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RESEARCH ARTICLE

The Development and Initial Feasibility of a Cognitive-Behavioural Group Intervention for COVID-19-Related Anxiety and Depression

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ABSTRACT

Background: The COVID-19 pandemic resulted in adverse psychological outcomes for many people in the general public globally.

Aim: This paper discusses the development and initial feasibility testing of a novel manualised online group cognitive behavioural therapy intervention targeting the maintenance factors of COVID-19-related anxiety and depression. The paper is in two sections describing: (i) the development of the intervention and (ii) a pilot study examined initial acceptability and feasibility of the intervention.

Methods: Section 1 used the Six Steps in Quality Intervention Development methodology to systematically develop the intervention. Section 2 used a mixed-method design to assess feasibility and acceptability. The quantitative assessment examined uptake, completion, and pre-post intervention changes in psychological distress (N=8). A thematic analysis of qualitative interviews measured subjective acceptability.

Results: A theoretically coherent, novel intervention that did not replicate existing treatment designs was developed. Low levels of engagement in online data-gathering did not allow for an assessment of effectiveness. However, there was a high level of participant retention, and qualitative data highlighted a high level of treatment appropriateness, positive post-intervention change and acceptability for those who took part.

Conclusion: This initial feasibility study indicated that the intervention was feasible and acceptable and warranted further investigation.

Keywords: Clinical Intervention, Group Telepsychology, Depression, Anxiety, CBT, Remote

Introduction

The COVID-19 pandemic has increased adverse psychological outcomes worldwide.^{1,2,3} Cross-sectional surveys have indicated that approximately that 20-30% of international populations experienced anxiety or depression in 2020.4,5. Due to how specific national responses, guidelines and restrictions to COVID-19 have been, there was likely a wide range of mental health variation between countries. In the Republic of Ireland, where this research occurred, data indicated that around 27% of a representative sample tested in April 2020 met the criteria for Generalised Anxiety Disorder or Depression.⁶ Irish tracking data have indicated that these rates deteriorated throughout 2020-2021,7,8,9,10 Correspondingly, posttraumatic stress symptoms related to the COVID-19 pandemic were common in the general Irish population at approximately 17%.¹¹ Furthermore, recent evidence demonstrates that the remission of the epidemic was associated with greater prevalence of severe depression and anxiety.12

The COVID-19 pandemic has created a range of mental health challenges, included is an increased rate of mental health problems in the community.⁶ A challenge to the existing evidence base is the unique nature of the societal restrictions and health risks faced by the public and restrictions on services' ability to provide treatment in traditional ways. This has impeded clinicians and researchers from designing effective, acceptable alternatives that address COVID-19-related needs. Due to a lack of knowledge of the effectiveness of standard psychological treatments within a pandemic, COVID-19-specific clinical interventions are required. In this paper, the authors present the development of a secondary care psychological intervention, specifically targeting COVID-19related anxiety and depression.

The paper is presented in two sections. Section 1 describes the systematic development of the intervention, and Section 2: a pilot study examined initial acceptability and feasibility of the intervention.

Section 1

Aim

This study set out to develop a specific psychological intervention to alleviate COVID-19-related anxiety and depression.

Method

Design

The six steps in quality intervention development framework (6SQuID)¹³ was used to

develop the intervention. The 6SQuID methodology uses six phases to amplify the likely effectiveness of interventions by ensuring a practical and evidencebased intervention development approach. These steps involve: (1) defining and understanding the problem and its causes; (2) identifying which causal or contextual factors are modifiable:(a) which have the greatest scope for change and (b) who would benefit most; (3) deciding on the mechanisms of change; (4) clarifying how these will be delivered; (5) testing and adapting the intervention; and (6) collecting sufficient evidence of effectiveness to proceed to a rigorous evaluation.

Procedure

The intervention development process utilised a rapid review of the emerging COVID-19 mental health literature. It also incorporated crosssectional data from the general population.¹⁴

Phases 1-4 of the 6SQuID methodology are presented in the Results section of Section 1, and Phases 5-6 are presented in Section 2.

Results

Step 1: Defining and understanding the problem

Repeated research has highlighted the mental health impact of living through the COVID-19 pandemic.^{2,15,16} Unlike typical anxiety disorders, the threat to health, livelihood and wellbeing posed by COVID-19 is high and realistic. It is unclear whether typical psychological treatments are appropriate and helpful in addressing a realistic and constant threat.^{17,18,19}

Step 2a: Identifying which causal or contextual factors are modifiable

Predictors of increased anxiety and depression during the COVID-19 pandemic include occupational, social financial, and health domains.^{5,15} Within cognitive models, it is hypothesised that disordered anxiety occurs when there is an overestimation of how likely a perceived threat is to occur. These models suggest that cognitive misappraisals, cognitive misinterpretation, safety-seeking and avoidance behaviours may underpin excess levels of distress.²⁰ Equally in of cognitive models depression, biased interpretations of events are attributed to the activation of negative representations of the self, the world, and the future (the Negative Cognitive Triad). A variety of dysfunctional beliefs that make individuals prone to depression make them vulnerable to specific life events.²¹

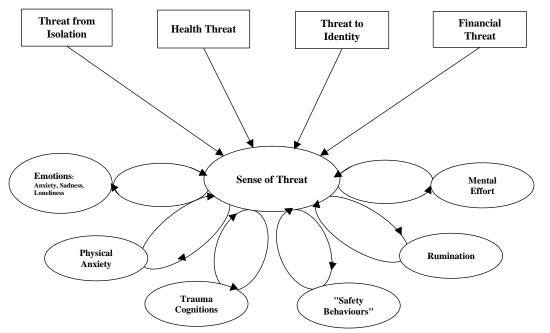
If identified as relevant factors in COVID-19-related distress, these cognitive maintenance factors are potentially modifiable. NICE guidelines indicate that treatments that address cognitive misappraisals, cognitive misinterpretation, safetyseeking and avoidance behaviours²² are likely to be amenable to change through psychological treatment.

Step 2b: Which has the greatest scope for change and who would benefit most

Certain populations have appeared at risk during the virus outbreak and may be more susceptible to favourable change. In the Republic of Ireland, it has been reported that those at risk for the onset of COVID-19-related anxiety and depression are younger, female sex and experienced a loss of income.⁶ This is similar to international studies.^{1,3} Although older adults (65+)have also displayed a large prevalence of COVIDparticularly 19-specific anxiety, due to vulnerability to the virus. These demographics may need increased psychological support along with front-line workers, who have displayed an increase in psychopathology.²³

Step 3: Deciding on the mechanisms of change

The second author developed and tested a cognitive model of COVID-19-related distress using a cross-sectional study, examining typical cognitive factors in a convenience sample from the general population.¹⁴ This study found, in a confirmatory factor analysis, that Loneliness, Posttraumatic Cognitions about Self, Posttraumatic Cognitions about the World, Emotional Stability, and Mental Effort related to COVID-19 loaded onto a single factor. The final model showed adequate fit (CFI=0.988, TLI=0.980, RMSEA=0 .059(0.034-0.086, GFI=0.984, SRMR=0.0232), x2=26.461, p=0.002). Stepwise linear regressions found that the model also significantly predicted Depression and Anxiety as measured by the Depression Anxiety Stress Scales 21 (DASS-21) (R²=.611; F(6, 548)=143.29, p<.000; $(R^{2} =$.529, F(8, 546)=76.55, p<.0001 (See Fig.1).



Note: Variables identified by square boxes represent causal factors as identified through meta-analyses. Variable identified by ovals represent maintenance factors, tested in this paper.

Figure 1: A proposed Cognitive Behavioural model of COVID-19-related anxiety and depression (Delz et al.¹⁴). This model was used to identify potential mechanisms of change. An 8-session group treatment was developed addressing six core processes (i) feelings of loneliness; (ii) physical anxiety, (iii) cognitions of threat and loss related to COVID-19, (iv) safety behaviours, (v) worry and rumination, (vi) mental effort related to COVID-19. Safety behaviours were carefully addressed as government guidance has often indicated that restricted social contact and increased handwashing are appropriate behaviours in the context of the pandemic. Therefore, safety behaviours that increased a sense of isolation were targeted while not creating a health risk (e.g., not engaging in phone calls/ zoom meetups) or cognitive load (e.g., over-analysing the news).

Cognitive restructuring throughout this intervention targeted cognitions of threat/vulnerability and loss, which are central themes in anxiety and depression.²⁰ Threat reappraisal is considered a key mediator underlying the effects of cognitive-behavioural therapy for anxiety disorders.²⁴ In addition, core beliefs about the world may be conducive to a traumatic response but also have the potential to develop traumatic growth.²⁶

Step 4: Delivery

Online group psychotherapy can be costeffective, treat multiple clients, and overcome physical barriers to engagement (location, geographical restrictions, infection concerns). Remote telepsychology psychotherapy has displayed "clear, consistent evidence of beneficial effect" with anxiety, depression, posttraumatic stress, and adjustment disorder.²⁶ Whilst recent findings on the outcomes are promising, there is limited research regarding online group psychotherapy.²⁷

This intervention provided a structured, manualised approach to facilitate the therapeutic group format, focusing on the underlying maintenance factors of COVID-19-related anxiety and depression using a CBT approach with a specified population.

The delivery of this therapeutic intervention was within an online synchronous group format. This online group format took place with two-hour sessions weekly for eight weeks. Each session had a central theme: worry, threat cognitions, and everchanging demands.

These themes were extrapolated from the maintenance factor model of COVID-19-related distress (see Figure 1). Participants were provided and encouraged to complete an associated workbook throughout the program.²⁸ The treatment has been manualised to assist practitioners/facilitators in implementing the intervention, and guidelines have been inserted on whom may deliver the intervention.

Steps 5 and 6 of the 6SQuID methodology "Testing and adapting the intervention" and "Collecting sufficient evidence of effectiveness to proceed to a rigorous evaluation" are discussed in Section 2 of the Results Section.

Section 2: Initial Feasibility and Acceptability of the Intervention Aim

This study set out to test the initial feasibility and acceptability of the intervention.

Design

A pilot study examined initial acceptability and feasibility of the intervention. A mixed-method design was utilised to assess the feasibility and acceptibility. The participants' opinions and experiences of the remote group CBT intervention were collected to assist in evaluating the acceptability of the intervention. Acceptability was assessed to confer intervention feasibility by judging to what extent the intervention was suitable for those who took part in it.^{29,30}

Recruitment

This online group CBT intervention was offered to a secondary mental healthcare outpatient population attending St. John of God Hospital, Stillorgan, Co. Dublin, Ireland. This is a private, health insurance-based service with both inpatient and outpatient services. The intervention was offered to all outpatients on an outpatient waiting list between October 2020 and February 2021 (40 approx.). It was offered to all Multi-Disciplinary Teams (MDTs) and consultant psychiatric teams to refer relevant clients.

Inclusion criteria

The treatment was offered via Zoom to any adult outpatient (aged 18-75) of the St John of God Hospital outpatient service presenting with COVID-19-related distress, anxiety or depression during this period. The intervention was also open to those who did not consent to research. Participants needed to have access to appropriate technology to be able to access the Zoom platform. The research team provided training in managing the platform.

Exclusion criteria

The intervention was not open to people with psychiatric presentations other than anxiety or depression, current inpatients of the hospital, or those open to services other than the adult outpatient department.

Measures

The COVID Stress Scale was used to examine COVID-19-related distress.¹⁹ The 36-item COVID Stress Scales (CSS) were developed to understand better and assess COVID-19-related distress. A stable 5-factor solution was identified, corresponding to scales assessing COVID-related stress and anxiety symptoms: (1) Danger and contamination fears, (2) fears about economic consequences, (3) xenophobia, (4) compulsive checking and reassurance seeking, and (5) traumatic stress symptoms about COVID-19. The scales performed well on various external validity indices and showed internal validity between 0.94 and 0.83 (as measured by Cronbach's Alpha).

Feasibility was assessed by demand, qualitative measures of quantitative and acceptability, and potential implementation.29 Demand was examined by comparing treatment uptake with the potential number of participants. Acceptability was examined in line with the Theoretical Framework of Acceptability (TFA)³⁰, comprising seven component constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and selfefficacy, as measured by qualitative interviews. Implementation was examined in how the intervention could be applied sufficiently to conduct a control trial.

Acceptability was assessed by participants' perceptions via the Client Change Interview Schedule³¹, exploring: (i) the participants' experience of taking part in the intervention; (ii) any noticeable change for participants due to the intervention; (ii) their perception of the source of how this change occurred (iii) to highlight any specific examples of positives or negatives of the intervention.

Procedure

This intervention provided an 8-session cognitive behavioural therapy intervention focused on the underlying maintenance factors of COVID-19-related anxiety and depression using a CBT. Group members were invited to participate in surveys before and after the intervention to assist in the evaluation process. Post-intervention interviews gathered further outcome data. The six-step thematic analysis methodology was followed as recommended by Braun and Clarke.³²

Power Analysis

This initial feasibility and acceptability study did not have sufficient power to detect quantitative measurement of symptom change over time. Quantitative data are used for indicative purposes.

Ethics

The study received ethical approval from the St John of God Regional Ethics committee (ID765).

Results

Study 2: Initial Feasibility Testing

Participants

Eight clients attended the group over two cycles of the intervention. Clients ranged in age from 25 to 83, indicating that age was not a barrier to engagement. Six out of the eight clients were female. Fifty per cent of the sample lived with their parents, and fifty per cent were owners/occupiers. Three of the participants were in full-time work. The others included a student, retired people, unemployed and a homemaker. Baseline data indicate that participants experienced high levels of anxiety or depression. Due to the low participation rate, post-intervention data cannot be interpreted meaningfully. However, they are shown in Table 1 for completeness.

 Table 1. Pre and post intervention scores on Covid Stress Scale

Covid Stress Scale						
PRE (n=5)			POST(n=3)			
Variable	M	SD	Μ	SD		
CSS Danger	13.25	6.91	6.33	2.50		
CSS	11.40	5.57	2.33	2.05		
Contamination						
CSS Trauma	7.50	4.56	2.33	1.25		
CSS Checking	5.8	4.71	2.67	1.25		
CSS Total Subscales	39.25	20.17	16.25	9.73		

Demand

Two cycles of the group were completed. Eight clients participated in the groups out of a potential 20 group spaces. This indicated a moderate level of demand.

Acceptability

All participants completed the intervention, with only one participant missing a session (due to a childcare issue on the day). These data indicate a high level of quantitative acceptability as measured by attendance and completion.³⁰

Qualitative Analysis of Intervention Acceptability

Three participants agreed to take part in post-intervention interviews. This follow-up

Table. 2 Description of Emergent Themes

interview was conducted 6 months after both cycles of the intervention took place. The interview length ranged from 35-50 minutes.

As a result of using a structured interview schedule, the self-reported experience of engaging in the intervention deductively mapped onto the following three themes – the period before the intervention, being in the intervention and mechanisms of change, and the participants' experience after engaging in the intervention. See Table 2 (and Supplementary Material) for a further description of inductively developed subthemes.

Structure	Theme	Examples
Pre- Intervention	Participants ' distress	I thought I was the only one in the world who was having the anxiety attacks and head going, always.
	Impact of	Well, I was in a different space, I was very uncomfortable with the anxiety. I just can't tell you how real it frightened me, and I wasn't sure what I was up to or what I was doing. I just felt an absolute loser and I was looking at everything like a doomsday scenario.
	Covid-19/	
	restrictions	The fact that you had to distance yourself from people and not get close to them, it kind of cut off your personal and social contacts a good bit which wasn't good and then you were afraid
	Pre- intervention	to meet people, so there was a fear factor there and it helped to kind of curb that fear factor.
	apprehensi on	I think, the prospect of a group situation, for somebody who's never done it before, it can be quite daunting. The actual execution of it was much easier than I thought.
Mechanism of Change	Participants experience of the intervention	It was just the normality of the meetings on the Monday morning with the group. It was very very nice, it would be different people having their problems, there was more than one facilitator there. Even the way the facilitators reacted, I just liked the whole thing, there was no tension, I wasn't working myself up to 90 about anything.
		I think what's been helpful about the group is that; what they presented was quite relevant, and it was easy enough to apply, but you did have to read over it a few times. I think that that subject on the inner critic was quite good that we're always criticising ourselves. And we're always, you know, our own worst enemy. So, I'm realising that there are things we can control and there are things we can't control. And there's people, the way they react to you, they can't control it, but you can control how you react to them. I think it does help day to day and what we come up against.
	Intervention Suggestions	I think the remote aspect of it, the fact that it was online in some ways it made it much easier to engage in a group situation. I don't know how. I'm not sure why – maybe there is a protective aspect which you didn't feel quite so exposed. I would imagine sitting in a in a small room full of people is intimidating. So, I actually thought the online aspect worked really well.
	Learning	I think in the beginning it was that we were all different age groups. So, we all had different life experiences and we were all, I suppose we were all doing it from home. I think maybe sometimes there was a bit of a cultural and age difference to how people took up the advice that was being presented.

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And you know, just listening to the small, or what looked to be very small incremental steps that they took to deal with their situation, so learning from other people and sharing stories, with the other participants.

I wouldn't have prioritised it, you know, self-care and self-compassion to the same extent, definitely not.

Post Intervention	Application of intervention techniques.	Well, I didn't really expect to get the strength from it that I did, you know? I think now when I am dealing with people. I can stand back and just let them say what they want to say, but you can remain detached, and you don't have to get so involved. You know you have a different way of coping with them and that. I don't have to let it affect me if they're feeling this way, I don't have to feel this way as well, kind of thing.
	Aspects of change	I think I just kind of realised - this is normal. That I shouldn't be ashamed of having been very, very anxious. Not wanting to even go see the family because I felt that it wasn't right for the younger ones to see me out of control. You know, because of that feeling in my chest, that I just couldn't, I didn't want to talk to anybody, so that was - all of that is just a bad memory.
		In the broader scheme of things over the last few months, I certainly felt I was able to draw on some of the insights if you like from the therapy sessions.

Pre-Intervention Theme

Participants' self-reported wellbeing before engaging in the remote intervention confirms baseline quantitative data that participants were experiencing mental health difficulties. Participants' pre-intervention distress was particularly around the Covid-19 virus and the associated restrictions, emphasising the impact of lockdown and a sense of threat. Where participants described emotion, it manifested in the form of anxiety, worry, obsessiveness and contamination fears. Fear and confusion were elicited in two forms; uncertainty in terms of the coronavirus and lockdown; the isolated experience of suffering without a shared experience to relate to or a sense of shared understanding. Participants were apprehensive about engaging in the intervention due to the novel group psychotherapy format but did not claim any concerns about the remote aspect.

Mechanisms of Change Theme

Participants emphasised a range of positive and negative aspects of the intervention and what they believed was the source of positive intervention change. Regarding the remote intervention, they highlighted that the content was relevant and appropriate. It applied to daily life. It provided psychoeducation alongside intervention techniques such as mindfulness, locus of control and thought regulation. This feedback provided strong indicators of intervention coherence.

Participants elicited that a key to the intervention experience was the concept of normalisation. All participants reported a sense of normality - whether from the psychoeducational intervention components, intra-group membership or the structure provided by a weekly organised event. They reported that it normalised their distressing experience and provided a shared experience to understand and manage one's symptomology.

Participants also described the intervention "atmosphere" as a central component of the intervention, whereby participants felt supported and encouraged to express themselves. This comforting atmosphere was attributed to facilitation and mediated positive group outcomes such as managing interpersonal dynamics, group sharing and learning. Shared experience and learning were two changes that were attained predominately due to the intervention structure group psychotherapy, providing evidence to retain the intervention format as a group intervention rather than individual.

Participants described their personal experience of the online group therapy structure as positive. Participants reported reduced vulnerability due to the intervention taking place online, as it felt "less intimidating" or "exposing", particularly for those new to group interventions. Moreover, two participants suggested that the remote aspect improved their engagement. However, as mentioned by one participant, they were fortunate to have enough privacy to participate.

In terms of burden, consistent feedback reported by all interviewed participants was the need for group members to be of relative age and clinically appropriate. Participants felt the intervention would have been more favourable if fellow group members were of similar age. Moreover, one participant found this lack of similarity to hinder their engagement. Participants also discussed group size. While a smaller group felt intimate, participants suggested they would have preferred a larger group – mainly to provide a greater variety of experiences and opportunities for learning.

Participants reinforced the notion of the importance of the intervention. All participants were certain that while some change might have occurred without the intervention, it would not have been to the same extent, would be more difficult to source and would have taken longer to occur, suggesting a sufficient degree of perceived effectiveness.

Post- Intervention Theme

There was a stark difference between the participants' description of their pre-intervention wellbeing and their post-intervention coping. The underlying features of this contrast were attributed to post-intervention change and a difference in perspective. Participants felt a dramatic change in their management of and focus on the ongoing coronavirus threat and the associated restrictions. This resulted in a reported reduction in experiencing hopelessness, obsessive behaviours, and anxious thoughts. Participation in the intervention provided a sense of self-efficacy or resilience described as "strength" in dealing with the pandemic, central to post-intervention coping. A favourable affective attitude towards the intervention was present.

Participants disclosed newly gained insights which led to a change of perspective toward the inner experience and interactions with the outside world. Participants reported developing a higher capacity to regulate and control their thoughts and emotions due to cognitive restructuring, a core component of the intervention. This contributed to findings of perceived effectiveness.

Discussion

This paper describes the development and initial feasibility testing of a novel cognitive behavioural therapy intervention for COVID-19related distress. The study used the 6SQuID methodology to ensure that the intervention was designed from a coherent theoretical base, did not replicate existing treatment designs, had a likelihood of therapeutic success, and included the target group experience. This approach was based on data on cognitive factors related to COVID-19 distress developed from a general population sample,¹⁴ a CBT intervention was designed and tested in a feasibility study. This increases the underlying validity of the approach.

Feasibility was assessed through demand, acceptability and the potential for further implementation. The demand for the intervention was moderate, with fewer than 50% of the places being taken up. Quantitatively, those who partook in the intervention showed a high level of acceptability with 100% retention and a high level of weekly attendance.

The moderate level of demand was potentially due to the teletherapeutic format. Previous studies have indicated that even regular therapeutic services can have low uptake levels.³⁴ Although we cannot predict the long-term impact of COVID-19, it is likely that teletherapy will be a necessary format for services in short to mediumterm. However, for a significant group of participants, it may be a barrier to accessing treatment. There is a range of reasons why this may be the case. Clients may not have adequate private space during lockdown or when isolating at home.³⁴ There may be technological discomfort²⁸ or lack of therapeutic alliance when engaging remotely.35 There may also be specific service-related reasons for the low referral and intervention uptake levels.

Qualitative data reinforced that participants struggled to cope with the pandemic before engaging in the intervention, particularly the sense of threat from anticipated danger and contamination, emphasising the need for problemspecific treatment. The intervention was appropriate in addressing their clinical problems, was convenient and suitable to individuals' lifestyles, and was effective from their perspective.

The emergent themes map well onto the constructs of acceptability described by Sekhon et al.³⁰ Participants reported a positive attitude to the intervention as indicated by post-intervention coping and a low level of burden as suggested by the heterogeneity of age and clinical presentation. They described a high degree of perceived effectiveness as indicated by a change in perspective and intervention importance. The intervention was experienced as appropriate, relatable, and applicable to daily life, reflecting intervention coherence. Participants described increased self-efficacy through using new strategies and techniques following the intervention. No ethical concerns or complications were identified. Participants highlighted potential improvements to the intervention: group size, age and clinical presentation similarity were highlighted as issues to be addressed.

Overall, participants who engaged in the remote online CBT intervention found it acceptable, highlighted by criteria found within the Theoretical Framework of Acceptability.³¹

These findings are in line with other research in the area.^{36,37} In particular, Solomonov et al. ³⁶ found that a brief, telehealth-delivered,

psychotherapy skills-based intervention significantly reduced symptoms of anxiety and depression among healthcare workers during the COVID-19 pandemic, with a high level of acceptability. In a qualitative study, Egan et al.³⁷ reported that participants described a low-intensity CBT intervention as useful and acceptable for their concerns related to the pandemic or any exacerbation of pre-existing anxiety and depression.

Limitations

There are several limitations to this study. It took place within a private, insurance-based service. The intervention was limited to those whose insurance policy covered it. This serious confounding variable undermined the ability to recruit the largest possible sample. It is a single-arm feasibility study. Due to the study design, it is impossible to determine the reason for the low level of treatment uptake and whether the content or teletherapeutic format had low demand. There was a small recruitment window.

Conclusion

This paper describes the development and initial mixed-method testing of the feasibility of a cognitive behavioural therapy intervention for COVID-related distress. The study describes the development of a novel intervention, designed from a coherent theoretical base, which did not replicate existing treatment designs and had a likelihood of therapeutic success. This feasibility study indicates a moderate level of demand within the service where this intervention was first tested. It described a high level of acceptability among participants and a high level of reported change. Future research within other services may experimentally examine the effectiveness of this intervention.

Conflicts of interest/Competing interests: n/a

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Data Availability Statement: The data that support the findings of this study are available from the corresponding author (KG) upon reasonable request.

Ethical Considerations: The Authors abided by the Code of Professional Ethics of the Psychological Society of Ireland (2019), in line with the Declaration of Helsinki. The study received ethical approval from the St John of God Regional Ethics committee (ID765). All participants provided fully informed consent.

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