma ligação de trabalho com o terapeuta, em que o importante é o vínculo entre ambos, a concordância sobre os objetivos da terapia e sobre o que deve ser feito para que sejam alcançados tais objetivos. Já está bem estabelecido que AT se associa aos desfechos nas psicoterapias presenciais. Porém, até o presente momento, havia poucos estudos sobre AT em tele-psicoterapias. As publicações que abordam essa questão são baseadas, principalmente, na abordagem cognitivo-comportamental, e a maioria destes estudos se utilizou de psicoterapias assíncronas, nas quais a interação entre paciente e terapeuta é limitada e não se dá em tempo real (SIMPSON et al, 2014; NORWOOD et al, 2018, FLUCKIGER et al., 2018; PROBST et al., 2019).

A presente dissertação apresenta, portanto, novidades para esse campo de estudo. No artigo 2 desta dissertação, são demonstrados resultados advindos de um ECR, evidenciando que altos níveis de AT foram formados entre paciente e terapeuta nos dois diferentes tipos estudados de tele-psicoterapia breve síncrona, tele-TCC ($WAI-s = 74,5 \pm 8,3$;) e tele-TIP ($WAI-s = 76,3 \pm 7,4$), sem diferença nos níveis de AT quando comparadas as duas intervenções entre si ($p = 0.852$). Os níveis de AT revelados aqui são similares àqueles das revisões sistemáticas e metanálise, sendo que essas baseiam seus resultados fundamentalmente em tele-TCC (SIMPSON et al, 2014; NORWOOD et al, 2018). Não foi encontrado nenhum outro

artigo que tenha investigado AT em tele-TIP. Em vista disso, o resultado apresentado nessa dissertação a respeito dos altos níveis de AT em tele-TIP é o primeiro na literatura científica.

Nas psicoterapias presenciais, já está comprovado que a AT se correlaciona com os desfechos clínicos (FLUCKIGER et al, 2018). Em contrapartida, nas tele-psicoterapias síncronas, faltavam evidências científicas para que essa afirmação pudesse ser feita. Os poucos artigos sobre a correlação entre AT e desfechos em psicoterapia baseada em internet têm seus resultados baseados em intervenções assíncronas (PROBST et al, 2019). Dessa forma, esta dissertação apresenta, em seu segundo artigo, dados que contribuem para essa área de estudo. Neste trabalho, demonstramos uma correlação significativa entre os níveis de AT e a redução da ansiedade na amostra completa estudada, que incluiu todos os pacientes que finalizaram as duas intervenções ($p=0.032$). Por outro lado, não foi encontrada correlação entre os níveis de AT e níveis de ansiedade quando as amostras foram analisadas separadamente (tele-TCC $p=0.311$; tele TIP $p=0.063$), assim como não houve correlação entre os níveis de AT e níveis de depressão ou irritabilidade ($p>0.05$).

Os resultados aqui demonstrados contribuem para o campo de pesquisa das tele-psicoterapias, que, embora esteja cada vez mais desenvolvido, apresenta diversas lacunas, estando ainda bastante baseado nas evidências de eficácia da tele-TCC. Além de contribuir para a literatura científica, nossos resultados embasam as práticas clínicas em tele-psicoterapia, que desde o surgimento da Covid-19 aumentaram seu uso de forma exponencial (MARKOWITZ, 2021; SAMMONS et al, 2020).

É fundamental, por conseguinte, que essa área de pesquisa siga se desenvolvendo. Novos ensaios clínicos randomizados com tele-psicoterapias síncronas, especialmente com bases teórico-práticas distintas da tele-TCC, como é o caso da tele-TIP, poderão se somar a esse. Além disso, sugere-se que, ao serem realizados futuros ECRs em tele-psicoterapia síncrona, a AT seja avaliada e os dados de correlação entre AT e os desfechos sejam testados, a fim de verificar se os dados aqui apresentados se confirmam ou não, tanto em amostras maiores, em amostras oriundas de outros contextos culturais, quanto - após um corpo de conhecimento mais robusto - estas hipóteses sejam avaliada em metanálises.

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ANEXO 1 - Divulgação do Projeto

1.1 Folder de divulgação do projeto Vale a Vida (impresso e para redes sociais)



VALE A VIDA

PROJETO DE ATENDIMENTO REMOTO EM PSICOTERAPIA PARA RESIDENTES DOS VALES DO TAQUARI E RIO PARDO NO CONTEXTO DA COVID-19

Se você mora na Região dos Vales do Taquari ou Rio Pardo, no Rio Grande do Sul, e tem se sentido triste, ansioso ou irritado nesse momento da pandemia da COVID-19, estamos oferecendo um tratamento gratuito que consiste de uma avaliação psiquiátrica e quatro sessões de psicoterapia, feitas de forma online através do seu celular, tablet ou computador

Para se inscrever, basta acessar diretamente o nosso site e preencher os seus dados

www.valeavida.com.br

FOMENTO: SECRETARIA DE INOVAÇÃO, CIÊNCIA E TECNOLOGIA

UNIVERSIDADES PROMOTORAS: UNIVATES, PPOCM, UNISC, UERGS

APOIO: 2019, 2020, 2021 Associação de Psicólogos do Rio Grande do Sul

PLATAFORMA DIGITAL: Tummi

APOIO TECNOLÓGICO: TEKANN

1.2 Divulgação em rádios locais (A Hora, Rádio Independente e Rádio Univates)



FRENTE VERSO

Segunda a sexta 8h10 às 10h

Apresentação: Fernando Weiss

Comentário e análise: Rodrigo Martini

NESTA QUARTA 21/04

MARCELO DALCON
VEREADOR DE LAJEADO
As propostas de melhorias para os passos públicos e como conseguiu a formalização do novo Plano de Mobilidade Urbana da cidade

LUÍZA LUCAS
PSICÓLOGA E PSICOTERAPEUTA
A experiência em resultados do programa Vale a Vida e como ele contribui para manter a saúde mental das pessoas em tempos de pandemia

MARCELO GAZEN
DIRETOR-PRÉSIDENTE DA ECA
Novo gestor da ECA fala sobre futuro da estatal, concedida da ECA 1913 30 e sobre previdência do Vale

ENTRE AS PÁGINAS:
Comentário diário de cinco formadores de opinião.
Ardêmio Heineck

Chá das Treze
apresentação Marcelo Petter

Entrevistas, música e informação.

Convidada:
Dra. Luiza Lucas
Psiquiatra e Psicoterapeuta
Projeto Vale a Vida

Data: 7/5
Hora: 13:00

Troca de Ideias
Nesta segunda-feira, 15 de março, às 10h10

Convidada às 10h40:
Dra. Luiza Lucas
Psiquiatra

Tema: Projeto "Vale a Vida" oferece atendimento psicológico online para pessoas em sofrimento durante e após a pandemia

Troca de Ideias de segunda a sexta das 10h10 às 11h30

Patrocinadores: LANGUIRU, STR

Independente
950AM+FM91.7
A rádio de todos!

1.3 Participação em matéria no Jornal A Hora (Ed. Final de Semana, 11 e 12 de setembro de 2021)

Vale a Vida

Em Lajeado, a Univates, em parceria com a Unisc e Uergs, organiza o projeto Vale a Vida, com um grupo de pesquisadores apoiados pela Secretaria de Inovação, Ciência e Tecnologia do estado.

O projeto atende pessoas do Vale do Taquari e Rio Pardo. As inscrições vão até outubro e, para participar, basta entrar no site do Vale a Vida, clicar em “Quero Participar”, preencher os dados, concordar em fazer parte do projeto de pesquisa e marcar uma consulta com o psiquiatra. Depois, o paciente passa por quatro sessões virtuais de psicoterapia com profissionais capacitados.

Entre os pesquisadores do projeto, está a médica psiquiatra e psicoterapeuta, mestranda da Pós-graduação em Ciências Médicas da Univates Luiza Lucas. Ela explica que são coletados dados sobre como os participantes se sentem antes, durante e após os atendimentos, para estudar como as tele-psicoterapias afetam as pessoas. “Por exemplo, se elas melhoram de sintomas de ansiedade, depressão e irritabilidade, como isso ocorre, em quais pessoas funciona melhor, etc”, explica Luiza.

Desde março, quando iniciou, mais de 550 pessoas se ca-



dastraram no projeto. Os principais motivos que levaram à procura das consultas são sintomas de ansiedade, depressão e irritabilidade.

“Os resultados têm sido ótimos, as pessoas estão aderindo bem às sessões de psicoterapia”, destaca Luiza.

Os dados serão publicados em periódicos científicos internacionais e nacionais.

Como ajudar

O primeiro passo para ajudar um paciente psíquico é não deixar que ele abandone o tratamento. Além de entender que são problemas crônicos, sem cura. Por isso, é importante aprender a conviver com as doenças ao invés de escondê-las.

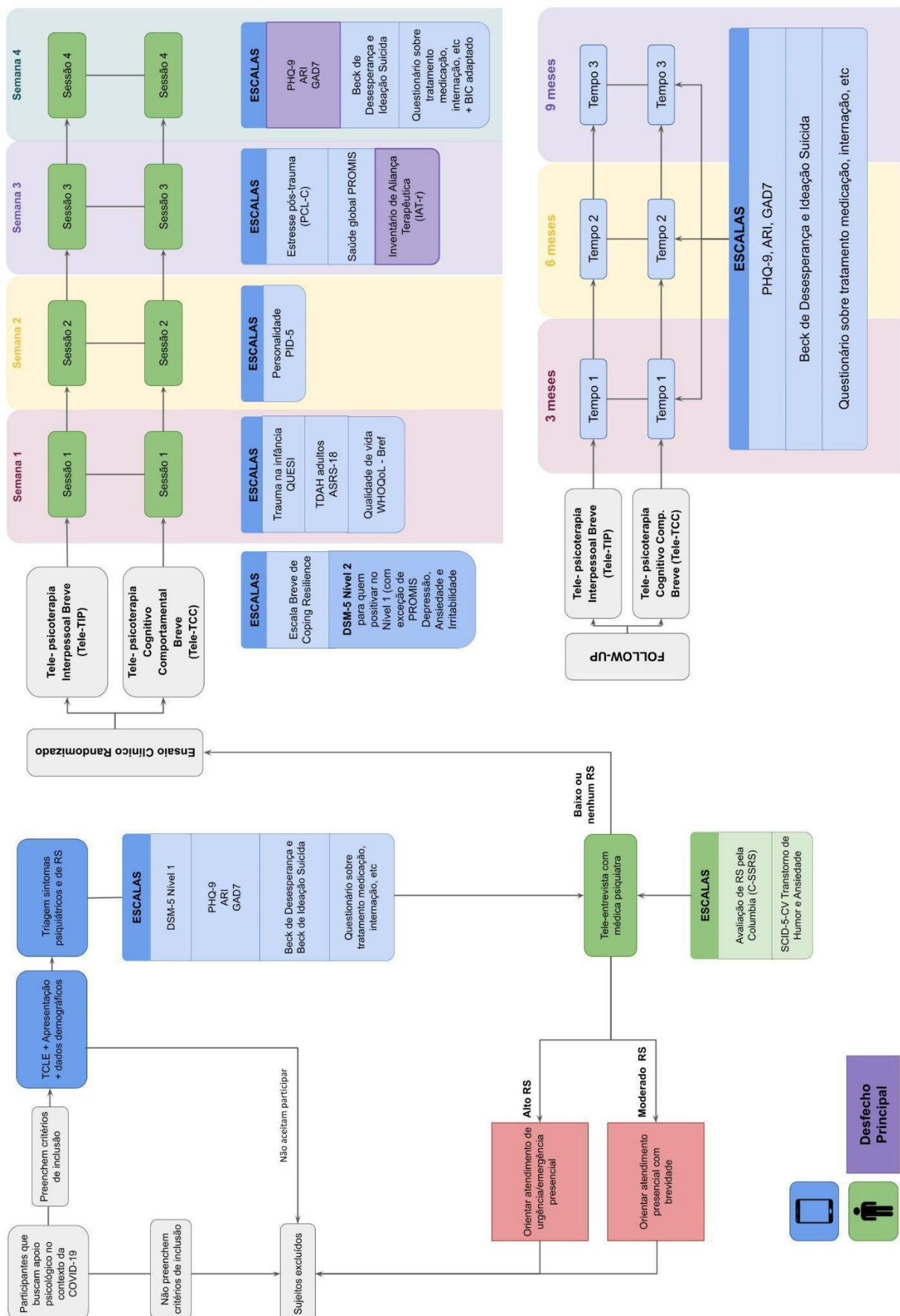


Dados no RS em 2019

- Estado é o segundo com mais casos de morte pela causa no país;
- Faixa etária com mais casos foi entre 40 e 59 anos;
- No ano, Lajeado registrou 15 óbitos. Dados mostram que em cada 100 mil habitantes, 19,01 cometem suicídio;
- A depressão é a causa mais frequente, seguida por problemas de relacionamento e de saúde.

Fonte: Governo do Estado e Instituto Geral de perícias.

ANEXO 2 - Desenho esquemático do estudo guarda-chuva, onde o presente projeto está inserido (destacado com a cor roxo).



ANEXO 3 - Instrumento WAI-s

Nas próximas páginas, você encontrará frases que descrevem o modo como uma pessoa pode pensar ou sentir acerca do seu terapeuta.

Abaixo de cada afirmação existe uma escala de sete pontos:

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

Por exemplo: Se a afirmação descrever o modo como se sente (ou pensa) sempre marque o número 7; se nunca marque o número 1. Use os outros números para descrever variações entre estes dois extremos.

Responda rapidamente, suas primeiras impressões são as mais importantes.

Por favor, não se esqueça de responder todos os itens.

Obrigado por sua colaboração.

1. O(a) meu(a) terapeuta e eu estamos de acordo acerca das coisas que são necessárias fazer em terapia para ajudar a melhorar a minha situação.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

2. O que eu faço na terapia permite-me ver o meu problema de novas formas.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

3. Acho que o(a) meu(a) terapeuta gosta de mim.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

4. O(a) meu(a) terapeuta não percebe aquilo que tento conseguir com a terapia.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

5. Tenho confiança na capacidade de meu(a) terapeuta para me ajudar.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

6. O(a) meu(a) terapeuta e eu trabalhamos para alcançar objetivos que foram mutuamente acordados.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

7. Sinto que o(a) meu(a) terapeuta me aprecia.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

8. Estamos de acordo acerca daquilo em que é importante eu trabalhar.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

9. O(a) meu(a) terapeuta e eu confiamos um no outro.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

10. O(a) meu(a) terapeuta e eu temos ideias diferentes acerca de quais são os meus problemas.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

11. Estabelecemos um bom entendimento quanto às mudanças que seriam boas para mim.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
------------	----------------	-------------------------	---------------	-------------------------	----------------------------------	-------------

12. Acredito que o modo como estamos trabalhando com o meu problema é correto.

1 Nunca	2 Raramente	3 Ocasionalm ente	4 Às vezes	5 Frequentem ente	6 Muito frequentem ente	7 Sempre
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© A. O. Horvath, 1981, 1984;

Versão autorizada para Língua Portuguesa: Paulo Machado e Cristiano Nabuco de Abreu

ANEXO 4 - Instrumento GAD-7

Durante as últimas 2 semanas, com que frequência você foi incomodado/a pelos problemas abaixo?	Nenhuma vez	Vários dias	Mais da metade dos dias	Quase todos os dias
1. Sentir-se nervoso/a, ansioso/a ou muito tenso/a	0	1	2	3
2. Não ser capaz de impedir ou de controlar as preocupações	0	1	2	3
3. Preocupar-se muito com diversas coisas	0	1	2	3
4. Dificuldade para relaxar	0	1	2	3
5. Ficar tão agitado/a que se torna difícil permanecer sentado/a	0	1	2	3
6. Ficar facilmente aborrecido/a ou irritado/a	0	1	2	3
7. Sentir medo como se algo horrível fosse acontecer	0	1	2	3

Somar o escore total. T = _____

Desenvolvido pelos Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke e colegas, com um subsídio educacional da Pfizer Inc.

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ANEXO 5 - Instrumento PHQ-9

Durante as últimas 2 semanas, com que frequência você foi incomodado/a por qualquer um dos problemas abaixo?	Nenhuma vez	Vários dias	Mais da metade dos dias	Quase todos os dias
1. Pouco interesse ou pouco prazer em fazer as coisas	0	1	2	3
2. Se sentir “para baixo”, deprimido/a ou sem perspectiva	0	1	2	3
3. Dificuldade para pegar no sono ou permanecer dormindo, ou dormir mais do que de costume	0	1	2	3
4. Se sentir cansado(a) ou com pouca energia	0	1	2	3
5. Falta de apetite ou comendo demais	0	1	2	3
6. Se sentir mal consigo mesmo (a) — ou achar que você é um fracasso ou que decepcionou sua família ou você mesmo (a)	0	1	2	3
7. Dificuldade para se concentrar nas coisas, como ler o jornal ou ver televisão	0	1	2	3
8. Lentidão para se movimentar ou falar, a ponto das outras pessoas perceberem? Ou o oposto – estar tão agitado(a) ou irrequieto(a) que você fica andando de um lado para o outro muito mais do que de costume	0	1	2	3
9. Pensar em se ferir de alguma maneira ou que seria melhor estar morto (a)	0	1	2	3

Somar o escore total. T = _____

Se você assinalou qualquer um dos problemas, indique o grau de dificuldade que os mesmos lhe causaram para realizar seu trabalho, tomar conta das coisas em casa ou para se relacionar com as pessoas?

☐ Nenhuma dificuldade
 ☐ Alguma dificuldade
 ☐ Muita dificuldade
 ☐ Extrema dificuldade

Desenvolvido pelos Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke e colegas, com um subsídio educacional da Pfizer Inc.

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ANEXO 6 - Instrumento ARI

Instruções: Para cada item, por favor, marque a opção para “Não é verdade”, “Um pouco verdade” ou “Certamente verdade”. Por favor, tente responder todas as questões.

Nos últimos 6 meses, em comparação com outras pessoas, o quanto cada uma das seguintes frases descreve o seu comportamento e os seus sentimentos?	Não é verdade	Um pouco verdade	Certamente verdade
1. Eu me incomodo facilmente com outras pessoas	☐	☐	☐
2. Eu perco a calma frequentemente	☐	☐	☐
3. Eu fico irritado por muito tempo	☐	☐	☐
4. Eu estou irritado na maior parte do tempo	☐	☐	☐
5. Eu me irrito frequentemente	☐	☐	☐
6. Eu perco a calma facilmente	☐	☐	☐
7. De modo geral, minha irritabilidade me causa problemas	☐	☐	☐

ANEXO 7- Comprovante de submissão do artigo 1.

Acta Psychiatrica Scandinavica
Original Article

Synchronous Tele-Interpersonal Psychotherapy versus Tele-Cognitive Behavioral Therapy for adults: which works better? Results from a Randomized Clinical Trial.

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This submission is under consideration and cannot be edited. Further instructions will be emailed to you from ScholarOne.

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