

UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS MÉDICAS: ENDOCRINOLOGIA



TESE DE DOUTORADO

**O IMPACTO DA COVID-19 EM INDIVÍDUOS QUE CONVIVEM COM O
DIABETES MELLITUS: REPERCUSSÕES NA SAÚDE MENTAL E
ESTRATÉGIAS PARA MITIGAÇÃO DO EFEITO DA PANDEMIA.**

JANINE ALESSI

Porto Alegre, Fevereiro de 2022

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Orientadora:

Profª Beatriz D'Agord Schaan, MD, PhD
Hospital de Clínicas de Porto Alegre
Universidade Federal do Rio Grande do Sul

Colaboradora:

Profª Gabriela Heiden Teló, MD, PhD
Hospital São Lucas da PUCRS
Pontifícia Universidade Católica do Rio Grande do Sul

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BANCA EXAMINADORA

Prof. Dr. Marcello Casaccia Bertoluci

Hospital de Clínicas de Porto Alegre

Universidade Federal do Rio Grande do Sul

Doutorado pela Universidade Federal do Rio Grande do Sul

Professor Associado da Universidade Federal do Rio Grande do Sul

Professor Associado do Programa de Pós-graduação em Ciências Médicas da Universidade Federal do Rio Grande do Sul

Prof^a. Dr^a. Melanie Rodacki

Hospital Universitário Clementino Fraga Filho

Universidade Federal do Rio de Janeiro

Pós-doutorado pela Universidade Federal do Rio de Janeiro, Brasil.

Professora Titular da Universidade Federal do Rio de Janeiro.

Prof. Dr. Giovanni Abrahao Salum Junior

Hospital de Clínicas de Porto Alegre

Universidade Federal do Rio Grande do Sul

Pós-doutorado em Psiquiatria pela Universidade Federal do Rio Grande do Sul, Brasil.

Professor Adjunto da Universidade Federal do Rio Grande do Sul

Professor Titular do Programa de Pós-graduação em Psiquiatria da Universidade Federal do Rio Grande do Sul

Prof^a. Dr^a. Ticiania da Costa Rodrigues (suplente)

Hospital de Clínicas de Porto Alegre

Universidade Federal do Rio Grande do Sul

Pós-doutorado pela Universidade do Colorado

Professora Titular da Universidade Federal do Rio Grande do Sul

Professora Titular do Programa de Pós-graduação em Endocrinologia da Universidade Federal do Rio Grande do Sul

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*“Life isn't about waiting for the storm to pass.
It's about learning how to dance in the rain.”
(Vivian Greene)*

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ABREVIATURAS E SIGLAS

A.C	Antes de Cristo
ACE	<i>Angiotensin-converting enzyme</i>
ARB	<i>Angiotensin II receptor blocker</i>
ASA	<i>Acetylsalicylic acid</i>
BMI	<i>Body mass index</i>
B-PAID	<i>Brazilian version of the Problem Areas in Diabetes Scale</i>
CEP	Comitê de Ética em Pesquisa
CI	Confidence interval
CONEP	Comitê Nacional de Ética em Pesquisa
CONSORT	<i>Consolidated Standards of Reporting Trials</i>
COREQ	<i>Consolidated Criteria for Reporting Qualitative Research</i>
COVID-19	Doença do coronavírus 2019
EAT	<i>Eating Attitudes Test</i>
FIPE	Fundo de Incentivo à Pesquisa
HADS	<i>Hospital Anxiety and Depression Scale</i>
HbA1c	Hemoglobina glicada
IC	Intervalo de confiança
IGF	<i>Insulin-like growth factor</i>
IQR	Interquartile range
MSQ	<i>Mini Sleep Questionnaire</i>
Nº	<i>Number</i>
OR	<i>Odds Ratio</i>
PHQ-9	<i>9-item Patient Health Questionnaire</i>
SAE	<i>Strategic Affairs Secretariat of Brazil</i>
SARS-CoV	<i>Severe acute respiratory syndrome coronavirus</i>
SCI-R	<i>Self-care Inventory Revised</i>
SD	<i>Standard Deviation</i>
SPSS	<i>Statistical Package for the Social Sciences</i>
SRI	<i>Serotonin reuptake inhibitors</i>
SRQ	<i>Self Report Questionnaire</i>
STROBE	<i>Strengthening the Reporting of Observational studies in Epidemiology</i>
XV	Quinze

α	Alfa
β	Beta
χ^2	Qui-quadrado

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RESUMO

O diabetes mellitus é uma doença crônica e progressiva, que resulta na dependência de cuidados de saúde contínuos, o que pode resultar em comprometimento das relações interpessoais e sobrecarregar emocionalmente os pacientes que vivem com a doença. Essas condições podem repercutir na saúde mental desses indivíduos, que apresentam prevalência de depressão e ansiedade de duas a quatro vezes maior quando comparados a seus pares sem diabetes. A sobrecarga emocional é também experienciada por aqueles que compartilham a responsabilidade do cuidado: para crianças e adolescentes com diabetes tipo 1, os cuidadores desempenham um papel fundamental no controle da doença, e é sobre eles que recai o sentimento de responsabilidade pelas complicações em curto e longo prazo. A maior vulnerabilidade emocional vivenciada por esses indivíduos é desafiada na medida em que uma pandemia se estabelece, trazendo mudança nas rotinas de atendimento, alterações de hábitos de vida e isolamento social.

Com o objetivo de caracterizar o impacto da pandemia de COVID-19 na saúde mental de pacientes com diabetes, foi realizado estudo transversal para identificar transtornos psiquiátricos após o terceiro mês de instalação da pandemia no Brasil. A avaliação de 120 participantes (52 com diabetes tipo 1 e 68 com diabetes tipo 2) mostrou elevada prevalência de positividade no rastreamento de distúrbios de saúde mental, com quase 43% desses participantes apresentando distúrbios psiquiátricos menores, como depressão e ansiedade. O rastreamento de sofrimento emocional relacionado ao diabetes foi positivo em 29.2% dos participantes, de distúrbios alimentares em 75.8% e de distúrbios do sono em 77.5%.

Considerando que o impacto emocional da pandemia se estende também aos responsáveis pelo cuidado de indivíduos com diabetes tipo 1, um estudo transversal, realizado por meio de inquérito *online* durante a pandemia, comparou a presença de sobrecarga emocional e de distúrbios psiquiátricos menores (depressão e ansiedade) entre cuidadores de crianças e adolescentes com e sem diabetes tipo 1. O estudo incluiu 764 participantes (381 cuidadores de jovens com diabetes e 383, sem diabetes) e mostrou que, no grupo responsável por crianças e adolescentes com diabetes, mais frequentemente se

observou a presença de sofrimento emocional relacionado à pandemia (OR 1,67; 95% IC, 1,10 - 2,53) e relacionado ao cuidado de seu dependente com diabetes (OR 2,28; 95% IC, 1,54 - 3,38) comparado ao grupo sem diabetes, além de mais comumente apresentar positividade no rastreamento de distúrbios psiquiátricos menores (OR 2,43; 95% IC, 1,70 - 3,47). Complementando essa análise, realizou-se um estudo qualitativo avaliando as percepções dos responsáveis por crianças e adolescentes com diabetes tipo 1 sobre como a pandemia afetou suas emoções pessoais e em relação ao cuidado de seu dependente. Os relatos descritos, que incluíram as impressões de 318 cuidadores, refletiram os sentimentos negativos relacionados à mudança de hábitos dos dependentes e a percepção de dificuldade no controle glicêmico durante a pandemia. Além de preocupação e medo sobre a possibilidade de infecção, os cuidadores de crianças frequentemente relataram sentirem-se sobrecarregados e exaustos com a “dupla jornada” que representou o fechamento das escolas e o maior tempo do filho em casa, enquanto os cuidadores de adolescentes discutiram sobre as dificuldades de lidar com a redução das interações sociais nessa fase.

Por fim, dada a importância da conservação de uma boa saúde mental tanto para reduzir os efeitos negativos emocionais, quanto para melhorar a adesão ao tratamento do diabetes, elaborou-se uma proposta de intervenção por meio de teleatendimentos a fim de oferecer acolhimento e continuidade no atendimento às demandas da doença durante a pandemia de COVID-19. Para testar a efetividade da estratégia, realizou-se um ensaio clínico randomizado, incluindo 91 indivíduos com diabetes tipo 2, o qual identificou que a utilização da teleintervenção proposta foi efetiva em reduzir a positividade no rastreamento de distúrbios de saúde mental (depressão e ansiedade) após 16 semanas de acompanhamento (rastreamento positivo em 37,0% dos participantes do grupo intervenção vs. 57,8% no grupo controle ao final do estudo, $P = 0,04$), além de reduzir sofrimento emocional relacionado ao diabetes (21,7% no grupo intervenção vs. 42,2% no grupo controle, $P = 0,03$). Também foi realizado um ensaio clínico randomizado testando a intervenção proposta entre indivíduos com diabetes tipo 1, para o qual foram incluídos 58 pacientes. Nesse grupo, a estratégia não apresentou benefício direto na redução de distúrbios de saúde mental; contudo, os participantes do grupo intervenção mais frequentemente

sentirem-se acolhidos e amparados em seus cuidados com o diabetes durante a pandemia (82,8% no grupo intervenção vs. 48,3% no grupo controle, $P < 0.01$).

Os estudos realizados para a construção desta tese possibilitaram a identificação precoce do impacto em saúde mental da pandemia de COVID-19 em pacientes com diabetes e a elaboração de uma estratégia eficaz para a mitigação desse efeito. Os resultados apresentados preencheram uma lacuna do conhecimento sobre os potenciais benefícios do uso de teleatendimentos no efeito psicopatológico da pandemia, e servem como base para o adequado e oportuno planejamento das equipes de saúde diante de situações semelhantes futuramente.

APRESENTAÇÃO

Este trabalho consiste na tese de doutorado " **O impacto da COVID-19 em indivíduos que convivem com o diabetes mellitus: repercussões na saúde mental e estratégias para mitigação do efeito da pandemia**", apresentado ao Programa de Pós-graduação em Ciências Médicas: Endocrinologia da Universidade Federal do Rio Grande do Sul em 08 de fevereiro de 2022. A descrição do conteúdo foi realizada em três etapas:

1. Introdução

2. Desenvolvimento

a. Artigo 1: *Mental health in the era of COVID-19: prevalence of psychiatric disorders in a cohort of patients with type 1 and type 2 diabetes during the social distancing.*

b. Artigo 2: *Caring for caregivers: the impact of the COVID-19 pandemic on those responsible for children and adolescents with type 1 diabetes.*

c. Artigo 3: *"Not having a minute of self-distancing during the social distancing is exhausting": a qualitative study on the perspective of caregivers of youth with type 1 diabetes during the COVID-19 pandemic.*

d. Artigo 4: *Telehealth strategy to mitigate the negative psychological impact of the COVID-19 pandemic on type 2 diabetes: A randomized controlled trial.*

e. Artigo 5: *Type 1 diabetes and the challenges of emotional support in crisis situations: Results from a randomized clinical trial of a multidisciplinary teleintervention.*

3. Conclusões

INTRODUÇÃO

Diabetes mellitus e saúde mental: do paciente ao cuidador

Desde o batizado da terminologia que caracterizou o diabetes na antiguidade, palavra de origem grega que significa “passar através de” e que simboliza o desconforto relacionado à rápida passagem de líquidos pelo corpo nos pacientes acometidos, reconhece-se as dificuldades experienciadas no enfrentamento e no manejo da doença(1). A composição “mellitus”, do latim “doce como o mel”, foi adicionada posteriormente em referência à urina adocicada que atraía formigas e abelhas, resultado da hiperglicemia que caracteriza o conjunto de distúrbios metabólicos do diabetes mellitus(2,3). A doença, cujos registros mais antigos datam sua identificação já no século XV A.C. no antigo Egito, atinge proporções epidêmicas atualmente, afetando mais de 460 milhões de pessoas no mundo(4,5). No Brasil, estima-se que havia cerca de 16,8 milhões de pessoas com diagnóstico de diabetes tipo 2 no ano de 2019, o que fez do país o quarto em número de indivíduos com esse tipo de diabetes no mundo. Para o diabetes tipo 1, havia aproximadamente 1,1 milhões de indivíduos com este diagnóstico no mesmo ano, refletindo um aumento na incidência anual da doença de aproximadamente 3%. O Brasil configura, atualmente, o terceiro país com maior incidência e prevalência de diabetes tipo 1 (aproximadamente 7,3 casos novos por mil habitantes)(5).

O diabetes tipo 1 e o diabetes tipo 2 são doenças heterogêneas que apresentam patogênese e história natural distintas. O diabetes tipo 2, cuja prevalência corresponde a 90-95% de todos os tipos de diabetes, acomete majoritariamente indivíduos com sobrepeso ou obesidade, condições que por si só provocam algum grau de resistência à insulina, além daquele inerente aos indivíduos predispostos. À resistência insulínica se associam graus variados de disfunção das células β pancreáticas, resultando em hiperglicemia e graus variados de sintomas, desde quadros assintomáticos. O risco desse tipo de diabetes aumenta com a idade, com a presença de obesidade e com a falta de atividade física, além de estar associado à história familiar positiva(2,3). Muitos dos pacientes com esse tipo de diabetes apresentarão bom controle da doença apenas com medicamentos administrados oralmente, especialmente nos

primeiros anos após o diagnóstico, mas a perda de função das células β pancreáticas é progressiva, levando ao uso de insulina na maioria deles, para atingir controle glicêmico.

O diabetes tipo 1, por sua vez, caracteriza-se pela destruição autoimune das células β pancreáticas, ocasionando deficiência completa na produção de insulina. O seu diagnóstico ocorre geralmente em crianças, adolescentes e adultos jovens(2), apesar de as evidências atuais apontarem que esse paradigma nem sempre é verdadeiro. Pacientes com esse tipo de diabetes necessitam de reposição insulínica por toda a vida. As formulações de insulina tradicionalmente utilizadas são de aplicação subcutânea, que pode provocar desconforto e ser um impeditivo à adesão adequada. Todavia, o uso correto das medicações é fundamental, considerando que tanto o uso excessivo, levando à hipoglicemia, quanto o uso irregular, sem proporcionar a correção adequada da hiperglicemia, são prejudiciais aos pacientes em longo prazo(6). O controle da doença e a prevenção do surgimento de complicações crônicas são o resultado direto do tratamento adequado e de cuidados dietéticos específicos, condições que exigem disciplina e autocuidado por toda a vida(2,6).

Academicamente, o estudo e o cuidado do diabetes frequentemente são abordados por uma perspectiva glicocêntrica, a qual falha em transmitir a complexidade dos desafios que a doença carrega. Além de demandas financeiras relacionadas ao tratamento e ao acompanhamento regular, a dependência de cuidados de saúde contínuos pode resultar em comprometimento das relações interpessoais e sobrecarregar emocionalmente esses indivíduos(7). Neste cenário, a saúde mental representa o ponto de confluência, sendo a manifestação clínica das situações que podem levar ao esgotamento sob a forma de psicopatologias.

As repercussões psicológicas no paciente que convive com o diabetes podem se apresentar em diferentes magnitudes. Na primeira ponta do espectro, o sofrimento emocional relacionado ao diabetes constitui a manifestação central da sobrecarga associada às demandas da doença(8). Conceitualmente, esse diagnóstico traduz a presença de preocupações, inseguranças e medos que acompanham as dificuldades de conviver com o diabetes cronicamente, incluindo aspectos relacionados ao manejo, ao risco de complicações crônicas e de potencial perda de funcionalidade, e as preocupações sobre acesso à

saúde(9). Os gatilhos para o sofrimento emocional relacionado ao diabetes diferem entre os pacientes com diabetes tipo 1 e diabetes tipo 2, assim como as demandas e características de cada um desses tipos de diabetes apresentam as suas particularidades(8,10). Nessa linha, os estudos mostram que até 43% dos adultos com diabetes tipo 1 apresentam algum grau de sofrimento emocional, o qual parece estar diretamente associado à duração do diabetes e ao controle glicêmico(8). Por outro lado, pouco mais de 30% daqueles que convivem com o diabetes tipo 2 apresentarão esses sintomas ao longo da vida(11).

Na outra extremidade do espectro, os distúrbios psiquiátricos propriamente ditos correspondem às formas mais graves, e incluem principalmente os transtornos afetivos e os transtornos alimentares. Estudos mostram que mais de um terço dos pacientes com diabetes enfrenta algum transtorno de saúde mental, incluindo depressão, ansiedade ou distúrbios alimentares(12–14). Quando comparados a seus pares sem diabetes, a prevalência de depressão e ansiedade chega a ser de duas a quatro vezes maior entre aqueles que vivem com a doença(15,16). No Brasil, cerca de 22% dos pacientes com diabetes tipo 2 e mais de 20% dos pacientes com diabetes tipo 1 apresentam rastreamento positivo para depressão segundo casuísticas recentes(17,18). A concomitância de diabetes e distúrbios psiquiátricos menores aumenta as taxas de não-adesão ao tratamento tanto no diabetes tipo 1, quanto no diabetes tipo 2, impactando negativamente no controle glicêmico desses indivíduos(19). Além do impacto direto na adesão medicamentosa e no controle da doença, a associação de depressão e diabetes aumenta o risco de complicações crônicas e triplica o risco de morbimortalidade geral(20).

A sobrecarga emocional que envolve o enfrentamento e o manejo do diabetes afeta, assim como os indivíduos acometidos pela doença, também aqueles que compartilham a responsabilidade do cuidado destas pessoas. Essa demanda é particularmente expressiva entre os responsáveis pelo cuidado de crianças e adolescentes com diabetes tipo 1, fases em que frequentemente os pacientes ainda não possuem autonomia para o autogerenciamento da doença e em que apresentam irregularidades alimentares e frequência imprevisível de atividade física, típicos dessa faixa etária(21). Dessa forma, os cuidadores desempenham não só um papel fundamental no controle da doença, como

também sentem-se responsáveis pelas consequências em curto e longo prazo, como a ocorrência de hipoglicemia, de complicações futuras e do impacto que isso terá na qualidade de vida do seu filho(22).

Além da responsabilidade pelo controle glicêmico ótimo, os pais também sofrem com a preocupação constante sobre o cuidado de seus dependentes durante os períodos de afastamento. A dificuldade em encontrar alguém de confiança e habituado com as demandas de um paciente com diabetes tipo 1 também dificulta o compartilhamento do cuidado, tornando o papel dos pais um trabalho em tempo integral(23). Neste cenário, reflete-se a necessidade de preparar essas famílias para lidar positivamente com a natureza crônica e progressiva da doença, e de identificar precocemente a presença de sinais de sofrimento psicológico. Reconhecer e lidar com a sobrecarga emocional de cuidadores de crianças e adolescentes com diabetes permite, não apenas intervir na qualidade de vida dos pais, mas também fornecer a eles o suporte e as ferramentas necessárias para o cuidado ótimo de seu filho e para a manutenção de atitudes mais positivas no ambiente familiar(23,24).

As repercussões em saúde mental, que apresentam prevalência similar às complicações diretas da doença, frequentemente são negligenciadas no cuidado dos pacientes com diabetes e de seus cuidadores. Além do impacto direto no controle do diabetes, a presença de psicopatologias está associada a menor motivação e pior qualidade de vida, constituindo fatores determinantes para a saúde e o bem-estar nessa população(20,25,26). Tudo isso reforça a importância de uma mudança de paradigmas na prestação do cuidado ao paciente com diabetes e seus familiares, ampliando os limites da abordagem tradicionalmente glicocêntrica e promovendo a compreensão integral dos domínios psicobiológicos da doença.

Diabetes mellitus e pandemia de COVID-19: uma dupla batalha

A pandemia de COVID-19 é o resultado da rápida disseminação internacional do coronavírus (SARS-CoV-2), agente causador da doença(27). Em meados de novembro de 2021, mais de 250 milhões de casos e mais de 5 milhões de mortes relacionadas à COVID-19 haviam sido documentadas no mundo, tornando essa uma das pandemias mais expressivas da história(8,28,29). Nesse cenário já desolador, o Brasil despontou como um dos

epicentros da pandemia, alcançando a marca de 610 mil mortes registradas pela doença no mesmo período(29,30). Cerca de 20 meses após a chegada do SARS-CoV-2 no Brasil, e após quase 60% da população ter sido vacinada, o país ainda experencia uma significativa crise econômica, política e social, situações que reverberam em sua população(31,32).

A luta contra a COVID-19 representou uma batalha ainda mais desafiadora para os indivíduos que apresentam doenças crônicas, como o diabetes, e interferiu em diferentes esferas do autocuidado. Primeiro, em qualquer situação de desastre biológico, temas como medo, incerteza e estigmatização são comuns e podem atuar como barreiras às intervenções médicas e de saúde mental apropriadas. Desde o início da pandemia de COVID-19, o diabetes foi associado a piores desfechos clínicos(33,34). Dessa forma, conviver com a ameaça de uma infecção potencialmente grave e fazer parte do grupo de maior risco para a doença pode despertar sentimentos de preocupação e ansiedade, tornando esses pacientes mais vulneráveis a transtornos de saúde mental nesse período(35). Segundo, a transferência de recursos para o combate à pandemia, as medidas de distanciamento social e a suspensão de consultas eletivas nos períodos de maior transmissibilidade de COVID-19 interromperam o fluxo de cuidado desses pacientes, podendo gerar angústia em relação ao impacto dessas mudanças no controle da doença(36). Terceiro, a mudança de rotina que acompanhou a pandemia de COVID-19 proporcionou hábitos mais sedentários e um padrão alimentar de pior qualidade, provocando sofrimento e preocupação em relação aos efeitos no peso e no cuidado com o diabetes(36,37). Esses desafios podem influenciar negativamente no bem-estar mental, na atitude frente à doença e na adesão ao tratamento, podendo gerar consequências negativas em curto e longo prazo.

A mudança na dinâmica familiar que ocorreu desde o início da pandemia também tem o potencial de impactar os responsáveis pelo cuidado de crianças e adolescentes com diabetes tipo 1. Muitos desses cuidadores necessitaram manter interações sociais e laborais no período, e a preocupação com a possibilidade de transmitir uma infecção potencialmente grave para a criança constitui, por si só, uma situação geradora de estresse(38). As repercussões financeiras, experienciadas por muitas famílias no período, podem resultar em dificuldade para a aquisição de insumos para o tratamento adequado do

diabetes, gerando o sentimento de “falha” como provedores. Não menos importante, a mudança das rotinas escolares para o modelo virtual e a suspensão de atividades extracurriculares durante a pandemia resultam em um maior tempo dessas crianças e adolescentes em casa, demandando atenção dobrada pelos seus cuidadores(39). Adicionalmente, o fechamento de parques e clubes de recreação resultam na adoção de hábitos mais sedentários e, conseqüentemente, em um menor gasto energético diário(40). Atividades restritas ao domicílio também propiciam alteração dos hábitos alimentares, com lanches mais frequentes e menos saudáveis(39). Tudo isso altera as demandas de insulina e pode provocar mudanças significativas no controle glicêmico das crianças e adolescentes com diabetes tipo 1, o que pode desencadear ainda mais preocupação e ansiedade nos responsáveis pelo seu cuidado.

A simbolização da pandemia como um desafio para a manutenção dos cuidados usuais do diabetes e como uma ameaça potencialmente grave para esses indivíduos a tornam gatilho para a incidência de distúrbios de saúde mental. Já nos primeiros meses de pandemia, estudos demonstravam seus potenciais efeitos psicopatogênicos na população geral, especialmente relacionados às medidas de distanciamento e ao isolamento social. A prevalência de depressão, que em situações usuais é estimada em menos de 5% da população geral, ultrapassou 23% em diferentes casuísticas, e a prevalência de ansiedade chegou a atingir 45% da população(41,42). Ademais, pensamentos repetitivos sobre a pandemia, distúrbios do sono e sobrecarga emocional são relatados com frequência(43,44). Soma-se um contexto potencialmente depressogênico a um grupo previamente vulnerável a distúrbios emocionais, como representado pelos pacientes com diabetes e seus cuidadores, e se obtém os elementos necessários para um iminente colapso psíquico.

Teleatendimento em situações de crise: uma luz no fim do túnel?

As estratégias de teleatendimento foram utilizadas de modo complementar à prática clínica presencial nas últimas duas décadas. Por definição, o teleatendimento é conhecido como a prática dos atendimentos médicos e não-médicos oferecidos à distância e aplicada por meio de uma interface eletrônica. Essa modalidade de atendimento foi desenvolvida no início

dos anos 90 a fim de promover maior acessibilidade e conveniência à oferta de cuidados(45). A procura por métodos complementares às estratégias tradicionais surgiu motivada pelas evidências de que, apesar de ser uma das doenças crônicas mais onerosas ao sistema de saúde, os pacientes que vivem com o diabetes frequentemente sentem-se insatisfeitos com os cuidados que recebem, sentimento especialmente relacionado à dificuldade no acesso oportuno ao atendimento de demandas imediatas da doença(46,47).

Em situações usuais, estudos avaliando a utilização de teleatendimentos demonstraram benefício limitado no controle do diabetes(45). Uma metanálise recente de 111 ensaios clínicos randomizados, incluindo tanto pacientes com diabetes tipo 1 e diabetes tipo 2, mostrou que a utilização sincrônica de teleatendimentos e rotina usual de atendimento apresenta resultados modestos na melhora do controle glicêmico, associando-se à redução na hemoglobina glicada (HbA1c) de -0,57% (-0.74 a -0.40) após 3 meses de acompanhamento(48). Contudo, a falta de um protocolo específico de teleatendimento e a heterogeneidade das intervenções realizadas contribui para as divergências dos resultados encontrados entre os estudos incluídos, o que dificulta a mensuração da real efetividade de tele-estratégias educativas e assistenciais bem delineadas e aplicadas.

Se, por um lado, o teleatendimento falha em fornecer benefícios robustos no controle glicêmico de pacientes com diabetes, por outro, trata-se de um potencial aliado para mitigar psicopatologias nesses indivíduos. Estudos prévios mostram que a prática de teleatendimentos concomitante ao cuidado usual apresenta o potencial de aumentar o acesso aos cuidados de saúde, reduzindo episódios de hipoglicemia grave e resultando em maior satisfação com o cuidado e melhor qualidade de vida nesses pacientes(49). Além disso, uma meta-análise realizada por Harkness *et al.*, demonstrou que, em situações de maior vulnerabilidade emocional, intervenções que proporcionam escuta qualificada e suporte psicossocial melhoram significativamente o nível de saúde mental em pacientes com diabetes(50). Tais benefícios são particularmente atraentes em um contexto de pandemia, em que o acesso à saúde é dificultado e em que os distúrbios de saúde mental se encontram exacerbados.

A pandemia de COVID-19 reforçou a importância da implementação e da regularização de protocolos que viabilizem a utilização de teleatendimentos na prática eletiva, especialmente reduzindo risco de contaminação pelo contato próximo com outros pacientes em centros de saúde, e promovendo acessibilidade multiprofissional. Apesar das expectativas otimistas, deve-se levar em conta que a prática ainda é recém-chegada em muitos meios: no Brasil, por exemplo, a regularização para a realização de teleatendimento aconteceu em março de 2020 e acompanhou a chegada abrupta da COVID-19 (51), o que reflete na presença de protocolos e rotinas assistenciais ainda frágeis nesse quesito. Acompanhando as questões éticas e legais que ainda rondam o tema, a falta de evidências sólidas sobre os benefícios clínicos dessas estratégias em situações de crise e a aplicabilidade em população de média e baixa renda ainda são lacunas que dificultam sua implementação em larga escala. Assim, considera-se a atual pandemia como a mola propulsora para a realização de estudos sobre o tema, visando a avaliação e documentação da efetividade do teleatendimento em grupos específicos e a sensibilização dos profissionais envolvidos no cuidado desses pacientes sobre as vantagens de sua utilização, situações que espelham uma fagulha de esperança em tempos sombrios.

Baseado no aqui disposto, os objetivos desta tese são (1) caracterizar o impacto da pandemia em aspectos de saúde mental de pacientes com diabetes mellitus; (2) caracterizar o impacto da pandemia em cuidadores de crianças e adolescentes com diabetes mellitus tipo 1; (3) avaliar a efetividade de estratégias de teleatendimento multidisciplinares para mitigar o efeito da pandemia na saúde mental de indivíduos com diabetes mellitus tipo 1 e diabetes mellitus tipo 2.

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ARTIGO 1

Mental health in the Era of COVID-19: Prevalence of Psychiatric Disorders in a Cohort of Patients with Type 1 and Type 2 Diabetes during the Social Distancing

Mental health and diabetes in COVID-19

Janine Alessi, MD^{1,2}; Giovana Berger de Oliveira³; Débora Wilke Franco, BSEd³; Bibiana Amaral³; Alice Scalzilli Becker; Carolina Padilla Knijnik³; Gabriel Luiz Kobe³ Taíse Rosa de Carvalho, MD⁴; Guilherme Heiden Telo, MD, MSc⁴; Beatriz D. Schaan, MD PhD^{1,5,6}; Gabriela Heiden Telo, MD PhD^{2,3,4}

1. Post-Graduate Program in Medical Science: Endocrinology, Universidade Federal do Rio Grande do Sul, Brazil
2. Internal Medicine Department, Hospital São Lucas - Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
3. School of Medicine, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
4. Post-Graduate Program in Medicine and Health Sciences, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
5. School of Medicine, Universidade Federal do Rio Grande do Sul, Brazil
6. Endocrinology division, Hospital de Clínicas de Porto Alegre, Brazil

ABSTRACT

BACKGROUND: In patients with diabetes, the prevalence of depression and anxiety symptoms is about two to four times greater than in the general population. The association between diabetes and mental health disorders could be exacerbated in a stressful environment, and psychological distress could increase depressive symptoms and cause adverse diabetes outcomes.

OBJECTIVES: To assess the prevalence of mental health disorders in patients with diabetes during the social distancing period due to COVID-19 pandemic.

METHODS: This is a cross-sectional study developed to assess the impact of social distancing on a cohort of adults with type 1 (n=52) and type 2 diabetes (n=68) in Brazil. Inclusion criteria involved having an HbA1c test collected in the past three months and having a valid telephone number in electronic medical records. The primary outcome was the prevalence of minor psychiatric disorders, assessed by survey (SRQ-20). Secondary outcomes included the prevalence of diabetes related emotional distress, eating and sleeping disorders, all assessed by validated surveys at the moment of the study. Statistical analyses included unpaired *t*-test for continuous variables and χ^2 test for categorical variables.

RESULTS: Overall (n=120), participants had a mean age of 54.8 ± 14.4 years-old, and HbA1c of $9.0 \pm 1.6\%$ (75 ± 17.5 mmol/mol); 93% of patients showed signs of current mental suffering based on the surveys measured. Almost 43% of patients showed evidence of significant psychological distress, with a significant greater tendency in patients with type 2 diabetes. The presence of diabetes related emotional distress was found in 29.2% of patients; eating disorders in 75.8%; and moderate/severe sleeping disorders in 77.5%.

CONCLUSIONS: We found a high prevalence of evidence of psychological distress among patients with diabetes during the COVID-19 pandemic and this highlights the need for mental health access and support for patients with type 1 and type 2 diabetes.

Key words: diabetes mellitus; mental health; COVID-19 pandemic; social distancing; quarantine.

INTRODUCTION

Diabetes mellitus and psychiatric disorders share a mutual interface: the challenge of living and overcoming diabetes may result in emotional overload, and the presence of depression and anxiety symptoms may be associated with lower treatment adherence, leading to worse glycemic control (1,2). In patients with diabetes, the prevalence of depression and anxiety symptoms is about two to four times greater than in the general population (3,4). Although more research is needed to fully understand the link between diabetes and depression, it is clear that metabolic dysregulation influences brain function and disturbances in peripheral glucose regulation might be associated with depressed mood (5,6). Some cases of depression might result from low levels of insulin-like growth factor (IGF) into the brain, which was shown to produce antidepressant behavioural responses in experimental studies (6-8). Nutrient-activated gut to brain signaling pathways also appear to play a role in the genesis of depressive symptoms. A highly significant association between leptin levels, depressed mood and sleep disturbances has been shown in normal-weight individuals (6,9). Also, ghrelin can exert antidepressant effects in men and carbohydrates appear to lead to ghrelin suppression (6,10,11) This association between diabetes and mental health disorders could be exacerbated in a stressful environment, and psychological distress could increase depressive symptoms and cause adverse diabetes outcomes (12,13).

The emergence of a potentially fatal pandemic represents a new reason for uncertainty and anxiety in this group of patients. Since December 2019, when a series of cases of severe pneumonia caused by a new coronavirus was described in Wuhan - China, the COVID-19 infection, as it became known, quickly spread throughout the world (14-16). On Jul 07th, more than 11 million and 600 thousand confirmed cases have been identified worldwide, totaling 538 thousand deaths (17). The first case of someone suffering from COVID-19 in South America was confirmed on February 26th, 2020 in São Paulo, Brazil. Since then, Brazil has recorded the largest number of cases in Latin America and recently has emerged as a new epicenter of the pandemic in the world (18).

A number of measures have been taken to prevent the spread of COVID-19, involving the isolation of suspected cases, tracking and monitoring of

contacts, and dissemination of regional and national information, which included the recommendation of social distancing, especially for high risk groups such as patients with diabetes (19). The social distancing recommendation have a psychological effect even in patients without diabetes, as shown by Talevi *et al.* (20). In this review, the authors report that up to 53.8% of people experienced psychological distress during the initial stage of the COVID-19 outbreak. A range of negative psychological responses were identified, such as anxiety, depression, insomnia and worries about individuals' own health and family. The levels of stress, anxiety and depression ranged from mild to moderate-severe (20-24). Among patients with confirmed infection, findings show that nearly 50% of people diagnosed with COVID-19 had depressive symptoms, over 55% had anxiety and almost 70% had somatic symptoms (20, 25).]

The psychological repercussion of the current scenario in patients with diabetes is still hypothetical. It is well known that those patients, due to the conditions of the underlying disease, already have a greater tendency to develop psychiatric disorders throughout life. It is possible that the COVID-19 pandemic, as well as the social isolation determined by it, may interfere with parameters of mental health in patients with diabetes. The present study aimed to investigate the impact of the current pandemic on the prevalence of mental health disorders in patients with type 1 and type 2 diabetes.

METHODS

Study Design and Setting

This is a cross-sectional study developed to assess the prevalence of mental health disorders in a cohort of patients living with diabetes during the social distancing period due to COVID-19 pandemic. Electronic medical records were used to select patients with diabetes in a follow-up at the Endocrinology department of a public hospital in Southern Brazil. Patients who met the inclusion criteria received a telephone call for an invitation and application of the informed consent form (by electronic means or audio recording). Participants who agreed to participate in this study received a second phone call for data capture. All the study procedures started one month after the disclosure of the national ordinance that standardizes the social distancing recommendation for risk groups, including diabetes, in Brazil. At the time of the evaluation, the state of Rio Grande do Sul

followed the *Contingency Plan and State Action for the Prevention of the Human Infection COVID-19*, which restricted the functioning of establishments that offer essential services and which regulated the indication of an exceptional teleworking regime for people with respiratory diseases, immunosuppressed or with chronic disease, upon medical recommendation. All data were collected in eight days in order to have the same pandemic time for all participants. All contacts were made by telephone by trained researchers in order to preserve participants from social exposure. All data collected during the phone calls were recorded directly on an electronic database validated by the study staff.

Participants

Patients with type 1 and type 2 diabetes in a regular follow-up at the Endocrinology outpatient clinic, who attended a medical appointment in a one-year period, for type 2 diabetes, and three-year period for type 1 diabetes (from 2016 to 2019), were identified in an electronic database. Inclusion criteria involved age ≥ 18 years old; an hemoglobin A1c (HbA1c) test collected between January and March 2020 at the hospital laboratory; and having a valid telephone number in the electronic medical record. Patients who had any physical or cognitive impairment that prevented the application of the study questionnaires (such as dementia and severe hearing impairment), as well as patients who were hospitalized at the time of the study, were excluded.

Variables and Data Sources

The primary outcome assessed was the prevalence of minor psychiatric disorders among patients with type 1 and type 2 diabetes. Secondary outcomes included the prevalence of diabetes-related emotional distress, eating disorders and sleeping disorders at the moment of the study.

For the assessment of psychological distress, such as anxiety and depression, the Brazilian validated version of the *Self Report Questionnaire - 20* (SRQ 20) was used (26, 27). This 20-item questionnaire addresses questions related to pain and problems that may have bothered the patient in the past 30 days, asking yes or no questions. A positive screening for minor psychiatric disorders was considered when the survey scored greater than or equal to 7, which was considered a sign of current mental suffering.

Diabetes-related emotional distress was assessed by the Brazilian validated version of the Problem Areas in Diabetes Scale (B-PAID), which is a 20-item questionnaire that contemplates the patient's perspective on the impact of certain issues related to diabetes on a 4-point response scale, with responses ranging from 0 = "it is not a problem" to 4 = "it is a serious problem". The scores for each item were summed up, and then multiplied by 1.25 to generate a total score out of 100. Severe diabetes emotional distress was considered present when the score was greater than or equal to 40 (28, 29).

The prevalence of eating disorders was assessed by the Brazilian validated version of the Eating Attitudes Test (EAT - 26). This survey addresses 26 issues related to eating habits and attitudes on a 3-point response scale, with responses ranging from 0 = "never" to 3 = "always". The presence of a significant eating disorder was considered when the score was greater than or equal to 20 (30, 31).

To assess sleep disorders, the Brazilian version of the Mini Sleep Questionnaire (MSQ), a 10-item scale, was used on a 7-point response scale, with responses ranging from 1 = "never" to 7 = "always". A sleep disorder (moderate or severe) was considered when a score greater than or equal to 28 was present (32, 33).

It should be noted that the scales used to assess mental health disorders were designed for self-application. The fact that those scales were applied by telephone contact could be a potential source of bias. To minimize this effect, the researchers strictly followed the steps of the questionnaires, repeating the alternative answers to each question only when requested to be as accurate as possible.

Demographics and clinical data, such as the presence of comorbidities, continuous use medications, weight and height – obtained from the last visit for calculating the body mass index (BMI) –, and HbA1c (high-performance liquid chromatography method) data from the last three months were collected from electronic medical records. Cardiovascular disease was considered present if there was a previous history of coronary heart disease, stroke, or heart failure registered in medical records. The presence of diabetes complications was also documented according to medical records. The presence of retinopathy was

considered based on the last registered fundus examination. For neuropathy, it was considered the presence of a documented diagnosis of previous neuropathy or a monofilament 10 g test altered in the last medical appointment. For diabetic kidney disease, it was considered the presence of microalbuminuria or chronic kidney disease in which the etiology was attributed to diabetes in the medical records.

Some clinical data, such as the use of antidepressant or anxiolytic drugs and previous diagnosis of psychiatric disorders, were obtained from both electronic medical records and checked directly with the patients during the phone calls. Previous diagnosis of common mental disorder was considered if there was a previous or current diagnosis of depressive episode, major depressive disorder or anxiety disorders. Compliance with the recommendation of social distance was questioned directly to the participants according to the follow: (1) total social distancing was considered when the patient did not leave the house under any circumstances; (2) partial social distancing was considered when the patient left the house only for basic activities (such as going to the market and pharmacy); or (3) no social distancing, when the patient maintained regular activities.

The institutional ethics committee approved the study protocol (number 4.029.368), and all authors signed the confidentiality document for data use.

Sample Size

The sample size was calculated for a prevalence survey with finite population correction. Considering that the prevalence of anxiety and depression disorders among patients with type 1 was 17.6% and type 2 diabetes was 16%, we considered a mean prevalence known of 17%. The calculation was performed taking into account that in 2019 there were 16.8 million individuals with diabetes in Brazil. The number required for an analysis with 5% accuracy and 85% confidence level was 117 patients (4,34,35). The limitations imposed by the current pandemic and the recommendation of social distancing to patients with diabetes added difficulty in approaching and contacting a greater number of patients, which motivated the choice of the 85% confidence level.

Statistical Methods

Analyses were performed using SPSS Statistics 20. Descriptive data are presented as mean and standard deviation (SD) or percentages. The data distribution was analyzed and, since it had a normal distribution, parametric tests were used. In order to evaluate possible differences according to diabetes type, statistical analyses included unpaired *t*-test for continuous variables and χ^2 test for categorical variables. The primary outcome (minor psychiatric disorders) was then evaluated as the dependent variable in a multivariable logistic regression model designed to control for possible confounders in the interaction between the primary outcome and the diabetes type. An α level of ≤ 0.05 was used to determine statistical significance. This study followed the STROBE statement for the reporting.

RESULTS

Participant characteristics

A total of 245 potentially eligible patients were identified, and 146 were randomly recruited to participate in the study. The recruitment stopped after inclusion of the planned sample size, when 120 individuals, 52 with type 1 and 68 with type 2 diabetes, agreed to participate and provided informed consent (see supplementary figure 1). Age, sex, diabetes duration, and HbA1c levels did not differ by enrollment status (data not shown).

Overall ($n = 120$), participants had a mean age of 54.8 ± 14.4 years old; 55.8% were female, 85.8% white and 76.7% overweight/obese. The mean diabetes duration was 21.8 ± 10.9 years and the HbA1c value was $9.0 \pm 1.6\%$ (75 ± 17.5 mmol/mol) (see table 1). Patients with type 2 diabetes were older (62.3 ± 9.1 vs. 45.0 ± 14.2 years of age; $p < 0.001$), had a greater racial representation (22.1% vs. 3.8% not white; $p = 0.02$) and a higher prevalence of overweight and obesity (95.6% vs. 51.9%; $p < 0.001$), when compared with patients with type 1 diabetes. Although younger, type 1 diabetes patients had a longer diabetes duration (25.2 ± 11.5 vs. 19.2 ± 9.7 years; $p < 0.01$). Both groups were comparable with respect to HbA1c levels and presence of diabetes complications.

From the whole group, 9 patients (7 type 1, and 3 type 2 diabetes) had some previous serious psychiatric diagnosis, which were not considered as common mental disorders in analysis. Among patients with type 1 diabetes, 3 had a diagnosis of schizophrenia; 1 bipolar mood disorder; 1 borderline personality disorder; and 1 self-mutilation history. Among patients with type 2 diabetes, 1 patient had a previous diagnosis of schizophrenia and 1 had a diagnosis of obsessive-compulsive disorder. There was no difference between type 1 and type 2 diabetes regarding the presence of previous common mental disorders. Regarding social distancing, in total, 42.5% of patients were following the guidance of total isolation, 50% were on partial social distancing (leaving home only for basic activities) and only 7.5% were not on doing any type of social distancing (keeping regular daily activities). There was no difference between groups with regard to social distancing.

Survey results

In the studied participants, 93.3% (94.2% in type 1 and 92.6% in type 2 diabetes, $p = 0.73$) had some sign of a psychiatric disorder, which was assessed by a positive screening in at least one of all the specific scales measured in this study (minor psychiatric disorders, diabetes-related emotional distress, and eating and sleeping disorders).

Regarding the primary outcome, the presence of psychological distress, that measure depressive and anxiety symptoms, 44.2% of patients had a positive screening based on the SRQ 20 (see figure 1). In the type 1 diabetes group, this prevalence was 32.7%, while in the group with type 2 diabetes, the prevalence of psychological distress was higher, 52.9% ($p = 0.03$). The question number 17 of the SRQ 20 (“*has the thought of ending your life been on your mind*”) addresses suicidal ideation, and, overall, 6.7% of patients had a positive response to this item. Also, considering all the demographic and clinical differences between type 1 and type 2 diabetes patients showed in table 1, we performed a multivariable logistic regression to evaluate the impact of variables of clinical interest on the interaction between the primary outcome (minor psychiatric disorders) and the type of diabetes (see table 2). We included into the model; age, sex, race/ethnicity, age of diabetes diagnosis, HbA1c, BMI, previous common mental disorders, and social distancing. The adjusted Odds Ratio and its 95% confidence

interval for the interaction between minor psychiatric disorders and type 2 diabetes was 7.60 (1.97 – 29.34).

Secondary outcomes included the prevalence of diabetes-related emotional distress, eating disorders and sleeping disorders. The presence of diabetes-related emotional distress was found in 29.2% of patients; eating disorders in 75.8%; and moderate/severe sleeping disorders in 77.5% of patients (figure 1). There was no significant difference in these outcomes between patients with type 1 and type 2 diabetes. In the type 1 diabetes group, the prevalence of diabetes-related emotional distress was 28.8% vs. 29.4% in the type 2 diabetes group ($p = 0.95$). For the eating disorders evaluation, 78.8% of patients with type 1 diabetes showed a positive screening for eating disorders vs. 73.5% of those living with type 2 diabetes ($p = 0.50$). In the analysis of sleep pattern, 76.9% of patients with type 1 diabetes showed signs of moderate/severe sleep disorder vs. 77.9% of those living with type 2 diabetes ($p = 0.89$). We also performed a multivariable logistic regression to evaluate the impact of BMI on the interaction between the positive screening for eating and sleeping disorders and the type of diabetes, and no significant interaction was identified (data not shown).

DISCUSSION AND CONCLUSIONS

In this study, we sought to investigate psychological characteristics of people living with diabetes after one month of social distancing recommendations in Brazil. We found a high prevalence of significant psychological distress among patients with type 1 and type 2 diabetes, with approximately 93% of the studied patients showing signs of current mental suffering in some psychological specific area. Almost half of the patients had a positive screening for psychological distress, such as anxiety and depression, with a significant greater tendency in patients with type 2 diabetes. The presence of diabetes-related emotional distress was present in only 29.2% of the interviewees, which does not appear to directly justify the high prevalence of psychiatric disorders found in this study. Approximately three out of four patients had a positive screening for eating and sleeping disorders, which may reflect the systemic repercussion of a latent anxiety condition.

It is well documented that depression and anxiety are more prevalent among patients with diabetes when compared to general population (36-38). An epidemiological study by Meurs *et al.* evaluating more than 90,000 patients found an 80% increased risk of depression and anxiety in patients with diabetes (36). The data described in the literature shows a co-prevalence of diabetes and depression ranging from 17.6 to 21% (39,40). In Brazil, the prevalence of depression in patients with diabetes, in usual situations, appears to be similar to that found in other countries, reaching 22% in the most recently published study (41). Considering the current scenario, a study by Huang *et al.* in China showed a prevalence of anxiety and depression in the general population of 35% and 20%, respectively (42). This makes us reflect about the possible impact that one month of social distancing, associated with all the stressors related to the current pandemic, has on this group of patients. Health appointments not fully available, difficulties in obtaining diabetes medications and supplies, besides the lack of scientific information regarding the real relationship between COVID-19 and diabetes, may have contributed to the high prevalence of psychological distress found in this study. The possible vulnerability intrinsic to diabetes seems to be exacerbated in the current scenario.

It is important to notice that the COVID-19 pandemic may impact patients with type 1 and type 2 diabetes differently. There is a tendency for a higher prevalence of depression in patients with type 2 diabetes when compared to those with type 1 diabetes in normal situations. A study performed by Bak *et al.* showed that patients with type 2 diabetes had almost twice the prevalence of depression symptoms when compared to those with type 1 diabetes (43). In addition, intrinsic differences in types of diabetes can be affected in different ways during the period of social distancing. In type 1 diabetes, which requires precision in terms of the amount and timing of insulin administration, having more time at home could result in improved adherence and disease control. On the other hand, in type 2 diabetes, the maintenance of healthy habits, including physical exercise and balanced diet, can be greatly impaired during quarantine. These possible differences can have a positive or negative impact in terms of glycemic control, contributing differently to the appearance of psychological distress during the COVID-19 pandemic. It should be noted that these differences are still hypothetical, requiring specific studies for a better understanding.

Besides the high prevalence of psychological distress, our findings highlight the observation that the risk of suicide may be increased during the period of social distancing by COVID-19 in patients with diabetes. In the studied cohort, almost 7% of patients expressed positive responses to the question "*has the thought of ending your life been on your mind?*" in the SRQ 20. It is important to notice that the questionnaires were applied in a single phone call interview generated by researchers who had no bond or previous connection with participants. It is possible that, if applied under other conditions, this number would be even higher. Our findings are compatible with what was exposed by Gunnell *et al.*, which stated that the pandemic would cause distress and leave many people vulnerable to mental health problems and suicidal behavior. Mental health consequences are likely to be present for longer and peak later than the actual pandemic (44). This reinforces the importance of the active and ongoing participation of mental health professionals in policy task forces during this critical period (45).

Our study also showed a high prevalence of eating disorders among patients with diabetes after one month of social distancing. Literature data show that approximately 14% to 35% of patients with diabetes have a positive screening for eating disorders when assessed by EAT-26, a percentage much lower than the one found in our cohort (46-47). A pilot study by Fernandez-Aranda *et al.* demonstrated that, after just two weeks of confinement, almost 38% of patients reported symptoms related to eating disorders. The authors reflect that concerns about health and fitness during confinement might serve as a precipitating factor for the development of an eating disorder in vulnerable individuals (48). It is important to note that our study was carried out after a longer period of social distancing, but in milder confinement conditions, different from the lockdown measures evaluated in the study by Fernandez-Aranda *et al.* Nevertheless, although not evaluated in our study, the high prevalence of eating disorders in this population could interfere in diet and, consequently, in glycemic control.

Another relevant aspect of our study was the high prevalence of sleep disorders in patients with diabetes during this period. Only one study was carried out to assess sleep quality during the COVID-19 pandemic, which showed 18%

prevalence of sleeping disorders (43). We believe that the presence of a positive screening for moderate and severe sleep disorder in our cohort is possibly multifactorial: the presence of obstructive sleep apnea in the groups with highest BMI, eventual nocturnal hypoglycemia episodes, staying longer time at home, practicing less physical activity, and having irregular sleep times may play an important role in this variable. In addition, it is possible that the presence of insomnia in this period reflects an anxiety sign related to a heightened concern about the risk of having COVID-19 while having diabetes. These hypotheses are merely speculation, requiring specific studies for better understanding.

It is important to highlight some limitations of the present study. This study involved a cross-sectional research design and data regarding mental health that was not assessed before the period of social distancing for comparison in this same population. The absence of a control group without diabetes is also a limitation of the study. It must be taken into account that a relatively small sample was included in this study, although in accordance to the sample size calculation. In addition, patients were selected from a single tertiary center, which can limit external validity. Some parameters, such as labor activities and patients' current purchasing power, and specific information on the use of antipsychotics and mood stabilizers were not available in the electronic medical records and were not assessed directly with the participants, not allowing us to interpret the medication use and economic impact of this period in mental health.

Some limitations should be considered in relation to the scales used. The scales used to assess psychiatric disorders work as screening tools and have no diagnostic value. The scales used were originally validated for self-application and, in our study, they were applied by researchers through phone calls due to the limitations imposed by the current scenario. The self-report-questionnaire (SRQ-20), which was used to assess the primary outcome, has validation for minor psychiatric disorders screening in primary health care in Brazil (48). Despite not presenting validation for screening in patients in tertiary care, patients with diabetes mellitus are included in primary care samples. For the assessment of eating disorders, the eating attitudes test (EAT-26) was used. Although there are no validation studies in the population with diabetes, their results are widely generalizable and used for screening, indicating food preoccupation and restriction (30,31). The EAT-26 is often indicated as one of the methods of choice

for the initial assessment of eating disorders in patients with diabetes, according to Young-Hyman *et al.* (49). The mini sleep questionnaire (MSQ) used to assess sleep disorders has validation only for the general population and there are no specific studies on its use in patients with diabetes (32, 33).

Despite not having a diagnostic purpose, this study found a high number of patients showing evidence of significant psychological distress among patients with type 1 and type 2 diabetes during the COVID-19 pandemic. Our results serve as an alarm for the impact that the current scenario may have on the mental health of patients with diabetes. The data from this study highlight the need for mental health access and support for patients with type 1 and type 2 diabetes during and after this pandemic. Future studies and actions should address the impact of strategies to care for mental health in diabetes and to prevent glycemic control deterioration during a quarantine period.

DECLARATIONS

Competing interests: There is no conflict of interest to declare.

Ethics approval and consent to participate: The study was approved by the National Research Ethics Commission of Brazil (CONEP), number 4.029.368. All participants agreed to the free and informed consent form, which was saved by electronic registration.

Consent for publication: All authors have reviewed the final version of the manuscript and agree with the publication of the results presented.

Availability of data and materials: The data collected for the study, including deidentified participant data and informed consent form, will be available for 1 year after publication of the article upon justified request to the e-mail address of the main researcher and with a signed data access agreement.

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CPK, TRC and GHT Methodology, Investigation. GHT Methodology, Investigation. BDS Conceptualization, Validation, Supervision, Writing- Reviewing and Editing. GHT Conceptualization, Data curation, Writing- Original draft preparation. Supervision.

JA is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Table 1: Demographics and clinical characteristics of study participants.

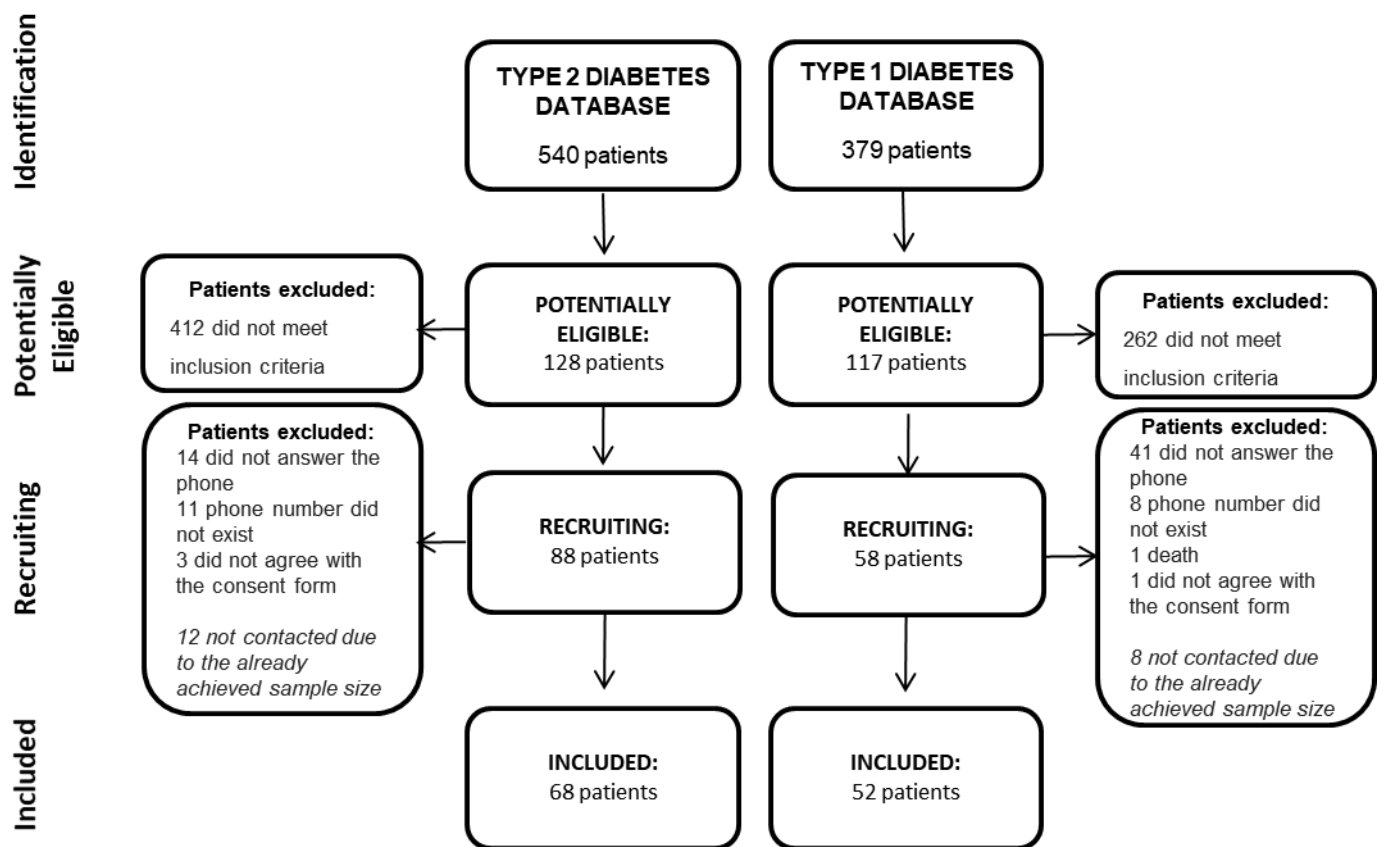
	Total (n = 120)	Type 1 diabetes (n = 53)	Type 2 diabetes (n = 68)	P value
Age (years)	54.8 ± 14.4	45.0 ± 14.2	62.3 ± 9.1	<0.001
Sex (% female)	55.8%	48.1%	61.8%	0.13
Race/ethnicity (% white)	85.8%	96.2%	77.9%	0.02
Diabetes duration (years)	21.8 ± 10.9	25.2 ± 11.5	19.2 ± 9.7	<0.01
Age at diabetes diagnosis (years)	32.7 ± 16.1	19.8 ± 12.7	42.8 ± 10.3	<0.001
HbA1c (%)	9.0 ± 1.6	8.8 ± 1.5	9.1 ± 1.7	0.29
(mmol/mol)	75 ± 17.5	73 ± 16.4	76 ± 18.6	
Diabetes complications				
Retinopathy	48.3%	55.8%	42.6%	0.15
Neuropathy	30.0%	30.8%	29.4%	0.87
Diabetic kidney disease	40.0%	38.5%	41.2%	0.76
Insulin use	92.5%	100%	86.8%	<0.01
Metformin use	42.5%	-	75%	<0.001
BMI (% overweight/obese)	76.7%	51.9%	95.6%	<0.001
Systemic arterial hypertension	58.3%	30.8%	79.4%	<0.001
Cardiovascular disease	29.2%	15.4%	39.7%	<0.01
ACE inhibitors use	46.7%	30.8%	58.8%	<0.01
Previous diagnosis of common mental disorders ¹	23.3%	25.0%	22.1%	0.70
Social distancing (% total/partial ²)	92,5%	88,5%	95,6%	0.14

Data are mean ± standard deviation or %. $\alpha < 0.05$ indicates significant difference. BMI: Body mass index; HbA1c: hemoglobin A1c. ACE: Angiotensin-converting enzyme; ¹Common mental disorders, which includes depressive episode, major depressive disorder and anxiety disorders. ²Social distancing includes patients who followed the orientation of total (home-staying only) or partial social isolation (left home only for basic activities, such as market, pharmacy and health care).

Table 2: Multivariable logistic regression to identify predictors of minor psychiatric disorders.

	Odds Ratio	Confidence Interval (95%)	<i>P</i> value
Age at diagnosis (per 1 year increase)	0.96	0.92 – 0.99	0.04
Sex (female)	2.24	0.95 – 5.32	0.06
BMI (eutrophic)	1.77	0.56 – 5.56	0.33
Age (per 1 year increase)	1.01	0.97 – 1.06	0.66
Previous diagnosis of common mental disorders	1.15	0.43 – 3.11	0.77
HbA1c (per 1% increase)	1.03	0.79 – 1.35	0.81
Race/ ethnicity (white)	1.01	0.28 – 3.64	0.98
Social distancing	2.04	0.35 – 11.81	0.42
Type 2 diabetes	7.60	1.93 – 29.71	0.004

Multivariable logistic regression model to assess predictors of the presence of minor psychiatric disorders ($\chi^2 = 17.94$, p 0.05, R^2 Nagelkerke 0.19). BMI: Body mass index; HbA1c: hemoglobin A1c. Common mental disorders includes depressive episode, major depressive disorder and anxiety disorders. Social distancing includes patients who followed the orientation of total or partial social detachment (left home only for basic activities, such as market, pharmacy and health care).



Supplementary figure 1. Number of patients with type 1 and type 2 diabetes who were screened, recruited, and included in the study.

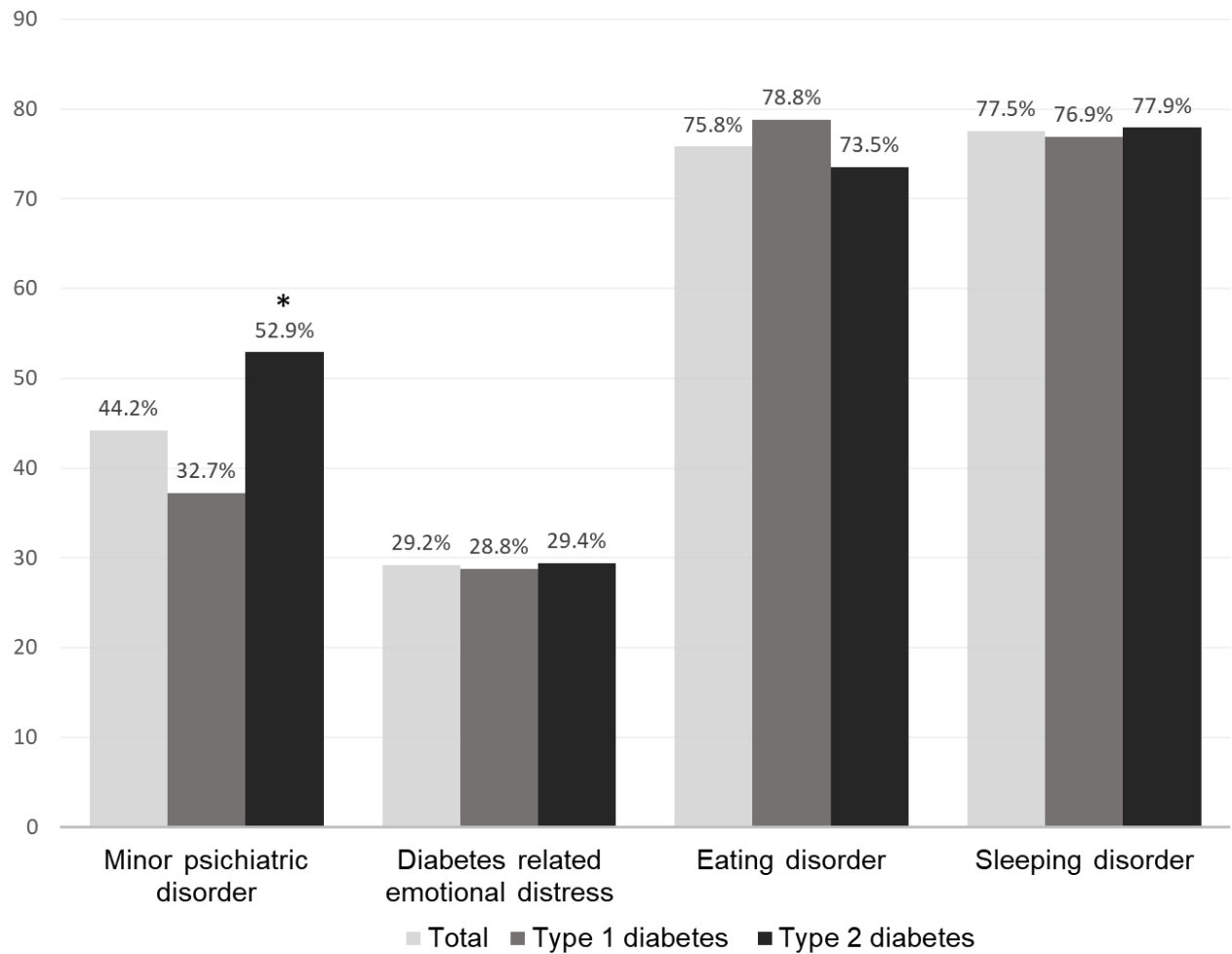


Figure 1: Prevalence of positive screening for psychiatric disorders among patients with type 1 and type 2 diabetes.

The *Self Report Questionnaire - 20 (SRQ 20)* was used for the assessment of minor psychiatric disorders, such as anxiety and depression. Diabetes related emotional distress was assessed by the *Brazilian Problem Areas in Diabetes Scale (B-PAID)*. The prevalence of eating disorders was assessed by the *Eating Attitudes Test (EAT – 26)*. The *Mini Sleep Questionnaire (MSQ)* was used to assess sleep disorders. * $P = 0.03$

ARTIGO 2

Caring for caregivers: the impact of the COVID-19 pandemic on those responsible for children and adolescents with type 1 diabetes.

COVID-19 pandemic and caregivers of children with diabetes

Janine Alessi, MD^{1,2}; Giovana Berger de Oliveira³; Gabriela Feiden, BSEd^{4,5};

Beatriz D. Schaan, MD PhD^{1,6,7}, Gabriela Heiden Telo, MD PhD^{2,3,8}

1. Post Graduate Program in Medical Science: Endocrinology, Universidade Federal do Rio Grande do Sul, Brazil
2. Internal Medicine department, Hospital São Lucas - Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
3. School of Medicine, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
4. Post Graduate Program in Epidemiology, Universidade Federal do Rio Grande do Sul, Brazil
5. Associação de Apoio aos Diabéticos do Rio Grande do Sul (AADIRS), Brazil
6. School of Medicine, Universidade Federal do Rio Grande do Sul, Brazil
7. Endocrinology division, Hospital de Clínicas de Porto Alegre, Brazil
8. Post Graduate program in Medicine and Health Sciences, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil

ABSTRACT

This study aimed to assess the psychological impact of the COVID-19 pandemic on guardians of children and adolescents with type 1 diabetes. An online survey was performed to assess the prevalence of pandemic-related emotional burden, mental health disorders and diabetes-specific emotional burden related to diabetes care during the COVID-19 pandemic. Caregivers of children and adolescents with diabetes under the age of 18 and caregivers of youth for the non-diabetes group were invited to participate. For the primary outcome, mental health disorders were evaluated using the Self-Reporting Questionnaire (SRQ-20), while pandemic-related emotional burden and diabetes-specific emotional burden related to diabetes care were evaluated in different domains with specific questions. For analyses, a hierarchical testing strategy was performed. A total of 764 participants were included in the study. Regarding the pandemic period, caregivers of youth with type 1 diabetes endorsed significantly more pandemic-related emotional burden for both themselves (OR 1.67; 95% CI, 1.10 to 2.53) and for their child (OR 2.28; 95% CI, 1.54 to 3.38) when compared to the non-diabetes group. The emotional burden evaluation on different age ranges showed that the two groups were similar when the dependent youth was younger than 6 years. Moreover, a positive screening for mental health disorders during social distancing was higher in the diabetes group compared to the non-diabetes group (OR 2.43; 95% CI, 1.70 to 3.47), particularly in those aged under 12 years old. There was no difference between groups in mental health disorders among caregivers of adolescents older than 12 years. Our results allow to conclude that concern, burden and mental health disorders can be present in caregivers of youth with diabetes, and behavioral changes during the COVID-19 pandemic may enhance this situation.

Keywords: COVID-19 pandemic, emotional burden, type 1 diabetes, diabetes care, mental health

INTRODUCTION

Caring for children and adolescents with type 1 diabetes mellitus involves daily challenges and can put a psychological strain on those responsible. A study carried out with children under 7 years old shows that caregivers play a fundamental role in controlling the disease and experience the responsibility for its short and long-term consequences, such as episodes of hypoglycemia, future complications, and the impact the disease will have on their children's quality of life [1]. Another study with children under 8 years old shows that, in addition to the responsibility for optimal glycemic control, parents also suffer from constant concerns about the care for their children while the parents are not present. The difficulty in finding someone reliable and used to the demands of diabetes is also challenging. This makes the role of caregiver a full-time job [2]. Despite these issues, concerns tend to be child-centered and the psychological demands of family members involved in childcare are often neglected.

The emotional burden experienced by caregivers of children and adolescents with type 1 diabetes may be aggravated by the current COVID-19 pandemic. The change in family dynamics that has occurred since the beginning of COVID-19 is reflected in different aspects of the care of children with diabetes. First, the concern and fear of a potentially serious infection for the child, constitutes a stressful situation [3]. Second, the suspension of school and extracurricular activities results in more time for children and adolescents at home, requiring greater attention from caregivers. Third, the closing of parks and recreation rooms results in more sedentary habits and, consequently, lower daily energy expenditure [4]. All these changes may significantly impact the glycemic control of the child, adding even more responsibilities and enhancing the stress on guardians.

Despite everything mentioned above, the psychological repercussion of the current scenario in guardians of children and adolescents with diabetes remains hypothetical. Several studies have shown that the deleterious effects of the caregiver's psychological distress apply to both caregivers and children, resulting in worse glycemic control and increasing the incidence of depression during adolescence [2, 5-10]. The care for caregivers' mental well-being, however, has received little priority when assessing the impact of stressful situations, such as the current pandemic of COVID-19 and the social distancing

it requires [11]. The present study aims to assess the psychological impact of routine changes and the demands of the disease on caregivers of children and adolescents with type 1 diabetes during the COVID-19 pandemic, and to identify factors that can guide strategies in similar situations in the future.

METHODS

Study design and setting

This was a cross-sectional study carried out to evaluate the prevalence of mental health disorders and pandemic-related emotional burden during the COVID-19 pandemic in caregivers of children and adolescents with type 1 diabetes. Caregivers of children and adolescents with a previous diagnosis of type 1 diabetes were recruited to participate in this study as the diabetes group, while caregivers of children and adolescents without diabetes were selected for the non-diabetes group. The invitation to participate in the diabetes group was carried out through the social media of the Juvenile Diabetes Association, a society that integrates associations throughout Brazil meant for children and adolescents with diabetes. The invitation to the non-diabetes group was carried out through social media of medical students across the country. An electronic invitation was sent to access an online survey between May 18th and June 9th of 2020, approximately two months after the beginning of the pandemic in Brazil and after the disclosure from the national ordinance that recommended social distancing for high-risk groups. At the time of the evaluation, Brazil was already considered one of the epicenters of the pandemic. National legislation restricted the functioning of establishments that offer essential services, and which regulated the indication of an exceptional teleworking regime for people with respiratory diseases, immunosuppressed or with chronic disease, upon medical recommendation. Moreover, school activities and non-emergency medical consultations have been suspended. The manuscript description follows the STROBE guideline [12].

Participants

Adults of any age who were parents or the primary caregivers of children and adolescents aged less than or equal to 18 years-old with type 1 diabetes were selected for the diabetes group. For the non-diabetes group, adults who

were parents or the primary caregivers of children and adolescents aged less than or equal to 18 years-old without diabetes, and who were invited through the social media of student leagues across the country were selected.

Variables and data source

1. Demographic and clinical data

Sociodemographic information about the caregivers and clinical information about the dependent under their responsibility (such as age, presence of comorbidities, diabetes duration, age at diagnosis, use of medication, last HbA1c levels, and presence of diabetes complications) were collected at the beginning of the questionnaire.

2. Support and relationships

After the gathering of initial information, an evaluation about the participant's social support and relationships was carried out using specific questions (see supplementary material). Participants were asked to choose, based on the last six months (to evaluate periods in addition to the pandemic period), one of the following options regarding the topics already mentioned: "most of the time", "occasionally" or "almost never / never". For analysis, a negative response was considered when participants answered "almost never / never".

3. Consequences of social distancing

Regarding the routine during the pandemic, the questionnaire included "yes", "no" or "partially" response options for the participants' compliance regarding social distancing since the beginning of the social distancing recommendation, the time spent by the child at home and possible difficulties related to income and medical care. It was considered that family income decreased if the patient answered yes to the reduction of some source of family income since the beginning of the pandemic.

Outcomes

The primary outcomes of this study included the presence of pandemic-related emotional burden, the presence of positive screening for mental disorders, and the presence of diabetes-specific emotional burden related to the

diabetes care during the period of social distancing, which was caused by the COVID-19 pandemic.

Pandemic-related emotional burden

The evaluation of pandemic-related emotional burden was carried out for both diabetes and non-diabetes groups and was performed using a 5-point Likert scale for different domains. The domains were evaluated using the following sentences: (1) personal concern - "I often feel worried and afraid of being infected with the coronavirus"; (2) child-related concern - "I often feel worried and afraid that my child may be infected with the coronavirus"; (3) personal emotional burden: "I often feel tired and exhausted due to the changes in routine since the social distancing related to the COVID-19 pandemic started"; (4) child-related emotional burden: "I often feel tired and exhausted from the responsibility to protect my child during the COVID-19 pandemic". For the analyses, "totally agree" and "agree" were considered affirmative answers.

Screening for mental health disorders during social distancing

The evaluation of mental health disorders was carried out for both diabetes and non-diabetes groups. For tracking mental health disorders such as anxiety-related disorders, depression and somatoform disorders, the Self-Reporting Questionnaire (SRQ - 20) was used in a version previously validated to the Brazilian population [13]. "Yes" or "No" answers were requested for each statement, and a positive screening was considered when the participant answered "Yes" in at least seven of the 20 items [13].

Diabetes-specific emotional burden related to diabetes care

The evaluation of diabetes-specific emotional burden was applied only to the diabetes group using a 5-point Likert scale. The following statements were used for the domains evaluated: (1) care sharing: "I feel frustrated because I am the only one responsible for helping my child in using medications and managing glycemic control"; (2) support: "I feel frustrated with the lack of understanding and support I get from my friends and family in relation to taking care of someone with diabetes"; (3) appreciation: "I feel underestimated for all the effort I put into helping my child to take care of diabetes"; (4) exhaustion: "I feel that my child's diabetes is consuming a lot of my physical and mental energy every day"; (5)

guilt: "I feel guilty if my child's diabetes is not well controlled". In order to facilitate interpretation, answers were categorized in (a) it is a problem, if the answer was "totally agree" or "agree"; (b) it is not a problem, if the answer was "strongly disagree" or "disagree"; and (c) not decided, if the answer was "not decided".

Sample size

The Krejcie & Morgan (1970) formula was used to determine sample size for a given population and for an analysis using a 95% confidence level and a margin of error of 0.05 [14]. Considering the estimate of 95800 individuals with diabetes and under 18 years of age in Brazil in 2019, 380 responses in the diabetes group was determined to be necessary to obtain the adequate power for the analyses performed¹⁵. The strategy was repeated for the non-diabetes group to obtain homogeneity in the procedure performed.

Statistical methods

The data were transcribed from the online platform SurveyMonkey, (San Mateo, CA, U.S.A.; <http://www.surveymonkey.com>) to the Statistical Package for Social Science (SPSS®) version 20 for analysis. A hierarchical testing strategy was performed to deal with the problem of multiplicity (*type I error inflation*), and the following outcomes were ranked in descending order of importance: (1) presence of pandemic-related emotional burden, (2) mental health during social distancing and (3) presence of diabetes-specific emotional burden during the COVID-19 pandemic. Just for those outcomes, P values were reported for until the first outcome with a P value greater than 0.05 was obtained and further tests were considered only for exploratory analyses. For all other analyses (*baseline characteristics and psychosocial profile during the pandemic*), the P value will be reported as usually done. For the diabetes-specific emotional burden related to diabetes care, considering that only the diabetes group was evaluated, P values are not shown.

Descriptive data are presented as mean \pm standard deviation or frequency (%). Statistical analyses of the results include Chi-square tests for categorical variables and *t* tests for continuous parametric variables. Logistic regressions were used to correct for possible confounders and data are presented as Odds Ratios (OR) and their respective 95% confidence intervals (CI). Only participants who answered at least 75% of the questionnaire were included on the analyses.

The missing values are excluded from the analysis if the participant did not answer the question (listwise deletion). A sensitivity analysis was performed to assess psychosocial aspects in caregivers based on different age groups [preschoolers (<6 years), young children (between 6 and 12 years), and adolescents (>12 years)], and the results were adjusted for the youth's age, ethnicity, region of origin and income using multivariable logistic regressions. Moreover, considering that there was a high prevalence of chronic diseases in the non-diabetes group, a sensitivity analysis with a healthy control group was performed, including only the participants in the non-diabetes group who did not report chronic diseases.

Finally, subgroup analyses are presented as OR and their respective 95% CI and represent the likelihood of subgroups of interest present diabetes-specific emotional burden. An alpha value <0.05 was used to determine statistical significance.

Ethical aspects

The study was done in accordance with the Helsinki Declaration, 2004, and performed in accordance with all relevant guidelines and regulations. The project was approved by the research ethics committee of the main researcher's institution (number 4.045.411). All patients included in the study agreed to the informed consent form available on the online platform before completing the questionnaire.

RESULTS

Characteristics of the Participants

A total of 1011 responses to the online questionnaire were collected: 485 from those responsible for children and adolescents with diabetes (diabetes group) and 526 from those responsible for children and adolescents without diabetes (non-diabetes group). After excluding participants who did not agree with the informed consent, did not meet the inclusion criteria or completed less than 75% of the questionnaire, 381 participants in the diabetes group and 383 in the non-diabetes group were included in the analyses (see supplementary Figure 1).

Overall, the participants included in the study had a mean age of 39.9 ± 8.5 years; 95.2% were female, 78.3% were white and 47.8% had medium-low family income. Regarding the relationship with the child, 89.1% were mothers, either biological or adoptive. The diabetes and non-diabetes groups did not differ in relation to the participants' age, sex, and relationship with the child. There was a higher prevalence of non-white and low-income participants in the diabetes group (31.2% vs. 12.3%, $P < 0.001$ and 54.1% vs. 41.5%, $P = 0.001$, respectively) (see Table 1). Representatives from all regions of Brazil were included, although a high proportion of participants in both groups were from the South-Southeast regions (79.0% in diabetes group and 97.4% in non-diabetes group).

Children and adolescents in the diabetes group were older (11.8 ± 4.3 vs. 8.1 ± 4.7 years, $P < 0.001$); 28.5% of the participants in the non-diabetes group reported the presence of a chronic illness in the child. Among these participants, 83 had respiratory tract diseases (asthma, bronchitis, cystic fibrosis or rhinitis requiring continuous treatment), three had congenital heart disease, seven had neuro-psychiatric diseases (autism spectrum disorder, attention deficit and hyperactivity or anxiety in need of pharmacological treatment), one had epilepsy, one polycystic kidneys disease, one lactose intolerance, one deafness and one cerebral palsy. Of these, 15.1% used medication daily.

Support, relationships, and consequences of social distancing

Considering the social-demographic differences between the two groups, the odds ratio for the characteristics evaluated in the psychosocial profile were adjusted for age of the child, race/ethnicity, income, and region of origin. Participants in the diabetes group more frequently reported unsatisfactory relationships (18.0% vs. 9.4%, adjusted OR 1.90; 95% CI, 1.16 to 3.12) and regarding family atmosphere, the diabetes group more frequently reported the atmosphere as not-welcoming (8.0% vs. 1.3%, adjusted OR 5.85; 95% CI, 2.09 to 16.43). In addition, a greater purchasing difficulty (38.7% vs. 10.8%, adjusted OR 4.65; 95% CI, 2.93 to 7.38) and a greater difficulty in getting medical assistance when necessary during the pandemic (44.2% vs. 18.5%, adjusted OR 3.36; 95% CI, 2.27 to 4.97) were reported by the diabetes group compared to non-diabetes group. Aspects related to the social distancing, the child being at home full time and reduced family income during the pandemic did not differ between groups (see Table 2). When the evaluation was carried out comparing

only to healthy controls, there was no difference between the groups regarding the maintenance of unsatisfactory relationships, but the diabetes group more frequently reported the family atmosphere as not-welcoming (8.0% vs. 0.4%, adjusted OR 17.39; 95% CI, 2.24 to 134.99). There were few differences in the other parameters (see supplementary table 2).

Pandemic-related emotional burden

The emotional burden evaluation during the COVID-19 pandemic was performed in four domains. Participants in the diabetes group most often expressed personal concern (84.4% vs. 78.3%, $P = 0.041$), child-related concern (92.6% vs 86.0%, $P = 0.005$), personal emotional burden (78.2% vs 65.3%, $P < 0.001$) and child-related emotional burden (75.2% vs. 57.1%, $P < 0.001$) when compared to the non-diabetes group (see Figure 1).

When adjusted by the age of the child, race/ethnicity, region of origin and income, the diabetes group maintained a greater likelihood of personal concern (OR 1.62; 95% CI, 1.01 to 2.58), a greater likelihood of concern for the child (OR 2.01; 95% CI, 1.11 to 3.64), a greater likelihood of personal emotional burden (OR 1.67; 95% CI, 1.10 to 2.53) and a greater likelihood of burden related to childcare (OR 2.28; 95% CI, 1.54 to 3.38).

A sensitivity analysis, adjusted by the same factors and excluding caregivers of youth with chronic disease in the non-diabetes group, was performed. The diabetes group maintained a greater likelihood of personal concern (OR 1.64; 95% CI, 1.02 to 2.64), a greater likelihood of concern for the child (OR 2.49; 95% CI, 1.35 to 4.59), a greater likelihood of personal emotional burden (OR 2.15; 95% CI, 1.41 to 3.27) and a greater likelihood of burden related to childcare (OR 2.62; 95% CI, 1.74 to 3.92) (see Supplementary figure 2).

Mental health during social distancing

The presence of a positive screening for mental health disorders was found in 50.3% of the participants in the non-diabetes group and in 69.0% of the participants in the diabetes group ($P < 0.001$ for the difference between groups). When adjusted for the age of the child, race/ethnicity, income and region of origin, the diabetes group was found to have a significantly higher likelihood of positive

screening for mental health disorders when compared to the non-diabetes group (OR 2.43; 95% CI, 1.70 to 3.47).

A sensitivity analysis, adjusted by the same factors and excluding caregivers of youth with chronic disease in the non-diabetes group, was performed. The diabetes group maintained a significantly higher likelihood of positive screening for mental health disorders when compared to the healthy control group (OR 2.68; 95% CI, 1.82 to 3.96) (see Supplementary table 2).

Diabetes-specific emotional burden related to diabetes care

In the diabetes group, the diabetes-specific emotional burden related to the care of a child / adolescent with diabetes was evaluated in five domains: 40.6% reported discontent in care sharing, 36.0% reported discontent in support, 41.8% reported discontent in appreciation, 48.3% reported exhaustion and 75.7% reported guilt problems (see Figure 2).

An exploratory analysis of subgroups was performed to identify the likelihood of emotional burden related to care of a child / adolescent with diabetes in certain interest groups. The presence of unsatisfactory relationships and family environment that is not welcoming were predictors of having a greater likelihood of reporting emotional burden related to care sharing, support, appreciation, and exhaustion in diabetes care, while the presence of a positive screening for mental health disorders was a predictor for burden in all areas of diabetes care evaluated (see Table 3).

The impact of the pandemic on different age groups

For the assessment of psychosocial profile and consequences of social distancing on different age groups, the results were adjusted for age of the child, race/ethnicity, income, and region of origin. When considering the different age range, the group of caregivers of youth aged 6 to 12 years with type 1 diabetes most often had unsatisfactory relationships (OR 7.86; 95% CI, 3.59 to 17.22) and had a not-welcoming family atmosphere (OR 5.98; 95% CI, 1.27 to 28.06) in comparison to the non-diabetes group. There was no difference in these aspects in the other age groups. In addition, in all age ranges, caregivers of youth with diabetes had a greater likelihood of having difficulty purchasing during the pandemic. In those aged between 6 and 12 years and those older than 12 years

there was a greater likelihood of presenting greater difficulty in getting medical assistance when necessary (OR 3.84; 95% CI, 2.12 to 6.94 and OR 3.69; 95% CI, 1.76 to 7.71, respectively) (see supplementary table 3).

The emotional burden evaluation on different age ranges was also performed in four domains and adjusted for confounders. The two groups were similar in all domains when the dependent youth was younger than 6 years. On the other hand, there was an increase in likelihood to present child-related concerns (OR 3.19; 95% CI, 1.23 to 8.27 and OR 3.26; 95% CI, 1.22 to 8.71), personal emotional burden (OR 2.05; 95% CI, 1.17 to 3.58 and OR 2.61; 95% CI, 1.34 to 5.10) and child-related emotional burden (OR 2.79; 95% CI, 1.62 to 4.82 and OR 2.56; 95% CI, 1.35 to 4.82) among caregivers of youth with type 1 diabetes aged 6 to 12 years and older than 12 years, respectively (see supplementary figure 3).

Regarding mental health disorders, the diabetes group showed greater likelihood of presenting disorders in those aged under 6 years old (OR 2.92; 95% CI, 1.08 to 7.94) and in those aged between 6 and 12 years old (OR 2.89; 95% CI, 1.73 to 4.84). There was no difference between groups in caregivers of adolescents older than 12 years (see supplementary table 3).

DISCUSSION

Caring for the mental well-being of people responsible for the care of children and adolescents with diabetes has been undervalued. This study was the first to evaluate the psychological impact of routine changes and disease demands on caregivers of children and adolescents with diabetes during the COVID-19 pandemic. When compared to those responsible for children without diabetes, caregivers of children and adolescents with diabetes more often expressed feelings of concern and burden during social distancing. These participants, even when adjusted for potential confounders, had a 60% higher likelihood of presenting feelings of personal concern and burden and up to twice the likelihood of having feelings of concern and burden related to caring for their child during the pandemic. The care of children and adolescents with diabetes has also been associated with a higher likelihood of having a positive screening for mental health disorders during the social distancing period. Moreover, considering the diabetes group, about 3 out of 4 participants reported feeling

guilty when the glycemic control of the dependents was not adequate, almost half reported experiencing feelings of exhaustion related to the care of these children and more than a third reported discontent in sharing care, support from family members and appreciation for their dedicated efforts.

The presence of concern, stress and anxiety in relation to glycemic control are part of the routine of the most caregivers of children with diabetes, and behavioral changes during the COVID-19 pandemic seem to enhance this situation [16]. Participants in the diabetes group more frequently reported the presence of feelings of concern and emotional burden, both personal and related to child care. The longer time at home related to the suspension of non-essential activities may result in an increased demand for those responsible for children with diabetes. Moreover, these individuals are required to coordinate insulin administration and the maintenance of a balanced diet full time.

In our study, those responsible for children and adolescents with diabetes had a higher likelihood of a positive screening for mental health disorders during the social distancing period compared to the non-diabetes group. Previous work has shown that the prevalence of symptoms of depression in the parents of children with newly diagnosed diabetes can reach 74% and, in about 20% of these parents, the symptoms remain for four years after diagnosis [6, 17]. The presence of a potentially fatal pandemic may work as a trigger for the manifestation of latent anxiety and depression symptoms. Caregivers with depressive symptoms may perceive the complexities of diabetes and the challenges associated with its treatment as more negative and distressing, and may lack the necessary coping skills to manage this distress [18-20]. In addition, studies have found depressive symptoms in parents are associated with lower parental involvement, lower family adaptability and higher family conflict, which corroborates the relationships found in the present study [6, 21-23].

Regarding diabetes care during the pandemic, those responsible for this group tended to have a higher prevalence of diabetes-specific emotional burden in different domains related to the demands of the disease. Whittemore *et al.* found, in a review of studies focused on parents of children with diabetes in usual situations, that those individuals experience considerable stress related to the demands of treatment management. They found that the prevalence of parental

psychological distress ranged from 20% to 30% in different studies and, in most of these studies, parents of children with diabetes were found to experience greater distress and problems with parenting than other parents, which may negatively affect their children [6]. It is difficult to say, based on our study data, how much of the burden found is due to the pandemic and how much is due to the basic conditions of the family members, which may already be weakened. It is possible to imagine, however, that the increase in demands related to social distancing and the anxiogenic context experienced may have contributed to the high levels of diabetes-specific emotional burden reported.

In our study, we chose to use the SRQ-20 questionnaire to assess the prevalence of mental health disorders in caregivers. The choice of this questionnaire was based especially on the wide range of psychiatric disorders assessed (minor disorders) compared to other mental health scores. Other commonly used options, such as the Hospital Anxiety and Depression Scale (HADS) and the Patient Health Questionnaire-9 (PHQ 9), could not be used [24,25]. The first because its validation for the Brazilian population was performed in hospitalized patients and the second because the evaluation is restricted to depressive disorders alone. All of them have been validated for self-application.

It is necessary to highlight some limitations of the present study. Considering that it is a cross-sectional study, it is not possible to establish cause and effect relationships using the identified associations; reverse causality may occur. The unavailability of validated and translated questionnaires to evaluate anxiety diabetes-specific distress in caregivers has limited the use of these tools in our population. In addition, given that this was an online survey, the results depend on the commitment of the participants and on the veracity of the information provided, which may constitute potential information bias. The dissemination of the questionnaire to the non-diabetes group through medical student leagues may also have selected families with the sickest children in this group and may not be a representative sample of the general population. Regarding the participants sample, although both questionnaires were released at the national level, the diabetes group had a greater representation of different regions of the country. Most participants are from the South and Southeast regions of the country, which limits the generalization of the results. The non-

diabetes group also showed less ethnic diversity and greater purchasing power, which may be related to the greater representation of states in Southern Brazil. Although all analyses have been adjusted for the region of origin, purchasing power, youth's age and ethnicity, these differences in baseline characteristics between groups may reflect a sample bias related to the study design and constitute a limitation of the manuscript. Adjusted analyses for age of the child, skin color, income and region of origin were performed to minimize the effect of these differences. Another aspect that should be highlighted is the high representativeness of female caregivers, which can reduce the validity of the results for male representatives. This high prevalence is in line with other studies conducted in pediatric outpatient care in Brazil, in which the mother plays the role of primary caregiver in 91 to 93.7% of cases [26,27]. Finally, it is necessary to highlight the possibility of selection bias among the participants because family members who are more engaged in childcare may be more interested in participating in the research.

Despite the limitations presented, our study should call attention to mental health and to the diabetes-specific emotional burden related to diabetes care during the pandemic. The evidence found suggests that situations of vulnerability and public calamity may enhance symptoms of concern, burden and mental health disorders in some caregivers of children and adolescents with diabetes, and studies comparing the time periods prior to and after the pandemic should be carried out to better understand this relationship. These results also reveal that additional studies are necessary to understand the burden that these families may be experiencing during the current scenario and to develop new strategies to support these caregivers, especially during the pandemic. The "caregivers and children" binomial approach is fundamental for treating the child's diabetes, and for taking care of the well-being and quality of life of everyone involved.

DECLARATIONS

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Authors' Contributions. JA Conceptualization, Methodology, Software, Data curation, Writing- Original draft preparation. GBO, GF Methodology, Investigation. BDS Supervision, Writing- Reviewing and Editing. GHT Conceptualization, Data curation, Writing- Original draft preparation. Supervision. JA is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Competing interests. The author(s) declare no competing interests.

Availability of data and materials. The data collected for the study, including deidentified participant data, will be available for 1 year after publication of the article upon justified request to the e-mail address of the main researcher and with a signed data access agreement.

Ethics approval and consent to participate. The study was done in accordance with the Helsinki Declaration, 2004, and performed in accordance with all relevant guidelines and regulations. The study was approved by the Research Ethics Committee of Hospital São Lucas da Pontifícia Universidade Católica do Rio Grande do Sul (CEP), number 4.045.411. All participants agreed to the free and informed consent form.

Consent for publication. All authors have reviewed the final version of the manuscript and agree with the publication of the results presented.

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Table 1. Demographics and clinical characteristics of study participants.

	Total (n = 764)	Non-diabetes group (n = 383)	Diabetes group (n = 381)	P value
Age (years)	39.9 ± 8.5	39.5 ± 9.0	40.3 ± 8.0	0.201
Sex (% female)	95.2%	95.0%	95.3%	0.879
Race/ethnicity (% white)	78.3%	87.7%	68.8%	<0.001
Lower-middle income* (%)	47.8%	41.5%	54.1%	0.001
Parentage (% mother)	89.1%	88.5%	89.8%	0.166
Age of the child (years)	10.0 ± 4.9	8.1 ± 4.7	11.8 ± 4.3	<0.001
Chronic illness in the child (%)	64.1%	28.5%	100%	<0.001
Age of the child at diagnosis (years)	6.0 ± 4.4**	2.9 ± 3.4**	6.9 ± 4.3	<0.001
Disease duration (years)	5.1 ± 4.0**	5.7 ± 4.3**	5.0 ± 3.8	0.096
Continuous-use medication (%)	57.5%	15.1%	100%	<0.001

Data are mean ± standard deviation or %. $\alpha \leq 0.05$ indicates significant difference.

*Lower-middle income: family that receives a total of less than 2564 reais per month, as defined by the *Strategic Affairs Secretariat (SAE)* of Brazil, equivalent to 495.8 dollars or 430 euros. ** Data included only participants in the non-diabetes group who have some chronic disease.

Table 2: Support, relationships, and consequences of social distancing in study participants.

	Non-diabetes group (N = 377)	Diabetes group (N = 381)	OR (95% CI)
Unsatisfactory relationships [‡]	9.4%	18.0%	1.90 (1.16 – 3.12)
Family atmosphere not-welcoming [‡]	1.3%	8.0%	5.85 (2.09 – 16.43)
Follows social distancing ^{*§}	93.7%	97.0%	1.60 (0.71 – 3.65)
Child full time at home ^{*§}	79.9%	86.1%	1.39 (0.89 – 2.19)
Family income decreased ^{*↓}	71.4%	72.4%	0.97 (0.66 – 1.42)
Purchase difficulty ^{*↓}	10.8%	38.7%	4.65 (2.93 – 7.38)
Difficulty in medical assistance ^{*↓}	18.5%	44.2%	3.36 (2.27 – 4.97)
Positive screening for mental health disorders ^{†¶}	50.3%	69.0%	2.43 (1.70 – 3.47)

Data are prevalence (%) and odds ratio (OR) with confidence interval (95%). An OR greater than 1 means that there was an increase in likelihood to present the psychosocial characteristic evaluated in the diabetes group in relation to the non-diabetes group (OR for comparator = 1). All OR are adjusted for age of the child, race/ethnicity, income and region of origin. *In relation to the period after the beginning of the COVID-19 pandemic. † Positive screening for mental health disorders accessed by a score greater than or equal to 7 on the SRQ-20. ‡ n = 383 for non-diabetes group and n = 377 for diabetes group. § n = 383 for non-diabetes group and n = 331 for diabetes group. ↓ n = 378 for non-diabetes group and n = 326 for diabetes group. ¶ n = 374 for non-diabetes group and n = 323 for diabetes group.

Table 3: Subgroup analysis to assess predictors of risk of diabetes-specific emotional burden during the COVID-19 pandemic among guardians of children and adolescents with type 1 diabetes.

Subgroup	Care sharing	Support	Appreciation	Exhaustion	Guilt
Age (participant) > 30 years old	0.98 (0.91 – 1.05)	0.97 (0.90 – 1.05)	0.94 (0.88 – 1.01)	1.01 (0.94 – 1.08)	0.99 (0.91 – 1.06)
Age (child) > 8 years old	1.00 (0.89 – 1.13)	0.95 (0.84 – 1.09)	1.02 (0.90 – 1.15)	0.98 (0.87 – 1.11)	0.87 (0.77 – 0.99)
Race/ethnicity Not white	0.75 (0.47 – 1.21)	0.76 (0.47 – 1.24)	0.76 (0.47 – 1.23)	0.78 (0.49 – 1.26)	1.69 (0.99 – 2.88)
Diabetes duration > 5 years	1.17 (0.89 – 1.54)	1.06 (0.80 – 1.40)	1.19 (0.90 – 1.56)	1.04 (0.79 – 1.36)	0.87 (0.64 – 1.17)
HbA1c > 7,5%	1.22 (1.02 – 1.47)	1.16 (0.97 – 1.40)	1.21 (1.01 – 1.45)	0.96 (0.80 – 1.15)	1.00 (0.80 – 1.24)
Quality of relationships Unsatisfactory	2.07 (1.29 – 3.33)	3.38 (2.07 – 5.52)	2.64 (1.61 – 4.33)	1.63 (1.01 – 2.63)	1.11 (0.63 – 1.95)
Family atmosphere Not welcoming	3.76 (1.62 – 8.75)	13.04 (3.99 – 42.63)	10.19 (3.11 – 33.37)	2.75 (1.18 – 6.41)	1.69 (0.60 – 4.76)
Child time at home Full time	0.96 (0.88 – 1.05)	0.99 (0.90 – 1.08)	1.00 (0.91 – 1.09)	1.00 (0.91 – 1.09)	1.02 (0.92 – 1.14)
Purchase conditions Reduced	1.39 (1.06 – 1.83)	1.49 (1.14 – 1.95)	1.71 (1.30 – 2.26)	1.28 (0.97 – 1.68)	0.86 (0.64 – 1.16)
Mental health disorders Positive screening	1.48 (1.29 – 1.70)	1.43 (1.25 – 1.63)	1.44 (1.25 – 1.66)	1.58 (1.36 – 1.85)	1.60 (1.25 – 2.04)

Data are odds ratio (OR) and 95% CI and represent the likelihood of subgroups of interest present diabetes-specific emotional burden in the respective domains related to the diabetes care. For each subgroup, the OR was calculated for the subgroup of interest versus the opposite group (eg, family atmosphere not welcoming vs welcoming). Only participants of diabetes group were included. In bold, the subgroups that presented significantly higher (>1.00) or lower (<1.00) likelihood for presenting diabetes-specific emotional burden in the respective domain in relation to the opposite group.

Supplementary table 1. Demographics and clinical characteristics of study participants considering only the healthy control group.

	Total (n = 655)	Healthy control group (n = 274)	Diabetes group (n = 381)	P value
Age (years)	40.1 ± 8.7	40.0 ± 9.6	40.3 ± 8.0	0.535
Sex (% female)	94.5%	93.4%	95.3%	0.301
Race/ethnicity (% white)	77.4%	89.4%	68.8%	<0.001
Lower-middle income* (%)	47.0%	37.2%	54.1%	<0.001
Parentage (% mother)	87.9%	85.4%	89.8%	0.069
Age of the child (years)	10.2 ± 4.9	8.0 ± 4.7	11.8 ± 4.3	<0.001
Chronic illness in the child (%)		-	100%	
Age of the child at diagnosis (years)		-	6.9 ± 4.3	
Disease duration (years)		-	5.0 ± 3.8	
Continuous-use medication (%)		-	100%	

Data are mean ± standard deviation or %. $\alpha \leq 0.05$ indicates significant difference.

*Lower-middle income: family that receives a total of less than 2564 reais per month, as defined by the *Strategic Affairs Secretariat (SAE)* of Brazil, equivalent to 495.8 dollars or 430 euros.

Supplementary table 2: Support, relationships and consequences of social distancing in study participants, considering only the healthy control group.

	Healthy-control group (n = 381)	Diabetes group (n = 381)	OR (95% IC)
Unsatisfactory relationships	9.1%	18.0%	1.74 (0.99 – 3.05)
Family atmosphere not-welcoming	0.4%	8.0%	17.39 (2.24 – 134.99)
Follows social distancing	93.4%	97.0%	0.68 (0.29 – 1.62)
Child full time at home	79.6%	86.1%	1.45 (0.89 – 2.38)
Family income decreased	68.3%	72.4%	1.02 (0.67 – 1.54)
Purchase difficulty	9.6%	38.7%	4.89 (2.87 – 8.32)
Difficulty in medical assistance	15.1%	44.2%	4.00 (2.54 – 6.30)
Positive screening for mental health disorders[†]	46.6%	69.0%	2.68 (1.82 – 3.96)

Data are prevalence (%) and odds ratio (OR) with confidence interval (95%). An OR greater than 1 means that there was an increase in likelihood to present the psychosocial characteristic evaluated in the diabetes group in relation to the comparator group (OR for control group = 1). All odds ratio are adjusted for age of the child, race/ethnicity, income and region of origin. † Positive screening for mental health disorders accessed by a score greater than or equal to 7 on the SRQ-20.

Supplementary table 3: Support, relationships and consequences of social distancing in study participants considering age range of the dependent.

	Diabetes group OR (95% IC)
<i>Age < 6 years</i>	n = 34
Unsatisfactory relationships	1.93 (0.68 – 5.47)
Family atmosphere not-welcoming	2.83 (0.43 – 18.86)
Purchase difficulty	6.50 (2.37 – 17.81)
Difficulty in medical assistance	1.88 (0.75 – 4.75)
Positive screening for mental health disorders †	2.92 (1.08 – 7.94)
<i>Age ≥ 6 and ≤ 12 years</i>	n = 144
Unsatisfactory relationships	2.37 (1.14 – 4.93)
Family atmosphere not-welcoming	5.98 (1.27 – 28.06)
Purchase difficulty	7.86 (3.59 – 17.22)
Difficulty in medical assistance	3.84 (2.12 – 6.94)
Positive screening for mental health disorders †	2.89 (1.73 – 4.84)
<i>Age > 12 years</i>	n = 146
Unsatisfactory relationships	1.29 (0.49 – 3.35)
Family atmosphere not-welcoming	*
Purchase difficulty	2.49 (1.12 – 5.52)
Difficulty in medical assistance	3.69 (1.76 – 7.71)
Positive screening for mental health disorders †	1.83 (0.99 – 3.38)

Data are odds ratio (OR) with confidence interval (95%). %. An OR greater than 1 means that there was an increase in likelihood to present the psychosocial characteristic evaluated in the diabetes group in relation to the non-diabetes group (OR for non-diabetes group = 1). All odds ratio are adjusted for age of the child, race/ethnicity, income and region of origin. *There is not enough data for the analysis. † Positive screening for mental health disorders accessed by a score greater than or equal to 7 on the SRQ-20.

Supplementary table 4: Support, relationships and consequences of social distancing in study participants considering ethnicity.

	Diabetes group OR (95% CI)
Race/ethnicity white	n = 262
Unsatisfactory relationships	1.63 (0.91 – 2.88)
Family atmosphere not-welcoming	4.19 (1.37 – 12.79)
Purchase difficulty	4.46 (2.65 – 7.52)
Difficulty in medical assistance	3.03 (1.95 – 4.71)
Positive screening for mental health disorders	2.06 (1.39 – 3.06)
Personal concern	1.32 (0.81 – 2.14)
Child-related concern	2.25 (1.20 – 4.24)
Personal emotional burden	2.10 (1.37 – 3.23)
Child-related emotional burden	1.94 (1.31 – 2.90)
Race/ethnicity not white	n = 119
Unsatisfactory relationships	3.65 (1.12 – 11.90)
Family atmosphere not-welcoming	1.05 (0.94 – 1.19)
Purchase difficulty	6.99 (2.30 – 21.21)
Difficulty in medical assistance	5.56 (2.09 – 14.80)
Positive screening for mental health disorders	4.69 (1.96 – 11.22)
Personal concern	3.21 (0.98 – 10.49)
Child-related concern	2.39 (0.55 – 10.53)
Personal emotional burden	2.19 (0.81 – 5.90)
Child-related emotional burden	6.84 (2.49 – 18.79)

Data are odds ratio (OR) with confidence interval (95%). An OR greater than 1 means that there was an increase in likelihood to present the psychosocial characteristic evaluated in the diabetes group in relation to the non-diabetes group (OR for non-diabetes group = 1). All odds ratio are adjusted for age of the child, income and region of origin.

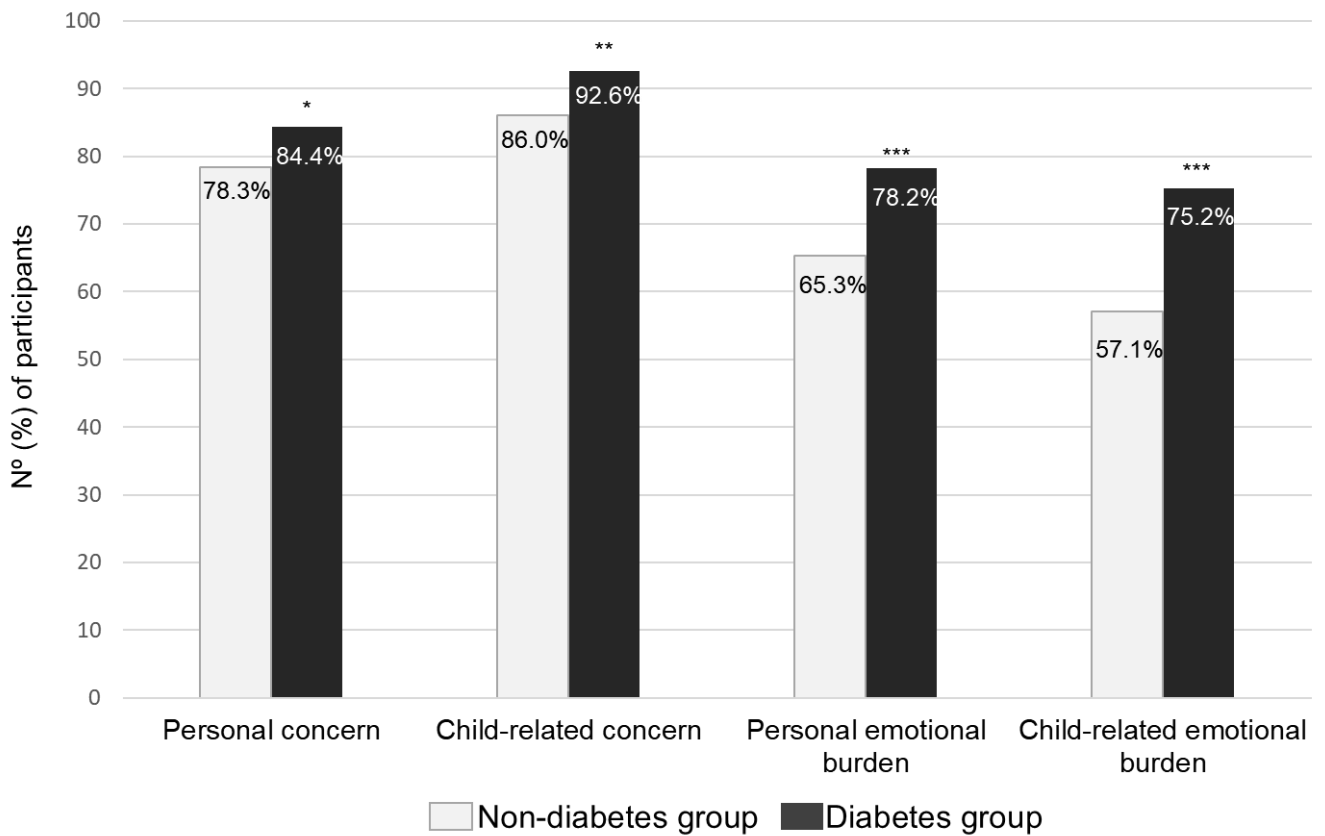


Figure 1. Assessment of pandemic-related emotional burden between the diabetes group and the non-diabetes group.

The evaluation of pandemic-related emotional burden between was performed in four domains using the Likert scale of 5 points of agreement. The domains were evaluated through the statements: (1) personal concern - "I often feel worried and afraid of being infected with the coronavirus"; (2) concern related to the child - "I often feel worried and afraid that my child may be infected with the coronavirus"; (3) personal emotional burden: "I often feel tired and exhausted due to the change in routine since the social distancing started due to the COVID-19 pandemic"; (4) child-related emotional burden: "I often feel tired and exhausted from the responsibility to protect my child during the COVID-19 pandemic". It was considered "totally agree" and "agree" as an affirmative answer. The graphs show the percentages of people with affirmative answers to the proposed statements in each group. *P = 0.041; ** P=0.005; *** P<0.001.

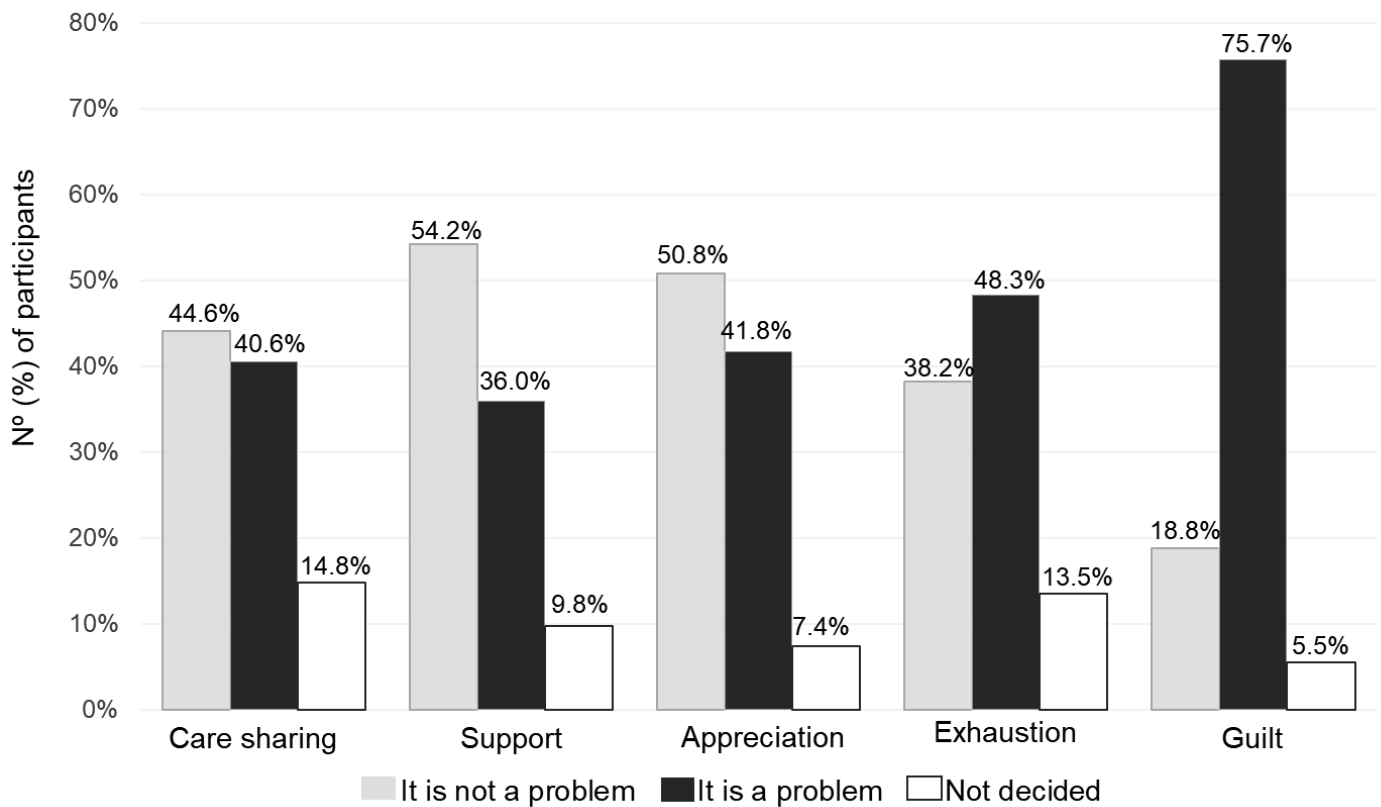
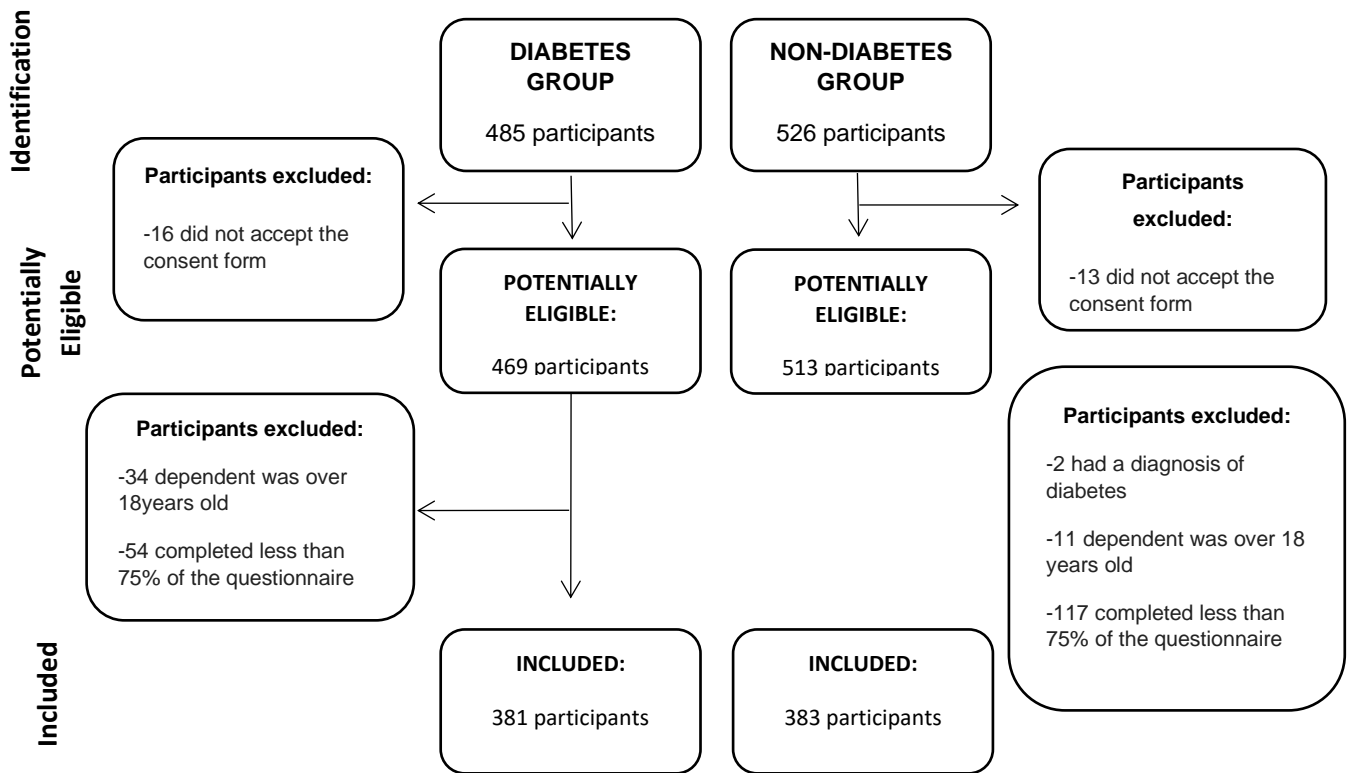
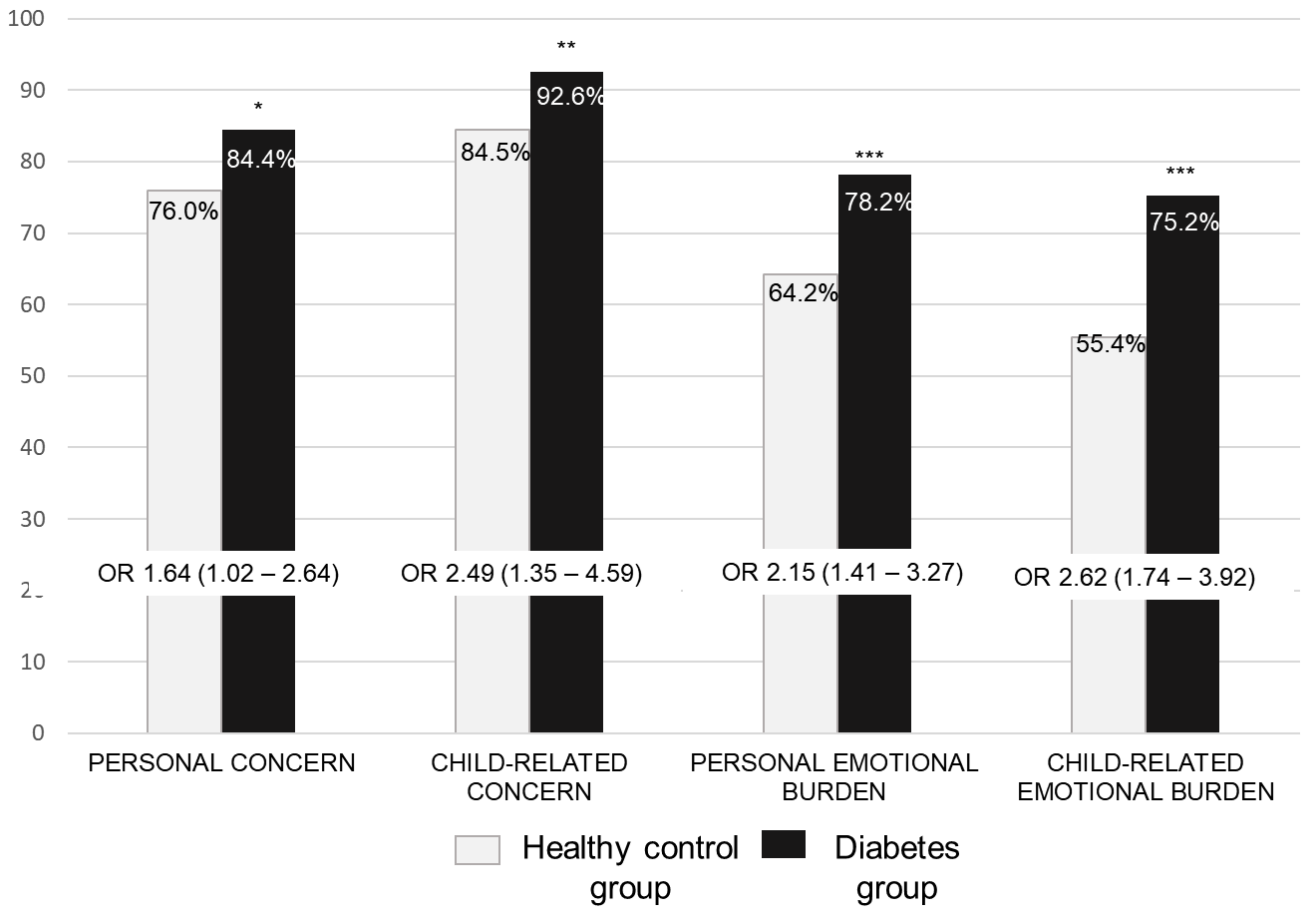


Figure 2. Assessment of diabetes-specific emotional burden related to diabetes care in caregivers of children and adolescents with a previous diagnosis of type 1 diabetes during the COVID-19 pandemic.

The evaluation of diabetes-specific emotional burden related to diabetes care was performed using the Likert scale of 5 points of agreement. The domains were evaluated through the statements: (1) sharing of care: "I feel frustrated because I am the only one responsible for helping my child use medications and manage glycemic control."; (2) support: "I feel frustrated with the lack of understanding and support I get from friends and family in relation to taking care of someone with diabetes."; (3) appreciation: "I feel underestimated for all the effort I put into helping my child to take care of diabetes."; (4) exhaustion: "I feel that my child's diabetes is consuming a lot of my physical and mental energy every day."; (5) guilt: "I feel guilty if my child's diabetes is not well controlled." It was considered that *it is a problem* if the answer was "totally agree" and "agree", and *it is not a problem* if the answer was "strongly disagree" or "disagree".

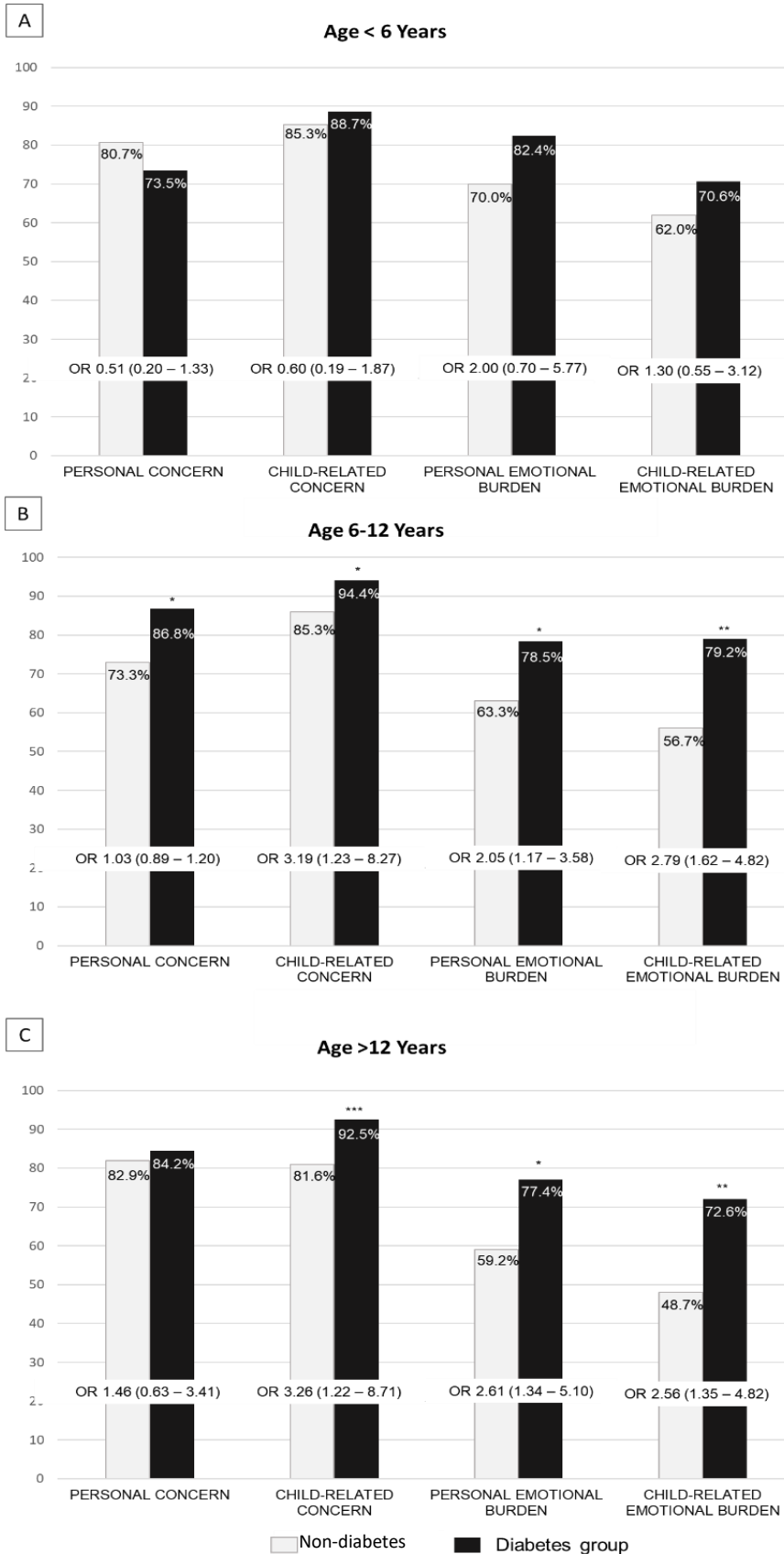


Supplementary figure 1. Number of patients identified, eligible and included in the study in the diabetes and non-diabetes groups.



Supplementary figure 2. Assessment of pandemic-related emotional burden between the diabetes group and the healthy control group.

In this evaluation, we included only participants who were caregivers of healthy children, without chronic diseases in the control group (n= 274). The graphs show the percentages of people with affirmative answers to the proposed statements in each group and OR (95% CI) adjusted by the age of the child, race/ethnicity, region of origin and income. *P = 0.01; ** P<0.01; *** P<0.001.



Supplementary figure 3. Assessment of pandemic-related emotional burden between the diabetes group and the non-diabetes group according to the age range of the youth.

The graphs show the percentages of people with affirmative answers to the proposed statements in each group and OR (95% IC) adjusted by the age of the child, race/ethnicity, region of origin and income. A: Includes children under 6 years old. B: Includes youth aged 6 to 12 years. C: Includes adolescents over 12 years old. * $p < 0.01$ ** $p < 0.001$ *** $p = 0.02$

ARTIGO 3

“Not having a minute of self-distancing during the social distancing is exhausting”: a qualitative study on the perspective of caregivers of youth with type 1 diabetes during the COVID-19 pandemic.

Perspectives of caregivers of youth with diabetes

Janine Alessi, MD^{1,2}; Giovana B. de Oliveira³; Isadora N. Erthal³; Julia B. Teixeira³; Milena S. Morello³; Raquel J.E. Ribeiro³; Taíse R. de Carvalho, MD^{3,4}; Eduarda H. Jaeger³; Beatriz D. Schaan, MD PhD^{1,5,6}; Gabriela H. Telo, MD PhD^{2,3,4}

1. Post Graduate program in Medical Science: Endocrinology, Universidade Federal do Rio Grande do Sul, Brazil
2. Internal Medicine Department, Hospital São Lucas - Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
3. School of Medicine, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
4. Graduate program in Medicine and Health Sciences, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
5. School of Medicine, Universidade Federal do Rio Grande do Sul, Brazil
6. Endocrinology Division, Hospital de Clínicas de Porto Alegre, Brazil

ABSTRACT

OBJECTIVE: To investigate the impact of the COVID-19 pandemic on caregivers of youth with type 1 diabetes.

METHODS: We performed a qualitative research based on an open-ended questionnaire that was conducted through an online platform for primary caregivers of children and adolescents with type 1 diabetes. Participants were asked to describe the impact of the COVID-19 outbreak on their caring for youth with diabetes, as well as the emotional burden that it has brought to their personal lives. Interview responses were coded and stratified by youth age: ≤ 12 years (youth aged ≤ 12 years) and between 13 and 18 years (youth aged > 12 years). The connections between the responses were identified based on either positive or negative content of the reported experience. Data were analyzed in accordance with an inductive reasoning methodology.

RESULTS: A total of 318 participants (mean age of 40.3 ± 8.1 years old) were included, representing caregivers of youth aged 11.7 ± 4.3 -year-old with diabetes duration of 5.1 ± 3.8 years. The preponderance of negative feelings was noteworthy. Regarding diabetes care, more than 80% of participants reported concern and anxiety about the changes in habits that accompanied the pandemic. Also, more than half of caregivers regretted the isolation of their youth, factors that were associated with greater difficulty in achieving good glycemic control. Regarding the personal burden experienced, the negative impact of uncertainties and concerns about the COVID-19 were present in almost all participants.

CONCLUSION: The period of pandemic may lead to exhaustion in caregivers of youths with type 1 diabetes, which reflects the need for mental health support strategies to help those families.

Keywords: COVID-19 outbreak, type 1 diabetes, emotional burden, mental health, caregivers, social distancing.

INTRODUCTION

The diagnosis and management of youth with type 1 diabetes may have a negative emotional impact on parents and caregivers. Concern about hypoglycemia, fear of future complications, and guilt about glycemic control can result in excessive worries, depressive symptoms, and anxiety disorders (1,2). A study carried out in a non-pandemic situation showed that caregivers of children play a fundamental role in controlling the disease and experience the responsibility for any short or long-term consequences related to diabetes (3). Another study showed that parents suffer from constant concerns about the care for their children even when the child was with a secondary caregiver. It makes the role of caregivers a full-time job (4). The emotional burden of caregivers might have consequences not only on the parents' psychological well-being, but may also have indirect effects on glycemic control of the youth (2,5). A better understanding of the negative feelings experienced by parents and caregivers is necessary for the development of supporting strategies that promote an improvement in family well-being (1).

The COVID-19 pandemic has the potential to cause a significant emotional burden on caregivers of youth with type 1 diabetes. In usual situations, these caregivers need regular support from health professionals to feel confident about the care of their youth's diabetes and to help in the management of emotional reactions and life changes that accompany the diagnosis (6). The unavailability of medical appointments and the difficulty in obtaining specialized support during the pandemic may generate feelings of concern and insecurity in this group. Moreover, the fear of possible infection by the new coronavirus and the uncertainty regarding its severity in patients with diabetes makes the current pandemic even more alarming for caregivers (7,8). These circumstances reveal a greater vulnerability of those responsible for youth with diabetes to experience emotional distress during the outbreak.

The social distancing measures required by the COVID-19 pandemic may also become a challenge for caregivers of children and adolescents with diabetes, who are forced to face a new reality with their youth at home full time. Also, children and adolescents may be lonelier and more anxious than usual, which can make it even more difficult for parents to deal with this new personal distress (9). Ergo, understanding how the pandemic is affecting these caregivers

and knowing the psychological demands of these families is essential for the development of coping strategies for similar situations in the future. A previous study evaluated the impact of the pandemic on the mental health of caregivers of youth with type 1 diabetes compared to caregivers of youth without diabetes. This study found a positive screening for mental health disorders during social distancing more often in caregivers of youth with type 1 diabetes (OR 2.43; 95% CI, 1.70 to 3.47), particularly in those aged under 12 years old (10). However, there are no studies to date assessing caregivers' impressions about the changes that occurred during the pandemic, and the importance of caring for caregivers of youth with type 1 diabetes in this situation is still overlooked. This inductive reasoning study aims to explore the experiences and perceptions of how the current pandemic is affecting these caregivers, generating important insights for future strategies and mental health support.

METHODS

Study Design and Participants

This study uses web-based qualitative research to evaluate the emotional repercussions of the COVID-19 pandemic in caregivers of youth with type 1 diabetes. A non-directive approach using free-form comments was used throughout the study. Guidelines for web-based qualitative health research were used for the study design (11-13). Adults of any age who were the primary caregivers of children and adolescents (aged less than or equal to 18 years old) with a previous diagnosis of type 1 diabetes were electronically recruited to participate in this study. Considering the limitations on interactions between the participants and the researchers during the pandemic, and aiming to preserve the safety of both, all study procedures were carried out remotely. The invitation to participate was issued through the social media of the Juvenile Diabetes Association, a society that integrates associations throughout Brazil intended for caregivers of children and adolescents with diabetes. Electronic invitations were sent between May 18 and June 9 of 2020, approximately two months after the beginning of the pandemic in Brazil. Inclusion criteria were being an adult over 18 years of age and being the parent or primary caregiver of children/adolescents aged less than or equal to 18 years old with type 1 diabetes. Caregivers of youth without type 1 diabetes were excluded from this study. During the evaluation, Brazil was considered one of the epicenters of the COVID-19 spread, justifying

the suspension of school activities and non-emergency medical consultations. The manuscript description follows the consolidated criteria for reporting qualitative research (COREQ) guidelines (14).

Data Collection

Free-form answers to non-directive questions were provided through the SurveyMonkey online platform (San Mateo, CA, U.S.A.; <http://www.surveymonkey.com>). There was no direct interaction between the researcher and the participant during the study. The choice of this model was based on its potential to acquire a subjective and deep understanding of the attitudes, feelings, and motivations of the participants, using open surveys and self-administered questionnaires in the form of free-form comments to examine the impact of the COVID-19 pandemic in caregivers. This format used reveals views and feelings normally inaccessible through direct questions and provides greater insight into attitudes and intentions than predefined questions, which are often directed or biased (11-13,15). Moreover, this model proved to be appropriate for assessing a large amount of data during the pandemic, saving participants from exposure and unnecessary risks.

The assessment was performed in two steps. First, an objective questionnaire regarding sociodemographic and clinical information was sent to participants. Data referring to the latest glycated hemoglobin, the presence of complications of the disease, and other aspects related to diabetes were based on the caregivers' report. Second, a subjective assessment was performed to explore the experiences and perceptions of how the current pandemic is affecting these caregivers. For this evaluation, free-form spaces were left to the participant to openly discuss the emotional impact of the pandemic. This assessment was conducted using the following non-directive questions:

1. The burden of care: Describe, in your words, how the current COVID-19 pandemic has impacted your life related to the child or adolescent for whom you are responsible.
2. Personal emotional impact: Describe how you feel, in the context of social distancing, about the emotional burden that the COVID-19 pandemic has brought into your life.

Responses were automatically recorded on the online platform. As there was no direct contact with the researcher and the answers were free text, the information was not discussed until it was saturated, which is a limitation of the chosen web-based model. Furthermore, considering the emergency of the COVID-19 pandemic and the need for quick responses to provide important insights for the psychological support of these caregivers, there was no time to conduct a pilot study with the proposed survey strategy.

Questionnaires were applied for changes that occurred during the COVID-19 pandemic. This assessment included social distancing, maintenance of school activities, family income, and difficulty in medical assistance. It was considered “partial social distancing” for participants who went out for basic activities, such as market, pharmacy, and health care. Total social distancing refers to participants who followed the orientation of home quarantine. School activities were considered partially suspended if the youth maintained remote scholar activities during the pandemic, and totally suspended if no school activities were performed. The questionnaire included “yes” or “no” response options for the presence of difficulties related to family income and medical care assistance during the pandemic.

Research Team and Reflexivity

Researchers J.A (MD), B.D.S (MD Ph.D.), and G.H.T (MD Ph.D.), females, were responsible for preparing the proposed open-ended questionnaire. B.D.S and G.H.T have extensive experience in caring for children and adolescents with type 1 diabetes, and the researchers, J.A, G.B.O, B.D.S, and G.H.T, have carried out several studies evaluating the impact of the COVID-19 pandemic on patients with diabetes (10,16). The study participants had no previous relationship with the researchers. In the enrollment, the interests and motivations for conducting the proposed interview were explored in an introductory text.

Sampling

One advantage of the online survey interview format was the convenience for participants, who could answer the questions from their homes, increasing the response rates. Besides, the absence of an interviewer reduced the risk of the social-desirability bias. The initial protocol of this study was designed for a quantitative evaluation of the impact of the pandemic on caregivers of youth with

type 1 diabetes. For this reason, the sample size included in this study was based on the calculation performed for the primary quantitative analyses. The results and detailed description of the quantitative evaluation were published previously (10). The Krejcie and Morgan Sampling Formula was used to determine a sample size for a quantitative analysis using a 95% confidence level and a margin of error of 0.05 (18). Considering the prevalence of youth with type 1 diabetes in Brazil in 2019, 380 responses in the diabetes group were determined to be necessary to obtain the adequate power necessary for the sampling (19). Therefore, this sample size was extrapolated for the qualitative assessment.

Analysis

The data were transcribed from the online platform SurveyMonkey, (San Mateo, CA, U.S.A.) to Microsoft Excel® (2010). Data were analyzed in accordance with the methodology for web-based qualitative data using an inductive reasoning methodology (14, 20). Interview responses were coded and stratified by the youth age group: ≤ 12 years (youth ≤ 12 years) and between 13 and 18 years (youth > 12 years). Each response was read and re-read, ensuring that new insights were generated, and the semantic content was fully explored. The main themes were previously defined, according to the questions in the online survey. The connections between the responses were identified based on the positive or negative content of the reported experience. Following this step, all responses were analyzed, and the patterns between them were investigated to describe the participants' shared experiences. Throughout the analysis, the topics were discussed between researchers (J.A, G.O.B, J.B.T, I.N.E, R.E, M.M.), which ensured uniformity and systematization of the analyses based on the participants' original responses. The coding tree is available in Supplementary figure 1.

Ethical Aspects

The project was approved by the research ethics committee (n^o 4.045.411) and all patients included in the study agreed to the informed consent form.

RESULTS

Participants

A total of 485 responses to the online questionnaire were collected, of which 16 did not accept the consent form, 35 youths were over 18 years old and 54 did not answer the free-form questions. The enrollment ended when 380 eligible participants had completed 75% of the questionnaire. A total of 62 participants chose not to answer the free-form non-directive questions. Thus, interviews with 318 participants were included in the analysis, being 174 of caregivers of youth ≤ 12 years and 144 of caregivers of youth > 12 years.

The included participants had a mean age of 40.3 ± 8.1 years; 95.6% were female; 69.5% were white; 50.6% had medium or low family income. Regarding youths, the mean age was 11.7 ± 4.3 years, with a mean diabetes duration of 5.1 ± 3.8 years. Concerning the COVID-19 pandemic, 36.5% of participants were following the guidance of total social distancing, without leaving home for any activity, and 67.3% of the caregivers reported that their youths had had their school activities suspended during the pandemic. Those who had school activities maintained these online (see table 1).

1.1. *The Burden of Caring for Type 1 Diabetes in Youth aged ≤ 12 Years during an Outbreak*

A total of 141 (81.5%) of the 174 interviewees reported that the pandemic had affected them negatively, increasing their burden related to the care of children's diabetes. Concern about diabetes control was the main feeling mentioned. According to most caregivers, the glycemic control became worse and more difficult during the pandemic, which increased their distress about the care of these youth aged ≤ 12 years.

We are having problems with glycemic control because staying at home all the time has made my daughter angry. This stress alters her glucose control and worsens the anxiety, which makes her want to eat all the time and not always healthy things. It worries me and tires me a lot. (Mother, 32 years old, 12-year-old child).

In addition to the impact on diabetes care, the pandemic was accompanied by challenges regarding the isolation of these youth aged ≤ 12 years. Not being able to go to school, practice their usual daily activities, and maintain their normal

routines were considered negative effects of social distancing measures, generating anxiety and concerns for children and caregivers. This reality brought even greater pressure to parents, who felt a duty to keep the children entertained during the day.

It is challenging occupying, to make children expend energy and not feel the impact of everything that is happening. It is a challenge not to have social interaction at my child's age, and this is having an impact on me.”
(Mother, 37 years old, 5-year-old child).

The overuse of electronics by youth was mentioned by several caregivers, generating different feelings. Some considered the increase in screen time (video games, computers, and smartphones) a negative consequence of social distancing, which aggravated sedentary behaviors and worsened glycemic control. This has become a serious concern for caregivers. However, some caregivers considered this technology a form of refuge and distraction for youth and supported its use.

He likes games, and, while playing, he doesn't pay much attention to the bad things that are happening. That's why I have let him play. (Mother, 42 years old, 11-year-old child).

1.2. *The Burden of Caring for Type 1 Diabetes in Youth aged > 12 Years during an Outbreak*

Overall, 120 (83.9%) of the 144 interviewees responsible for youth aged > 12 years reported that the pandemic had affected them negatively. Similar to the caregivers of youth aged \leq 12 years, most caregivers reported “distress” and “sadness” due to the isolation of youth, which is an even greater challenge in this age group. These parents associated confinement with changes in their youth's mood, such as irritability, lack of patience, and aggressiveness in speech.

There is a lot of frustration because she is very sensitive and does not accept the confinement. That makes me sad, without reaction. I often get lost when she doesn't want to eat or eats the wrong foods. (Mother, 52 years old, 18-year-old adolescent).

Also, many interviewees reported that changes in daily habits during the pandemic significantly impaired their youth's glycemic control. These changes,

added to the suspension of medical appointments, were associated with increased “anxiety” and “distress” in the caregivers, resulting in a feeling of “helplessness” in the face of difficulties and uncertainties related to the young adult’s health. “Frustration” at inadequate glycemic control proved to be common among those caregivers.

She is just at home, unable to practice physical exercises. The routine of being alone inside the house ends up complicating the control of diabetes. Eating more, spending more time lying down watching TV; it’s very difficult.
(Mother, 40 years old, 18-year-old adolescent).

Many caregivers regretted their financial difficulties in ensuring nutritious food and supplies for their youth during the pandemic, resulting in “guilt” and “uncertainty” regarding the possibility of continuing treatment. Finally, during times of uncertainty and anxiety, some parents also reported that they were trying to transmit security to their youth, which can become a burden and, consequently, another exhausting factor.

A minority of caregivers expressed being “calmer” and “less exhausted” during the pandemic. Some caregivers said that the youth aged > 12 years autonomy on diabetes care has doubled.

I feel my son is more mature, more willing to take care of himself. I hope this pandemic was the key he needed. (Mother, 39 years old, 18-year-old adolescent).

2.1. *Personal Impact of the Pandemic Era on Youth aged ≤ 12 Years Caregivers*

Regarding the personal impact that caregivers of youth aged ≤ 12 years with type 1 diabetes reported during the pandemic, approximately 155 (89.6%) interviewees felt that the pandemic had affected them negatively. Fear of the COVID-19 infection was the most addressed sentiment. Many caregivers emphasized this feeling due to their child’s disease and were fearful about a possible relationship between type 1 diabetes and serious outcomes if infected. The lack of information about the relationship between COVID-19 and type 1 diabetes was remembered as an aggravating factor for the fear presented. Furthermore, several other responsibilities triggered weariness and exhaustion in

caregivers, such as the financial situation and the condition of health institutions during the pandemic.

I feel like my hands and feet are tied, because I can't get the supplies my son needs, while dealing with the lack of medical care at the center where he should be cared for. (Mother, 41 years old, 12-year-old child).

Feelings often reported were “tiredness,” “exhaustion,” and “overload”, present in about one-third of the responses. Caregivers’ statements reflected the changes that had occurred since the beginning of the social distancing measures when they were forced to assume the dual role of family provider and full-time caregiver. The workplace, which for many became a home office, has been challenging considering the child's presence and interference throughout the day. Also, the child's increased time at home after the closing of schools increased the demand for attention from caregivers. Many of them indicated that it had been very difficult to conciliate the demands of work and the necessity of caring for the youth at home, which made them feel unable to succeed in either role, generating more distress and anguish. Moreover, the lack of privacy and time for themselves made these caregivers feel overwhelmed.

I am overloaded by having a triple journey: taking care of my son, the house and working, since all three tasks have an increased load. (Father, 44 years old, 4-year-old child).

I feel unhappy. Not having a minute of self-distancing during the social distancing and always being available to everyone is exhausting. (Mother, 30 years old, 4-year-old child).

2.2. Personal Impact of the Pandemic-Era on Youth aged > 12 Years Caregivers

Concerning the emotional impact that caregivers of youth aged > 12 years with type 1 diabetes are experiencing, a total of 132 (92.3%) interviewees felt that the pandemic had affected them negatively. The first major source of worry was related to the COVID-19 infection and its consequences. This concern seemed to be expressed even more among youth aged > 12 years caregivers considering the youth's greater autonomy and desire for socialization. For those youth who followed social distancing measures, caregivers reported concern and guilt

related to the possibility of contracting the virus, a situation that aggravated their distress.

I feel constantly worried and guilty in the rare moments when I work outside the home. (I am) fearful of being contaminated and bringing the virus to my son, who is in total isolation at home. I miss socializing with friends and family, but the responsibility for him is a priority. (Mother, 42 years old, 13-year-old adolescent).

Caregivers also suffered frustration with youth' expectations about their desires and routine. The lack of freedom to come and go, the desire to see friends and family, and the suboptimal diabetes control during the pandemic were some factors that resulted in disagreements and worsened family relationships. The conflictual relationship with the youth during this period of greatest vulnerability led to emotional exhaustion in caregivers.

I feel very scared for her. She's in her teens, so it's more complicated. She wants to go out, but my husband and I won't let her, so she gets mad. It is a delicate time for all of us, and I feel exhausted. (Mother, 34 years old, 15-year-old adolescent).

The feelings of “uncertainty” and “powerlessness” were also expressed by caregivers. Not having control over the spread of the coronavirus, not knowing when this pandemic will end, and not having confidence about an improvement in the family's income made caregivers feel as their “hands were tied”. The reduction of work and unemployment were cited by some parents as important causes of suffering during the pandemic. Among with financial difficulties, caregivers dealt with the anguish of being unable to buy the necessary supplies to care for their youth's diabetes. This resulted in an unimaginable burden for these individuals.

(I have) uncertainty about what will become of my work, because I work on my own, and do not receive help from anyone. The SUS [public health system in Brazil] has already failed to supply the diabetes treatment several times, and, without that, I had to buy them. During the pandemic, the work decreased, and expenses increased. How will I be able to maintain my child's treatment? (Mother, 49 years old, 13-year-old adolescent).

DISCUSSION

Social distancing measures and the psychological burden of facing a pandemic have negatively sensitized most of the caregivers of children and adolescents with type 1 diabetes. Regarding the care of their youth, most participants reported concern and anxiety related to changes in habits that accompanied the social distancing, factors that were associated with worsening glycemic control in some cases. Additionally, feelings of anguish and guilt accompanied the financial difficulties that some families have faced during this period. The inability to provide quality food and supplies for diabetes may imply worse glycemic control, which was mentioned as a cause of emotional distress. Most of the participants also regretted the isolation of their youth. The perception of changes in mood and irritability in the youths brought even more anguish and sadness to their caregivers. Despite the uncertainties and concerns about the COVID-19 infection being spread to the participants, feelings of weariness and exhaustion were pervasive among caregivers, although their origins differed. Increased family discussions and the difficulties involved with keeping the youth at home were the main sources of emotional burden in youth aged > 12 years' caregivers. The greater demand for attention and care of the children who were at home full time was the main cause of overload among youth aged ≤ 12 years' caregivers.

In pandemic situations, caregivers play a fundamental role in ensuring family care, stability, and security, which ends up consuming their time and energy (21). Our results show that caregivers for youth with type 1 diabetes felt an increased need to provide care and a greater responsibility during the COVID-19 pandemic. Whitemore et al., in a study conducted in a non-pandemic context, showed that parents of children with type 1 diabetes had a higher basal rate of stress and greater concern, given that diabetes care requires a lot of responsibility, time, work, and routine (22). When we consider a pandemic scenario in which many caregivers report a change in youth habits, a worse glycemic control, and an increase in concerns related to the youth's health, the negative feelings are exacerbated.

Social distancing measures also negatively affected both the youth and caregivers. School-age and younger child caregivers more often reported feelings of exhaustion and fatigue, which were mostly related to the increased

demand for attention at home. Similar results were found in studies conducted with caregivers of children without diabetes during the COVID-19 pandemic (24, 25). An Italian study evaluated exhaustion in parents during the lockdown by COVID-19 and showed that the cancellation of children's classes and social activities makes it very difficult for caregivers to reconcile work with the needs for attention, play, and education demanded by children (26). This demand is even greater for caregivers of children with diabetes, considering an additional concern about glycemic control, which can trigger a physical and psychological burden.

In addition, the consequences on the social and psychological development of children have been even more pronounced than in adults, with irritability, distraction, and anxiety being commonly expressed by this age group (27). Social distancing measures may also affect the adolescent's mental health, as a result of losing interaction with peers and, consequently, affecting the child's interpersonal relationships (28). In the present study, most caregivers regretted the isolation of their youth and associated this with feelings of frustration, boredom, and irritability for the young adult. Another factor to consider is the young adult's perception of the pandemic. On one hand, it is common for adolescents to underestimate the danger of COVID-19, which causes concern for caregivers and may trigger confrontations (29). On the other hand, teens are more attentive and have the ability to understand what is happening. These factors may directly impact the caregivers, who experience the consequences of such emotional upheaval.

The difficulties pointed out by the caregivers make us reflect on possible strategies that could be used to mitigate the psychological impact in similar situations. First, the concern of family members draws attention to the lack of information that they have received about the relationship between COVID-19 and type 1 diabetes. The provision of easily accessible channels with reliable information could be an important ally and reduce the feeling of incompetence in these families. Second, the concern about the lack of care and the preoccupation with glycemic control is evident. The creation of specialized and low-cost telehealth centers for patients with type 1 diabetes is one way to meet the demands of care during the pandemic and should be prioritized. Third, channels for listening to these caregivers and providing guidance on emotional self-care should be made available. These could be effective and prevent the sense of

overload. Fourth, the provision of multidisciplinary channels, through social media or phone, which allows free and easily accessible information on physical and nutritional guidance and mental health care for youth with type 1 diabetes could be very useful in such situations. Fifth, the use of applications that encourage playful activities for children and keep them entertained without the need for full-time parental attention could alleviate parents' exhaustion. Finally, creating groups on social media that allow peer interaction could be beneficial in allowing these caregivers to share their perceptions and help each other.

Our study has some limitations. The nature of the interviews, which were conducted via a website and without interaction with the researchers, did not allow the discussion of the issues until they were saturated. In addition, it is possible that caregivers who were most concerned and impacted by the pandemic were also more interested in answering the proposed questionnaire. Given that this was an online survey, the results depend on the commitment of the participants and on the veracity of the information provided, which may constitute potential information bias. Finally, most participants were female caregivers, which may reduce the validity of the results for male representatives. This high prevalence is in line with other studies conducted in pediatric outpatient care in Brazil, in which the mother plays the role of primary caregiver in 91.0 to 93.7% of cases (10, 30-31). Still, the emotional and physical overload that caregivers of youth with type 1 diabetes are experiencing during the current COVID-19 pandemic is plausible and deserves attention.

Despite these limitations, our study shows a potential negative impact on parents of children or adolescents with type 1 diabetes during the COVID-19 pandemic and it should not be neglected. The results suggest that periods of pandemics may create an emotional overload and lead to exhaustion those responsible for the care of youth with diabetes. More than ever, the mental well-being of caregivers should be prioritized, and coping strategies should be encouraged. The ability of parents to care, assist and protect their families depends mainly on their emotional well-being and resilience in the face of adversity.

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JA is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity and accuracy of the data.

Authors' Contributions. J.A: Conceptualization, Methodology, Data curation, Writing- Original draft preparation. G.O.B, J.B.T, I.N.E, R.E, M.M, T.C: Methodology, Writing- Original draft preparation. E.H.J: Writing- Reviewing and Editing. B.D.S Supervision, Writing- Reviewing and Editing. G.H.T Conceptualization, Supervision, Writing- Reviewing and Editing.

Consent for publication. All authors have reviewed the final version of the manuscript and agree with the publication of the results presented.

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Availability of data and materials. The data collected for the study, including deidentified participant data, will be available for 1 year after publication of the article upon justified request to the e-mail address of the main researcher and with a signed data access agreement.

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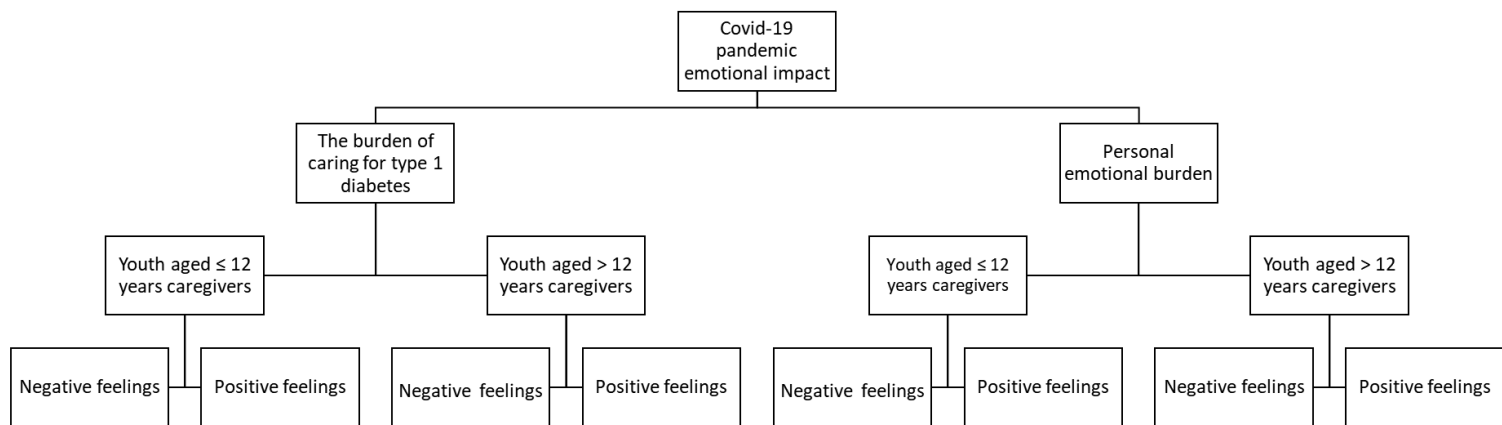
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Table 1. Sociodemographics and clinical characteristics of study participants.

	Total (n = 318)
Age (years)	40.3 ± 8.1
Sex (% female)	304 (95.6)
Race/ethnicity (% white)	221 (69.5)
Lower-middle income*	161 (50.6)
Parentage (% mother/father)	290 (91.2)
<i>Youth with type 1 diabetes characteristics</i>	
Age of the youth (years)	11.7 ± 4.3
Disease duration (years)	5.1 ± 3.8
HbA1c (%)	7.9 ± 1.4
mmol/mol	63 ± 15.6
<i>COVID-19 period assessment</i>	
Follows social distancing	
Totally	116 (36.5)
Partially	192 (60.4)
School activities	
Totally suspended	214 (67.3)
Partially suspended	79 (24.8)
Financial difficulty	122 (38.4)
Difficulty in medical assistance	139 (43.7)

Data are mean ± standard deviation or n (%). *Lower-middle income: a family that receives a total of fewer than 2564 reais per month, as defined by the *Strategic Affairs Secretariat (SAE)* of Brazil in 2012, equivalent to 495.8 dollars or 430 euros. It was considered “partial social distancing” for participants who go out for basic activities: market, pharmacy, and health care. Total social distancing includes participants who follow the orientation of home quarantine. School activities were considered partially suspended if the youth maintained remote scholar activities during the pandemic, and totally suspended if no school activities were performed.



Supplementary figure 1. Hierarchical coding tree of the research.

ARTIGO 4

Telehealth Strategy to *Mitigate* the Negative *Psychological Impact* of the COVID-19 Pandemic on Type 2 Diabetes: A Randomized Controlled Trial.

Tele-intervention and mental health in diabetes.

Janine Alessi, MD^{1,2}; Giovana Berger Oliveira³; Débora Wilke Franco, BSEd³; Alice Scalzilli Becker³; Carolina Padilla Knijnik³; Gabriel Luiz Kobe³; Bibiana Amaral³; Ariane Brito¹; Beatriz Dagord Schaan, MD PhD^{1,4,5}; Gabriela Heiden Telo, MD PhD^{2,3,6}

1. Post-graduate program in Medical Science: Endocrinology, Universidade Federal do Rio Grande do Sul, Brazil
2. Internal Medicine department, Hospital São Lucas - Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
3. School of Medicine, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
4. Post-graduate program in Medicine and Health Sciences, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil
5. School of Medicine, Universidade Federal do Rio Grande do Sul, Brazil
6. Endocrinology division, Hospital de Clínicas de Porto Alegre, Brazil

ABSTRACT

OBJECTIVES: To assess the impact of teleintervention on mental health parameters in type 2 diabetes patients during the coronavirus disease 2019 pandemic.

METHODS: This is a controlled randomized trial for a multidisciplinary telehealth intervention in Southern Brazil, with social distancing measures. Adults 18 years or older with previous diagnosis of type 2 diabetes were included in the study. The intervention performed was a set of strategies to help patients stay healthy during the COVID-19 pandemic and included the maintaining telephone contacts and providing educational materials on issues related to mental health, healthy habits, and diabetes care. The primary outcome was a positive screening for mental health disorders (Self-Reporting Questionnaire) after 16 weeks of intervention. A positive screening for mental health disorders was considered when the survey scored greater than or equal to 7. Secondary outcomes included a positive screening for diabetes-related emotional distress (Problem Areas in Diabetes), eating (Eating Attitudes Test), and sleep disorders (Mini Sleep Questionnaire). Comparisons with χ^2 tests for dichotomous outcomes, along with the Mann-Whitney U test, which was used for between group analyses.

RESULTS: A total of 91 individuals agreed to participate (46 intervention group and 45 control group). There were no differences in demographic and clinical data at baseline. After 16 weeks of follow-up, a positive screening for mental health disorders was found in 37% of participants in the intervention group vs. 57.8% in the control group ($P = 0.04$). Diabetes-related emotional distress was found in 21.7% of participants in the intervention group vs. 42.2% in the control group ($P = 0.03$). No differences were found between groups with regard to eating and sleep disorders.

CONCLUSION: This study demonstrated that maintaining remote connections with health professionals during social distancing and quarantine have the potential to reduce the prevalence of positive screening for mental health disorders and diabetes-related emotional distress in adults with type 2 diabetes.

KEYWORDS: COVID-19 pandemic, diabetes-related distress, Teleintervention, type 2 diabetes.

INTRODUCTION

Since the beginning of the coronavirus disease 2019 (COVID-19) pandemic, diabetes was one factor associated with worse clinical outcomes, due to mechanisms not fully understood [1,2]. The threat of a potentially serious infection and being part of a high-risk group creates worry and anxiety in patients with diabetes, making them vulnerable to mental health disorders. In addition to concerns about the COVID-19 pandemic and the possibility of a potentially serious infection, patients with diabetes experienced other challenges during the pandemic. Health appointments not fully accessible, difficulty in obtaining diabetes medications, and a lack of scientific information about the relationship between diabetes and COVID-19 result in psychological and emotional strain [3]. This becomes alarming when realizing that people with diabetes have more mood and anxiety disorders compared to the general population [4-6]. This greater psychological vulnerability was exacerbated during the COVID-19 pandemic [4], reflecting the need to care for the mental health of patients with diabetes.

So far, there is a lack of evidence-based guidelines, as well as a clear intervention plan to safeguard the health of patients with diabetes and mitigate COVID-19 pandemic effects on mental health with social distancing [7,8]. Remote interventions and virtual platforms could be potential strategies to allow providers to assist patients in the quarantine period [9]. This study aims to assess the impact of teleinterventions on mental health parameters in those with type 2 diabetes during the COVID-19 pandemic. We hypothesize that remote assistance may improve mental health outcomes.

METHODS

Study Design

An open-label and controlled randomized trial was conducted for a telehealth intervention during the COVID-19 pandemic. Electronic medical records were used to identify adults with a previous diagnosis of type 2 diabetes with regular outpatient follow-up in one of two public tertiary care hospitals in Southern Brazil. Study procedures started in April 2020, about a month after the national ordinance required social distancing for risk groups in Brazil. The study was done in accordance with the Helsinki Declaration, 2004, approved by the National Scientific Committee (No. 4.059.760). This trial was registered at

ClinicalTrials.gov (NCT04344210). Enrollment began on April 14, 2020 and ended on April 29, 2020. This reporting follows the CONSORT statement. [10]

Participants

Inclusion criteria involved: adults 18 years or older with a previous diagnosis of type 2 diabetes based on guideline recommendations; a HbA1c evaluation in the laboratory of the study's reference hospital in the three months prior to inclusion; and availability for weekly phone calls during the study. Patients hospitalized at the time of recruitment and those who had some serious limitation, preventing the necessary interaction, such as advanced dementia or severe hearing loss, were excluded.

Recruitment Procedure

Potential participants were identified by electronic databases from the main institutions. Patients who met inclusion criteria were randomly selected for a telephone call that included an invitation to participate in this study. Those who agreed provided informed consent electronically, including audio recording.

Allocation

After providing informed consent to participate in this study, patients were randomly assigned a 1:1 ratio with an electronic database, generated by the *Randomization.com* website. Due to characteristics of the intervention, blinding of participants and researchers was not possible. To minimize potential bias, inclusion in the study and assessment of outcomes were performed by different researchers, who were not involved in the randomization and data analyses.

Intervention Characteristics

The intervention was a set of strategies to help patients stay healthy during the COVID-19 pandemic. This included telephone calls, offering educational skills on healthy lifestyles, and complementing patients' usual clinical care. Remote methods preserved patients with diabetes from unnecessary exposure during social distancing. To develop intervention protocols and provide support for patient demands, a multidisciplinary team of general practitioners, cardiologists, endocrinologists, physical educators, and psychologists was available.

- 1) Telehealth intervention: Each participant was randomly assigned to be followed by a same trained researcher, called a *case manager*, responsible for making weekly calls for 16 weeks of follow-up. The calls lasted around 5 to 10 minutes and followed a pre-established script to ensure all patients received a similar intervention. Intervention protocols were developed by physicians, physical educators, and psychologists. Each week, a different topic was selected for participants. Topics included issues related to mental health and coping strategies, physical activity, healthy eating habits, and diabetes care. Complete scripts used for the 16 weeks of intervention are available in supplementary material.
- 2) Educational materials: Patients with difficulty in a specific area related to mental health or diabetes care received additional digital educational material. Information about healthy eating habits and physical exercise adapted to age and physical limitations were offered to all participants.
- 3) Clinical care: Intervention sought to complement the usual diabetes care. Adherence to treatment was encouraged on every call. Patients were routinely asked for reports on glycemic controls, following their provider's recommendation. Treatment adjustments were made in severe cases, such as recurrent hypoglycemia and difficulty in contacting health care providers. In those cases, treatment was recommended by an endocrinologist from the study team. If patients had outdated prescriptions and difficulty in contacting the health care providers, renewal was electronically carried out by the researchers. All specific issues that arose during the intervention were discussed with the multidisciplinary team.

Active-Control Group

At randomization, the active-control group received access to a website prepared by the multidisciplinary team. On this site, there were weekly posts about diabetes care, mental health, and lifestyle habits, similar to phone call protocols. Access to the website was free, with no control on the frequency of access. This group did not have direct contact with the researchers during 16 weeks of the study.

Outcome Measures

The original protocol was designed to assess metabolic outcomes, and mental health would be included as secondary outcomes. However, considering the expressive impact of the pandemic on mental health, a new sample size calculation was carried out to determine the sample size necessary for mental health as the primary outcome. This entire procedure was performed before the inclusion of participants in the study. Due to the extent of the pandemic in Brazil, which lasted longer than expected, and the limitation of laboratory tests during social distancing, it was impossible to perform glycemic control and mental health at the same time. So the primary outcome in this analysis was only about mental health.

Mental health outcomes were assessed using specific questionnaires, applied by trained researchers in telephone calls. To assess the effects of the intervention, all participants were evaluated at two different times: at inclusion in the study (baseline) and after 16 weeks of intervention. Baseline represents the first four weeks of social distancing during the COVID-19 pandemic, while follow up (evaluated after 16 weeks) represents the results after 20 weeks of social distancing in Brazil. The follow-up for the primary outcome was performed within 14 days, to yield the same pandemic period for all participants.

The primary outcome was a comparison between the two groups of the presence of a positive screening for mental health disorders at the 16-week follow-up period. For this, the Brazilian validated version of the *Self Report Questionnaire - 20* (SRQ-20) was used. A positive screening for mental health disorders was considered when the survey scored greater than or equal to 7 [11].

Secondary outcomes included a comparison of the 16-week follow-up period, between the two groups for a positive screening and for diabetes-related emotional distress, eating disorders, sleep disorders and treatment adherence. Diabetes-related emotional distress was assessed by the Brazilian validated version of the Problem Areas in Diabetes Scale (B-PAID) and considered when the score was greater than or equal to 40 [12]. Eating disorders were assessed by the Brazilian validated version of the Eating Attitudes Test (EAT - 26). A positive screening for eating disorders was considered when the score was greater than or equal to 20 [13]. To assess sleep disorders, the Brazilian version of the Mini Sleep Questionnaire (MSQ) was used: a positive screening was

considered for a score greater than or equal to 31 [14]. To assess treatment adherence, a Brazilian-Portuguese version of the Self-Care Inventory-revised (SCI-R) was used, and higher scores represent greater adherence [15].

At the end of the follow-up period, questionnaires were applied for changes that occurred during the COVID-19 pandemic. This assessment included: social distancing, maintenance of work activities, financial difficulties, and medical assistance. An assessment of patients' respiratory symptoms as well as the presence of COVID-19 was also carried out.

Demographics and clinical data on diabetes, presence of comorbidities, continuous use of medications, and the HbA1c value evaluated by high-performance liquid chromatography were collected from electronic medical records. Information about antidepressant or anxiolytic drugs and a previous diagnosis of psychiatric disorders were found in electronic medical records, and checked with patients.

Power Estimations for Primary Outcome

The initial protocol was designed for two outcomes: mental health and HbA1c levels. To detect a difference in HbA1c values of moderate effect size between groups with a power of 80%, a significance level of 0.05, and a total of 84 participants was necessary. For the mental health primary outcome, a total of 78 participants was required to detect a moderate effect size (0.5) for a minimum difference of 5.8 points between the groups in mental health disorders (16). Considering estimated withdrawal from the study, the sample size was inflated by 10% to a total of 92 participants (46 in each group). This final sample size ensured that a two-sided test with $\alpha = 0.05$ would have 95% power to detect a mean difference between groups for the mental health primary outcome.

Statistical Analysis

Analyses were performed using IBM-SPSS v.22 (Chicago, IL, US). For the presentation of the participants' characteristics, data were reported as mean \pm standard deviation (SD) for those in which the assumption of normal distribution did not seem violated; otherwise, data were reported as median \pm interquartile range (IQR). Differences between groups for baseline data were evaluated by the

unpaired *t*-test and the Mann-Whitney U test for continuous variables, plus Chi Square tests for categorical variables.

Data were analyzed with the intent-to-treat principle. A conservative, single-imputation approach with ‘last observation carried forward’ replaced missing values at follow-up. In our study, the baseline score replaced the missing follow-up value of an individual who did not provide follow-up data. Sensitivity analyses for the primary outcome were performed, including patients who completed the follow-up.

Results of the questionnaires were analyzed with the total scores and presence of a positive screening for the disorder based on cutoff values. Comparisons of positive screening between groups were performed with Chi Square tests. Data are reported as percentages (%) and odds ratios (OR) with the 95% confidence interval (CI). For total scores, we performed non-parametric tests to compare differences between and within-groups, given the baseline and follow-up values. The Mann-Whitney U test was used for between-group analyses, and the Wilcoxon Signed Ranks Test was used for within-group analyses. Data for total scores were reported as median \pm IQR. Primary outcomes used a significance level of 0.05.

Social Aspects During the Study

On March 19, 2020, the city of Porto Alegre, where most study participants reside, presented its first decree of a state of public calamity to prevent and tackle the epidemic of COVID-19. The ordinance that guides social distancing and regulates establishments was published on March 22, requiring social distancing for people older than 60, as well as prohibition of squares and parks. In the following weeks, measures were tightened, restricting establishments that offer essential services under the condition of using personal protective equipment, such as masks and maintaining a minimum interpersonal distance of two meters to maintain basic activities. A teleworking regimen was always encouraged when possible. On May 11, 2020, a strategy called “*controlled distancing*” was announced and put into practice in the state of Rio Grande do Sul, including Porto Alegre. This model defines structured and dynamic plans for each region based on new cases, the number of hospitalized patients, and the number of available hospital beds. Depending on the degree of risk, each region receives restrictive

measures, as per local peculiarities. Despite flexibility of restrictions at some points, social distancing for risk groups, such as those with diabetes, remained high throughout the study period.

During the pandemic period, the endocrinology service restructured the assistance organization in order to offer teleconsultations to patients with diabetes. The service's adaptation to remote assistance took place from May to June and gradually improved, reaching the peak of teleconsultations performed in the months of August and September. Thus, the usual care during the pandemic consisted of the delay of face-to-face medical appointments and the provision of telephone calls by the attending physician periodically.”

RESULTS

A total of 138 potentially eligible patients were identified, and recruitment stopped after finding the planned sample size. One patient was lost due to registry error. Despite 16 phone calls were proposed, some participants did not answer all weekly calls. The median number of phone calls received by participants in the intervention group was 15 (IRQ 14 - 16). Two patients received less than 10 calls, as requested (one received five calls and the other two calls). During the intervention, only two participants needed clinical support with adjustment of insulin doses, due to recurrent hypoglycemia; all other interventions were focused on mental health support and multidisciplinary strategies. At the end of the study, six patients did not respond to the final questionnaires, two patients did not answer the final phone call, one patient was hospitalized and did not want to interact with the researcher, and one patient was confused during the evaluation, unable to respond (see Figure 1).

Participant Characteristics

Overall (n = 91), participants had a mean age of 61.3 ± 9.1 years; 64.8% were female, 78.0% white, and 50.6% married. Eighty percent had lower-middle income and 30.6% had regular employment before the COVID-19 pandemic. The mean diabetes duration was 18.1 ± 9.5 years and the HbA1c value was $8.8 \pm 1.7\%$ (73.0 ± 18.6 mmol/mol), with 83.5% of participants on insulin treatment. Given the whole group, 20.9% of participants had a previous depression diagnosis, 6.6% had anxiety diagnosis, and 2.2% had bipolar disorder diagnosis.

Around 25.3% regularly used antidepressants and 9.9% used neuroleptic drugs. The two groups were comparable in all baseline characteristics (see Table 1).

Regarding social aspects during COVID-19, 32.9% followed total social distancing and 57.6% followed only partially (leaving home for basic activities, such as market, pharmacy, and health care). Most participants (69.4%) had contact with family during the study and 17.6% did not. The majority of participants (54.1%) had reduced family income and 5.9% lost their jobs during the pandemic. Regarding clinical issues, 24.7% had respiratory symptoms during the pandemic, 5.9% had confirmed COVID-19 infection, and 7.1% required hospitalization for any reason.

Primary Outcome:

Mental Health Disorders Screening

Considering the pre-established cutoff values, a positive screening for mental health disorders was equal between groups at the time of inclusion (baseline). After 16 weeks of follow-up, positive screening was found in 37.0% of participants in the teleintervention group vs. 57.8% of participants in the active-control group ($P = 0.04$) (see Figure 2). The control group had a likelihood of 2.33 (95% CI, 1.01-5.42) of presenting positive screening for mental health disorders in relation to the intervention group in the follow up (see Table 3). Sensitivity analysis was performed, including only participants who completed the follow-up ($n = 81$). Of them, 36.6% in the teleintervention group and 62.5% in the active-control group had a positive screening at follow-up ($p = 0.02$).

Given the total score of the SQR-20 questionnaire at follow-up, the teleintervention group presented a median of 5.0 (2.0 - 9.0) vs. 8.0 (3.0 - 12.0) in the active control group ($P = 0.09$) (Table 2). When including participants who completed the follow-up, this difference was greater [5.0 (2.0 - 9.5) in the teleintervention group vs. 8.5 (3.25 - 12.0) in the active control group; $P = 0.05$].

Secondary Outcomes:

1. Diabetes-related Emotional Distress

Considering cutoff values at follow-up, the presence of positive screening for diabetes-related emotional distress was found in 21.7% of participants in the

teleintervention group vs. 42.2% in the active-control group ($P = 0.03$) (see Figure 2). The control group had a likelihood of 2.63 (95% CI, 1.05-6.58) of presenting positive screening for diabetes-related emotional distress in relation to the intervention group in the follow up (see Table 3). Considering the B-PAID total score, groups were comparable at baseline. In the follow-up, the teleintervention group presented a median of 12.5 (6.0 to 29.5) vs. 27.0 (6.0 – 47.5) in the active control group ($P = 0.08$) (see Table 2).

2. *Eating Disorders*

At follow up, the presence of positive screening for eating disorders was found in 73.9% of participants in the teleintervention group vs. 77.8% of participants in the active-control group ($P = 0.67$). Considering the total score, the groups were comparable at both baseline and follow up.

3. *Sleep Disorders*

Positive screening for sleep disorders was found in 73.9% of participants in the teleintervention group vs. 73.3% of participants in the active-control group ($P = 0.95$). Groups were comparable at baseline and follow up in the MSQ total score.

4. *Treatment Adherence*

Considering the total score for treatment adherence, the groups were comparable at baseline. At follow-up, the teleintervention group presented a median of 53.0 (46.8 to 57.3) vs. 53.0 (44.0 – 60.0) in the active control group, with no difference between ($P = 0.73$) or within-groups.

DISCUSSION

This was a controlled randomized trial to assess the impact of a teleintervention on mental health parameters in patients with type 2 diabetes during the COVID-19 pandemic. After 16 weeks of follow-up, participants in the teleintervention group had a 36% lower prevalence of positive screening for mental health disorders than the control group. The proposed teleintervention reduced diabetes-related emotional distress by almost half. Despite the high prevalence of eating and sleep disorders in this period, there was no change in scores related to the proposed teleintervention.

The psychosocial repercussions of COVID-19 represent one phase of the disease, with potential to generate lasting damage. Fear of illness and uncertainty about the future can precipitate anxiety and stress-related disorders [17]. Beyond stress inherent to the illness itself, mass home-confinement directives raised concerns about how people would react individually and collectively [18]. A recent review of psychological impact of quarantined people revealed numerous emotional outcomes, including stress, depression, irritability, insomnia, and fear, which can persist even after the quarantine ends [19]. Some groups may be more vulnerable to the psychosocial effects of pandemics [18]. Patients with diabetes have a higher prevalence of mood and anxiety disorders compared to the general population under normal conditions [4-6], so it was expected that they could be affected more significantly. A recent study published by our group showed 44.2% prevalence of minor psychiatric disorders in patients with diabetes during the COVID-19 pandemic [3]. In this study, at the end of four months of the pandemic, almost 60% of participants in the control group had a positive screening for mental health disorders, with the possibility of reducing this to 36% by maintaining regular telephone calls with health professionals. The benefits of contact reduced diabetes-related emotional distress as well. These data reinforce the importance of developing remote care strategies to mitigate the psychological effects of the COVID-19 pandemic, especially for patients with diabetes.

Despite high expectations regarding telemedicine, only a few studies evaluated the benefits of remote interventions for chronic diseases during the COVID-19 pandemic. Van Dijk *et al.* assessed maintaining a telephone conversation program in a sample of older adults with chronic affective disorders. This study showed positive results in this group, especially in relation to the development of resilience and adaptation to the new phase [20]. Another study by Wei *et al.* performed an internet-based intervention for relaxation and self-care, and found that patients exhibited significantly decreased levels of depression and anxiety symptoms vs. those in the control group during the COVID-19 pandemic [21]. In patients with diabetes, studies carried out in previous years in non-pandemic situations show that remote interventions are well-received and have the potential to improve psychological well-being [16,22]. Our study found that the benefits of teleinterventions in patients with diabetes are also positive when applied in catastrophic situations. Although our intervention

presented a multidisciplinary approach and complemented medical care, it should be noted that only two patients needed prescription adjustments during the intervention period. We hypothesize that its impact on mental health was mainly due to active listening and emotional support offered during the pandemic.

This study has some limitations. First, patients were selected from two tertiary centers, which can limit external validity. Moreover, a high number of patients used insulin regularly (about 83%), which differs from what is expected for patients with type 2 diabetes in our population and reflects a more severe and long-standing disease. A meta-analysis carried out by Bai *et al.* showed that patients on insulin therapy had a higher risk of depressive symptoms compared with only oral antidiabetic drugs users (OR = 1.42, 95% CI 1.08 to 1.86) [23]. Thus, it is possible that patients included in our sample were more vulnerable to developing mental health disorders. Second, the scales used to assess mental health disorders were designed for self-application. As the questionnaires were applied via telephone contact, that could be a potential source of bias. To minimize this effect, the researchers strictly followed steps of the questionnaires, repeating alternative answers to each question when requested. Moreover, the scales used to assess psychiatric disorders work as screening tools and have no diagnostic value. Third, we considered that a relatively small sample was included in this study, but still in accordance with sample size calculation. The small sample did not allow subgroup analyses to be carried out, which could be important for future studies. Fourth, considering the scarcity of studies evaluating the impact of teleinterventions in mental health outcomes on patients living with diabetes, there are no answers to date on the ideal frequency of telehealth appointments in crisis situations. Thus, it is possible that the proposed intervention model does not reflect accurately what would usually happen in pandemic situations. Even so, it has an undeniable value to guide telehealth strategies to support these patients in similar situations in the future. Fifth, considering the availability of participants' electronic devices, we opted for the use of remote contact through telephone calls in the intervention proposed. The non-use of new technologies, such as video calls and automated data capturing, may be considered a limitation of the strategy performed. Finally, the limitations related to the control group must be mentioned. The lower availability of health care during the COVID-19 pandemic may have had a negative impact on this

group. To reduce the gap between the intervention and control group during the study period, an informational website was made available for this group.

The COVID-19 pandemic has had serious repercussions on psychological and social functioning, which seems more significant for patients with diabetes. Developing strategies to mitigate this effect are urgently needed. This study demonstrated that maintaining remote connections with health professionals during the period of social distancing had the potential to reduce mental health disorders and diabetes-related emotional distress. In addition to providing adequate care for physical demands, monitoring psychological needs and providing psychosocial support for these patients is essential. Strategies to keep patients in contact with health professionals in periods of social crisis are essential, and should be encouraged for similar situations in the future.

DECLARATIONS

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CONFLICTS OF INTEREST. There is no conflict of interest to declare.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE. The study was approved by the National Research Ethics Commission of Brazil (CONEP), number 4.029.368. All participants agreed to the free and informed consent form, which was saved by voice record and electronic registration.

CONSENT FOR PUBLICATION. All authors have reviewed the final version of the manuscript and agree with the publication of the results presented.

AUTHORS' CONTRIBUTIONS. Alessi, J. Conceptualization, Methodology, Software, Data curation, Writing- Original draft preparation. Berger de Oliveira, G., Wilke Franco, D., Kobe, G. L., Scalzilli Becker, A. Padilla Knijnik, C., Brito, A., and Heiden Telo, G., Methodology, Investigation. D'Agord Schaan, B. Conceptualization, Validation, Supervision, Writing- Reviewing and Editing.

Heiden Telo, G., Conceptualization, Data curation, Writing- Original draft preparation. Supervision.

Alessi, J., is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Table 1. Baseline characteristics of study participants.

	Total (N = 91)	Active-control group (n = 45)	Teleintervention group (n = 46)	P value
Age (years)	61.3 ± 9.1	61.0 ± 9.0	61.6 ± 9.2	0.76
Sex (% female)	64.8%	66.7%	63.0%	0.71
Race/ethnicity (% white)	78.0%	73.3%	82.6%	0.29
Marital status (% married)	50.6%	46.3%	54.5%	0.45
Lower-middle income*	80.0%	85.4%	75.0%	0.23
Regular employment	30.6%	31.7%	29.5%	0.82
<i>Diabetes aspects</i>				
Diabetes duration (years)	18.1 ± 9.5	18.7 ± 9.0	17.5 ± 9.6	0.56
HbA1c (%)	8.8 ± 1.7	9.0 ± 1.6	8.5 ± 1.7	0.11
(mmol/mol)	73.0 ± 18.6	75.0 ± 17.5	69.0 ± 18.6	
Diabetes complications				
Retinopathy	40.7%	44.4%	37.0%	0.47
Neuropathy	29.7%	28.9%	30.4%	0.87
Diabetic kidney disease	42.9%	40.0%	45.7%	0.59
Insulin use	83.5%	82.2%	84.8%	0.74
Metformin use	75.8%	80.0%	71.7%	0.36
<i>Previous diseases</i>				
Systemic arterial hypertension (82.4%	80.0%	84.8%	0.55
Cardiovascular disease	39.6%	34.8%	44.4%	0.35
ACE or ARB inhibitors use	82.4%	80.0%	84.8%	0.55
Statins use	82.4%	84.4%	80.4%	0.62
ASA use	52.7%	55.6%	50.0%	0.60
<i>Psychiatric history</i>				
Depression	20.9%	20.0%	21.7%	0.84
Anxiety	6.6%	2.2%	10.9%	0.10
Bipolar disorder	2.2%	2.2%	2.2%	0.99
Other psychiatric condition	2.2%	2.2%	2.2%	0.99
SRI use	24.2%	22.2%	26.1%	0.67
Tricyclic antidepressant use	8.8%	8.9%	8.7%	0.97

Lithium use	2.2%	2.2%	2.2%	0.99
Antipsychotic use	6.6%	4.4%	8.7%	0.41
Benzodiazepine use	3.3%	2.2%	4.3%	0.57
<i>Pandemic-related aspects</i>				
Social distancing				
Partial	57.6%	51.2%	63.6%	0.46
Total	32.9%	36.6%	29.5%	
None	9.4%	12.2%	6.8%	
Social contact				
Only family	69.4%	73.2%	65.9%	0.43
Family and friends	12.9%	14.6%	11.4%	
None	17.6%	12.2%	22.7%	
Reduction in family income	54.1%	61.0%	47.7%	0.22
Lost the job	5.9%	2.4%	9.1%	0.19
Presented respiratory symptoms	24.7%	29.3%	20.5%	0.35
Confirmed COVID-19 infection	5.9%	7.3%	4.5%	0.59
Hospitalization	7.1%	4.9%	9.1%	0.45

Data are mean \pm standard deviation or n (%). Plus, $\alpha \leq 0.05$ indicates significant difference. HbA1c: hemoglobin A1c. ACE: Angiotensin-converting enzyme; ARB: Angiotensin II receptor blocker; ASA: Acetylsalicylic acid. SRI: Serotonin reuptake inhibitors (includes selective serotonin reuptake inhibitors and dual serotonin/norepinephrine reuptake inhibitors). Partial social distancing includes patients who go out for basic activities: market, pharmacy, and health care. Total social distancing includes patients who follow the orientation of home-quarantine. *Family monthly income less than the equivalent of \$ 539.19 (USD).

Table 2. Comparison of questionnaires' total scores for baseline and for follow-up after 16 weeks.

	Active-control group (n = 45)	Teleintervention group (n = 46)	P value
Mental health disorders (SRQ 20)			
Baseline	6.0 (2.5 to 11.0)	6.0 (3.0 to 9.3)	0.76
Follow up	8.0 (3.0 to 12.0)	5.0 (2.0 to 9.0)	0.09
Change in scores	0.0 (-0.3 to 1.4)	0.0 (-0.3 to 0.7)	
Difference within-group (P value)	0.32	0.53	
Diabetes related distress (B-PAID)			
Baseline	18.0 (6.5 to 39.0)	21.0 (11.8 to 8.0)	0.43
Follow up	27.0 (6.0 to 47.5)	12.5 (6.0 to 29.5)	0.08
Change in scores	0.1 (-0.6 to 0.1)	-0.3 (-0.7 to -0.3)	
Difference within-group (P value)	0.29	0.04	
Treatment adherence (SCI-R)			
Baseline	51.0 (44.0 to 57.0)	51.5 (46.8 to 6.0)	0.80
Follow up	53.0 (44.0 to 60.0)	53.0 (46.8 to 7.3)	0.73
Change in scores	0.0 (-0.2 to 0.2)	0.0 (-0.1 to 0.2)	
Difference within-group (P value)	0.54	0.25	
Eating disorders (EAT 26)			
Baseline	29.0 (20.5 to 32.5)	26.5 (21.0 to 1.3)	0.67
Follow up	27.0 (20.0 to 33.0)	24.5 (18.8 to 0.3)	0.50
Change in scores	-0.1 (0.3 to -0.1)	0.0 (-0.3 to 0.3)	
Difference within-group (P value)	0.44	0.58	
Sleep disorders (MSQ)			
Baseline	39.0 (27.5 to 48.0)	35.0 (25.8 to 6.8)	0.47
Follow up	38.0 (28.0 to 52.0)	36.0 (28.0 to 5.0)	0.35
Change in scores	0.0 (-0.2 to 0.5)	0.0 (-0.1 to 0.4)	
Difference within-group (P value)	0.55	0.47	

Data are median and interquartile range. Also, $\alpha \leq 0.05$ indicates a significant difference. The change in scores was evaluated using the formula (follow up score – baseline score)/baseline score.

Table 3. Likelihood for positive screening in the proposed assessments based on cutoff values and comparison between intervention and control groups.

	Active-control group (n = 45)	Teleintervention group (n = 46)
Mental health disorders (SRQ 20)	1.15 (0.50 –	
Baseline	2.63)	1
Follow up	2.33 (1.01 – 5.42)	1
Diabetes related distress (B-PAID)	1.14 (0.47 –	
Baseline	2.76)	1
Follow u	2.63 (1.05 – 6.58)	1
Eating disorders (EAT 26)	0.74 (0.26 –	
Baseline	2.08)	1
Follow up	1.24 (0.47 – 3.24)	1
Sleep disorders (MSQ)	1.17 (0.49 -	
Baseline	2.78)	1
Follow up	0.97 (0.38 – 2.46)	1

Data are odds ratio and 95% confidence interval. Odds ratio ≥ 1 represents a greater likelihood for the proposed disorder in relation to the intervention group.

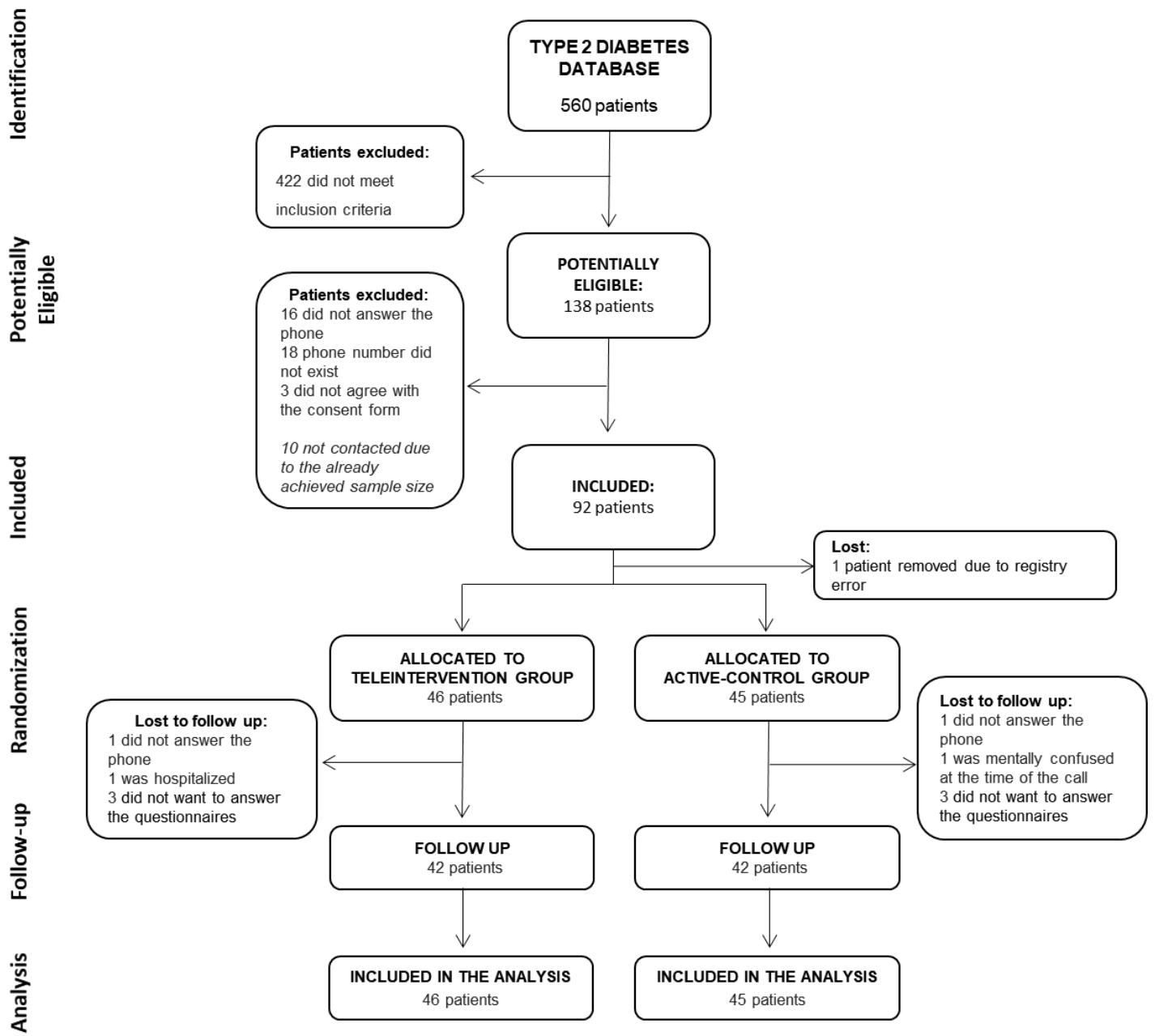


Figure 1. Flow diagram of the study.

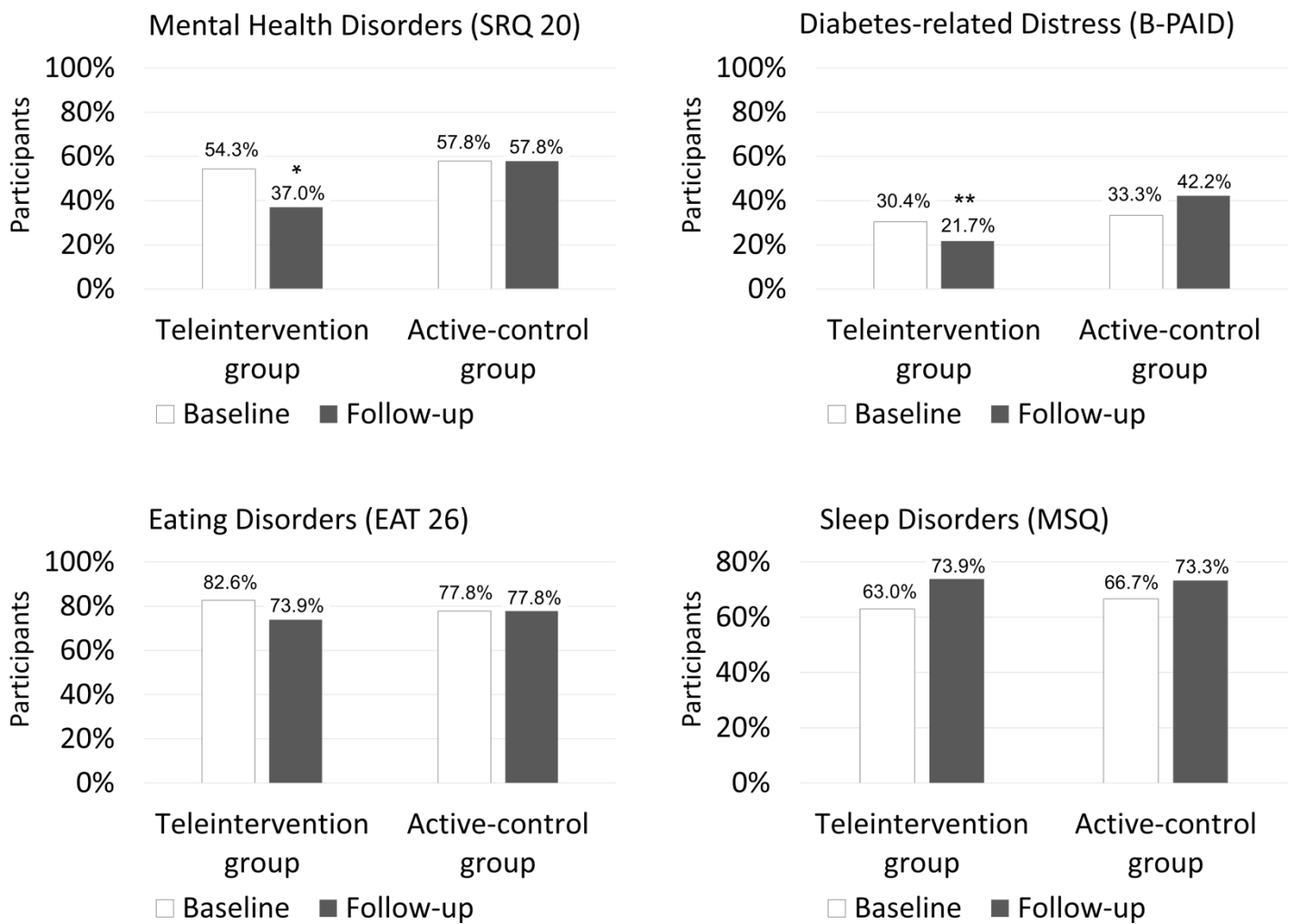


Figure 2. Participants with positive screening for proposed assessments, based on cutoff values and comparison between intervention and control groups.

Number of participants who present positive screening based on pre-established cutoff values. For the evaluation of mental health disorders, a score greater than or equal to 7 on SRQ 20 is considered positive. Diabetes-related emotional distress is considered when the B-PAID score is greater than or equal to 40. The presence of positive screening for an eating disorder is considered when the EAT 26 score is greater than or equal to 20. A positive screening for sleep disorder is considered when a score greater than or equal to 31 is present in the MSQ. *P = 0.04. **P = 0.03.

CONCLUSÕES

A pandemia de COVID-19 impôs um novo desafio ao bem estar psicossocial dos pacientes com diabetes e interferiu em diferentes esferas do autocuidado, aumentando a sobrecarga emocional tanto para o paciente quanto para seus familiares. A partir de dados deste trabalho, identificou-se que, logo nos primeiros meses de pandemia, houve um aumento expressivo no rastreamento de distúrbios de saúde mental em relação à prevalência previamente conhecida, tanto entre os pacientes com diabetes tipo 1, quanto entre aqueles com diabetes tipo 2. O impacto psicopatológico da pandemia também afetou os cuidadores de crianças e adolescentes com diabetes tipo 1, que mais frequentemente apresentaram positividade no rastreamento de distúrbios de saúde mental e na avaliação de sobrecarga emocional em comparação aos cuidadores de jovens sem diabetes. Os relatos desses cuidadores permitiram identificar, além da preocupação e do medo inerentes à pandemia, diferentes origens para o sofrimento reportado entre os responsáveis pelo cuidado de crianças em comparação aos cuidadores de adolescentes: entre os primeiros, há predomínio de exaustão e cansaço relacionados ao aumento das demandas da criança em casa em tempo integral, enquanto entre os segundos, prevalecem os sentimentos de impotência e preocupação em relação ao convívio social abortado, tão importante nessa faixa etária. A exacerbação dos distúrbios de saúde mental e a identificação das dificuldades enfrentadas por esses indivíduos precocemente na pandemia foi fundamental para a conscientização dos profissionais da saúde sobre as vulnerabilidades dessa população e para a promoção de estratégias visando o seu acolhimento emocional.

Entre as alternativas para complementar os cuidados do diabetes durante a interrupção dos atendimentos eletivos, o teleatendimento demonstrou ser um recurso viável para o suporte interdisciplinar às demandas imediatas do paciente. Nossos resultados complementam os conhecimentos atuais sobre os potenciais benefícios dessa estratégia na mitigação do efeito psicopatológico da pandemia, demonstrando que, entre os pacientes com diabetes tipo 2, o uso do teleatendimento é capaz de promover redução no rastreamento de distúrbios psiquiátricos menores, como depressão e ansiedade, e de sofrimento emocional relacionado ao diabetes após 16 semanas de acompanhamento. Entre os pacientes com diabetes tipo 1, apesar de não haver benefício direto em

distúrbios de saúde mental com a intervenção proposta, a manutenção do contato por teleatendimentos foi efetiva em proporcionar a esses pacientes um maior acolhimento e suporte em seus cuidados com o diabetes durante a pandemia. Esses resultados apresentam o potencial de apresentar implicações práticas ao corroborar os efeitos positivos esperados do acompanhamento continuado e focado na integralidade do cuidado durante a pandemia, e fornecem informações fundamentais para o adequado e oportuno planejamento das equipes de saúde diante de situações semelhantes futuramente. Assim, esta tese propõe e ratifica, por meio de seus achados, três fundamentos principais: (1) situações de crise, como a pandemia de COVID-19 e outros desastres naturais, devem levantar a suspeita e justificar a busca ativa por sinais de sofrimento emocional em pacientes com diabetes e seus familiares; (2) a utilização de novas tecnologias, que possibilitem acessibilidade e permitam a continuidade do acompanhamento à distância, parece ser benéfica ao promover suporte nos cuidados de saúde e ao reduzir distúrbios de saúde mental, especialmente entre os pacientes com diabetes tipo 2; (3) a suspeição clínica e a identificação precoce de distúrbios de saúde mental são fundamentais para traçar estratégias potencialmente eficazes e mitigar os potenciais danos a longo prazo nesses pacientes.

ANEXO

Além dos artigos apresentados nesta tese, as seguintes produções científicas foram realizadas durante o período de 19 meses deste doutorado:

Premiações:

1. 1º Lugar no XI Premio IESS de Produção Científica em Saúde Suplementar, na categoria Promoção da Saúde, Qualidade de Vida e Gestão de Saúde, 2021.
2. Menção Honrosa e Premiação de 2º Lugar na categoria de melhores pôsteres do XXIII Congresso da Sociedade Brasileira de Diabetes, 2021.
3. Menção Honrosa e Premiação de 3º Lugar na categoria de trabalhos científicos de apresentação oral do 34º Congresso Brasileiro de Endocrinologia e Metabologia, 2020.
4. Premiação de 3º Lugar na categoria de melhores pôsteres do 17º Encontro de Endocrinologia Feminina - Endofeminina, 2020.
5. Apresentação Destaque no XXI Salão de Iniciação Científica da PUCRS, 2020.

Artigos completos publicados:

1. **Alessi J**, de Oliveira GB, Erthal IN, Teixeira JB, Scherer GDLG, Jaeger EH, Schneiders J, Telo GH, Schaan BD, Telo GH. Diabetes and Obesity Bias: Are We Intensifying the Pharmacological Treatment in Patients With and Without Obesity With Equity? *Diabetes Care*. 2021 Oct 8;dc211294. doi: 10.2337/dc21-1294.
2. **Alessi J**, Scherer GDLG, Erthal IN, Teixeira JB, de Oliveira GB, Jaeger EH, de Carvalho TR, Schaan BD, Telo GH. One in ten patients with diabetes have suicidal thoughts after 1 year of the COVID-19 pandemic: We need to talk about diabetes and mental health not only during Suicide Prevention Awareness Month. *Acta Diabetol*. 2021 Oct 14:1–3. doi: 10.1007/s00592-021-01807-6.
3. **Alessi J**, de Oliveira GB, Schaan BD, Telo GH. Dexamethasone in the era of COVID-19: friend or foe? An essay on the effects of dexamethasone and the potential risks of its inadvertent use in patients

with diabetes. *Diabetol Metab Syndr.* 2020 Sep 7;12:80. doi: 10.1186/s13098-020-00583-7.

4. **Alessi J**, Telo GH, de Oliveira GB, Schneiders J, Zanella MJB, Schaan BD. The rational treatment of diabetes mellitus in older adults: The adequacy of treatment decisions based on individualized glycemic targets in primary and tertiary care. *J Diabetes Complications.* 2021 Apr;35(4):107835. doi: 10.1016/j.jdiacomp.2020.107835.
5. Franco DW, **Alessi J**, Becker AS, do Amaral BB, de Oliveira GB, Schaan BD, Telo GH. Medical adherence in the time of social distancing: a brief report on the impact of the COVID-19 pandemic on adherence to treatment in patients with diabetes. *Arch Endocrinol Metab.* 2021 Nov 3;65(4):517-521. doi: 10.20945/2359-3997000000362.
6. de Carvalho TR, Blume CA, **Alessi J**, Schaan BD, Telo GH. Polysomnography in pre-operative screening for obstructive sleep apnea in patients undergoing bariatric surgery: a retrospective cohort study. *Int J Obes (Lond).* 2022 Jan 4. doi: 10.1038/s41366-021-01055-2.

Artigos completos submetidos para publicação:

7. **Alessi J**, Jaeger EH, de Oliveira GB, Erthal IN, Teixeira JB, Scherer GDLG, de Carvalho TR, Schaan BD, Telo GH. Adjusting to the “New Normal”: How were mental health and self-care affected in patients with diabetes mellitus one year into the COVID-19 crisis? A longitudinal study. Em revisão em “*Journal of Affective Disorders*”.
8. **Alessi J**, Jaeger EH, Scherer GDLG, Costa FL, Telo GH. Weight-centric primary treatment goal in people with type 2 diabetes: are we ready to bite the bullet? Em revisão em “*The Lancet*”.
9. de Oliveira GB, **Alessi J**, Erthal EN; Teixeira JB, Morello MS, Ribeiro RJE, Telo GH, Schaan BD, Telo GH. Healthy lifestyle gone bad: The impact of COVID-19 pandemic on the daily habits of children and adolescents with type 1 diabetes. Em revisão em “*Archives of Endocrinology and Metabolism*”.

10. Foppa L, **Alessi J**, Nemetz B; de Matos R; Telo GH; Schaan BD. Schaan Quality of care in patients with type 1 diabetes during the COVID-19 pandemic: a cohort study from Southern Brazil". Em revisão em "Obesity/Metabolism Research".

Artigos completos em submissão:

11. **Alessi J***, Erthal IN^{*1}, Teixeira JB*, Jaeger EH, de Oliveira GB, Scherer GDLG, de Carvalho TR, Schaan BD, Telo GH. Lifestyle pattern changes, eating disorders and sleep quality in diabetes: How are the effects of 18 months of COVID-19 pandemic being felt?
12. Franco DW, **Alessi J**, Kobe GL, de Oliveira GB, Knijnik CP, Amaral B, Becker AS, Schaan BD, Telo GH. The impact of a telehealth intervention on the metabolic profile of Diabetes Mellitus patients during the COVID-19 pandemic - a randomized clinical trial.
13. Borges RP, Avila GO, Ritter AC, Reichelt AJ, Oppermann MLR, Telo GH, **Alessi J**, Schaan BD. Impact of the COVID-19 pandemic on healthcare of a cohort of women with pregnancies complicated by diabetes on Brazil: could a positive legacy have been born?
14. Borges RP, **Alessi J**, Oppermann MLR, Schaan BD. It's not just insulin: an essay on the inaccessibility to essential supplies among women with pregnancies complicated by diabetes in Brazil.
15. Borges RP, Avila GO, Ritter AC, Reichelt AJ, Oppermann MLR, Telo GH, **Alessi J**, Schaan BD. Turning crisis into opportunity: the reduction in hypertensive disorders in pregnancies complicated by diabetes during the COVID-19 pandemic in Brazil.

Apresentações orais:

1. **Alessi, J**. Tele-health strategy to mitigate the negative psychological impact of the covid-19 pandemic in type 2 diabetes: a randomized controlled trial. Congresso Brasileiro de Endocrinologia e Metabologia. 2020.

2. **Alessi, J.** The legacy of the covid-19 pandemic in prioritizing care for gestational diabetes: how has the pandemic affected quality care indicators and pregnancy outcomes?. Congresso Brasileiro de Diabetes. 2021.

Apresentações de pôster:

1. **Alessi, J;** Teixeira JB ; erthal IN ; Scherer GDLG ; De Oliveira GB ; Telo GH . Perspectivas de cuidadores de jovens com diabetes durante a covid-19. Salão de Iniciação Científica da PUCRS. 2021.
2. **Alessi, J;** Telo, Gabriela H. ; De Oliveira, Giovana B. ; Schneiders, Josiane ; Zanella, Maria José Borsato ; Schaan, Beatriz D. The Adequacy Of Treatment Decisions Based On Individualized Glycemic Targets In Older Adults. Congresso Brasileiro de Endocrinologia e Metabologia 2020.
3. **Alessi, J;** De Oliveira, Giovana B. ; Franco, Debora Wilke ; Amaral, Bibiana Brino ; Becker, Alice Scalzilli ; Knijnik, Carolina Padilla ; Kobe, Gabriel Luiz ; Schaan, Beatriz D. ; Telo, Gabriela H. The Impact Of The Covid-19 Pandemic On Those Responsible For Children And Adolescents With Type 1 Diabetes. Congresso Brasileiro de Endocrinologia e Metabologia. 2020.
4. **Alessi, J.;** Teixeira, Julia B. ; Erthal, Isadora N. ; De Oliveira Gb ; Scherer Gdlg ; Telo Gh . Hábitos De Vida E Covid-19: O Impacto Da Pandemia Nos Cuidados Diários De Crianças E Adolescentes Com Diabetes Tipo 1. Salão de Iniciação Científica da PUCRS. 2021.
5. **Alessi, J.;** De Oliveira Gb ; Franco, Debora Wilke ; De Carvalho, Taíse R. ; Telo, Guilherme Heiden ; Telo Gh . Diabetes tipo 1 e suporte emocional na era COVID-19: resultados de um ensaio clínico randomizado de tele intervenção multidisciplinar. Salão de Iniciação Científica da PUCRS. 2021.
6. **Alessi, J.;** De Oliveira Gb ; Becker, Alice Scalzilli ; Knijnik, Carolina Padilla ; Amaral, Bibiana Brino ; Kobe G ; Telo GH ; Schaan BD . Efeitos de uma teleintervenção em desfechos de saúde mental em uma coorte de

- mulheres com diabetes mellitus durante a pandemia de COVID-19. Endofeminina 2021.
7. De Oliveira, GB ; **Alessi, J.** ; Telo GH ; Schaan BD . Associação entre a estatura de adolescentes brasileiras e fatores socioeconômicos: análise do Estudo de Riscos Cardiovasculares em Adolescentes (ERICA). Endofeminina 2021.
 8. Erthal In ; Scherer Gdlg ; De Olveira Gb ; Teixeira Jb ; **Alessi, J.** ; Schaan BD ; Telo GH . O impacto da pandemia de COVID-19 nos hábitos de vida de meninas com Diabetes Mellitus tipo 1. Endofeminina 2021.
 9. Scherer Gdlg ; **Alessi, J.** ; De Olveira Gb ; Erthal In ; Teixeira Jb ; Jaeger, Eduarda H. ; Schaan BD ; Telo GH . Diabetes mellitus e viés da obesidade: avaliação da intensificação do tratamento farmacológico em mulheres com e sem obesidade. Endofeminina. 2021.
 10. Becker, Alice Scalzilli ; **Alessi, J.** ; Telo GH . Saúde mental na era da COVID-19: prevalência de transtornos psiquiátricos em uma coorte de pacientes com diabetes tipo 1 e 2. Salão de Extensão da PUCRS 2021.
 11. Eduarda Herscovitz Jaeger ; **Alessi, J.** ; Telo GH . Adequação terapêutica baseada nos alvos da hemoglobina glicada em idosos. Salão de Extensão PUCRS. 2021.
 12. Nemetz B ; Foppa, L. ; Matos R ; **Alessi, J.** ; Telo Gh ; Schaan B D. O impacto da pandemia do COVID-19 na qualidade do atendimento de mulheres com diabetes tipo 1 em hospital universitário do sul do Brasil. Endofeminina 2021.
 13. Scherer Gdlg ; **Alessi, J.** ; Mottin, C.C. ; Padoin, A. V. ; Telo, GH. Avaliação da composição corporal após 3 a 5 anos de gastroplastia em Y de Roux. Congresso Brasileiro de Obesidade (ABESO) 2021.
 14. Jaeger EH; **Alessi, J.** ; Scherer Gdlg ; Erthal IN ; Telo, GH. Diabetes mellitus e viés da obesidade: avaliação da intensificação do tratamento em pacientes com e sem obesidade. Salão de Iniciação Científica da PUCRS 2021.
 15. De Olveira Gb ; **Alessi, J.** ; Telo GH . Tele Intervenção com Suporte Emocional para Pacientes com Diabetes tipo 2 na era COVID-19: Um Ensaio Clínico Randomizado. Salão de Iniciação Científica da PUCRS. 2021.

16. Kobe G ; Knijnik, Carolina Padilla ; **Alessi, J.** ; Telo GH . Saúde Mental e Diabetes na COVID-19. Salão de Iniciação Científica da PUCRS. 2020.
17. De Oliveira Gb ; **Alessi, J.** ; Telo Gh . Alvos de hemoglobina glicada em pacientes idosos. Salão de Iniciação Científica da PUCRS. 2020.