

# World Journal of *Clinical Cases*

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## Contents

Thrice Monthly Volume 10 Number 24 August 26, 2022

### EDITORIAL

- 8432** Evolution of *World Journal of Clinical Cases* over the past 5 years  
*Muthu S*

### OPINION REVIEW

- 8436** NF- $\kappa$ B: A novel therapeutic pathway for gastroesophageal reflux disease?  
*Zhang ML, Ran LQ, Wu MJ, Jia QC, Qin ZM, Peng YG*

### MINIREVIEWS

- 8443** Obligate aerobic, gram-positive, weak acid-fast, nonmotile bacilli, *Tsukamurella tyrosinosolvens*: Minireview of a rare opportunistic pathogen  
*Usuda D, Tanaka R, Suzuki M, Shimozawa S, Takano H, Hotchi Y, Tokunaga S, Osugi I, Katou R, Ito S, Mishima K, Kondo A, Mizuno K, Takami H, Komatsu T, Oba J, Nomura T, Sugita M*
- 8450** Diffusion tensor imaging pipeline measures of cerebral white matter integrity: An overview of recent advances and prospects  
*Safri AA, Nassir CMNCM, Iman IN, Mohd Taib NH, Achuthan A, Mustapha M*
- 8463** Graft choices for anterolateral ligament knee reconstruction surgery: Current concepts  
*Chalidis B, Pitsilos C, Kitridis D, Givissis P*
- 8474** Overview of the anterolateral complex of the knee  
*Garcia-Mansilla I, Zicaro JP, Martinez EF, Astoul J, Yacuzzi C, Costa-Paz M*
- 8482** Complication of lengthening and the role of post-operative care, physical and psychological rehabilitation among fibula hemimelia  
*Salimi M, Sarallah R, Javanshir S, Mirghaderi SP, Salimi A, Khanzadeh S*

### ORIGINAL ARTICLE

#### Clinical and Translational Research

- 8490** Pyroptosis-related genes play a significant role in the prognosis of gastric cancer  
*Guan SH, Wang XY, Shang P, Du QC, Li MZ, Xing X, Yan B*

#### Retrospective Study

- 8506** Effects of propofol combined with lidocaine on hemodynamics, serum adrenocorticotrophic hormone, interleukin-6, and cortisol in children  
*Shi S, Gan L, Jin CN, Liu RF*
- 8514** Correlation analysis of national elite Chinese male table tennis players' shoulder proprioception and muscle strength  
*Shang XD, Zhang EM, Chen ZL, Zhang L, Qian JH*

- 8525** Clinical value of contrast-enhanced ultrasound in early diagnosis of small hepatocellular carcinoma ( $\leq 2$  cm)

*Mei Q, Yu M, Chen Q*

- 8535** Identification of predictive factors for post-transarterial chemoembolization liver failure in hepatocellular carcinoma patients: A retrospective study

*Yuan M, Chen TY, Chen XR, Lu YF, Shi J, Zhang WS, Ye C, Tang BZ, Yang ZG*

- 8547** Clinical significance of half-hepatic blood flow occlusion technology in patients with hepatocellular carcinoma with cirrhosis

*Liu D, Fang JM, Chen XQ*

- 8556** Which octogenarian patients are at higher risk after cholecystectomy for symptomatic gallstone disease? A single center cohort study

*D'Acapito F, Solaini L, Di Pietrantonio D, Tauceri F, Mirarchi MT, Antelmi E, Flamini F, Amato A, Framarini M, Ercolani G*

### Clinical Trials Study

- 8568** Computed tomography combined with gastroscopy for assessment of pancreatic segmental portal hypertension

*Wang YL, Zhang HW, Lin F*

### Observational Study

- 8578** Psychological needs of parents of children with complicated congenital heart disease after admitting to pediatric intensive care unit: A questionnaire study

*Zhu JH, Jin CD, Tang XM*

### Prospective Study

- 8587** Quantitative differentiation of malignant and benign thyroid nodules with multi-parameter diffusion-weighted imaging

*Zhu X, Wang J, Wang YC, Zhu ZF, Tang J, Wen XW, Fang Y, Han J*

### Randomized Controlled Trial

- 8599** Application of unified protocol as a transdiagnostic treatment for emotional disorders during COVID-19: An internet-delivered randomized controlled trial

*Yan K, Yusufi MH, Nazari N*

- 8615** High-flow nasal cannula oxygen therapy during anesthesia recovery for older orthopedic surgery patients: A prospective randomized controlled trial

*Li XN, Zhou CC, Lin ZQ, Jia B, Li XY, Zhao GF, Ye F*

### SYSTEMATIC REVIEWS

- 8625** Assessment tools for differential diagnosis of neglect: Focusing on egocentric neglect and allocentric neglect

*Lee SH, Lim BC, Jeong CY, Kim JH, Jang WH*

## CASE REPORT

- 8634** Exome analysis for Cronkhite-Canada syndrome: A case report  
*Li ZD, Rong L, He YJ, Ji YZ, Li X, Song FZ, Li XA*
- 8641** Discrepancy between non-invasive prenatal testing result and fetal karyotype caused by rare confined placental mosaicism: A case report  
*Li Z, Lai GR*
- 8648** Paroxysmal speech disorder as the initial symptom in a young adult with anti-N-methyl-D-aspartate receptor encephalitis: A case report  
*Hu CC, Pan XL, Zhang MX, Chen HF*
- 8656** Anesthetics management of a renal angiomyolipoma using pulse pressure variation and non-invasive cardiac output monitoring: A case report  
*Jeon WJ, Shin WJ, Yoon YJ, Park CW, Shim JH, Cho SY*
- 8662** Traumatic giant cell tumor of rib: A case report  
*Chen YS, Kao HW, Huang HY, Huang TW*
- 8667** Analysis of two naval pilots' ejection injuries: Two case reports  
*Zeng J, Liu XP, Yi JC, Lu X, Liu DD, Jiang YQ, Liu YB, Tian JQ*
- 8673** Beware of the DeBakey type I aortic dissection hidden by ischemic stroke: Two case reports  
*Chen SQ, Luo WL, Liu W, Wang LZ*
- 8679** Unilateral lichen planus with Blaschko line distribution: A case report  
*Dong S, Zhu WJ, Xu M, Zhao XQ, Mou Y*
- 8686** Clinical features and progress of ischemic gastritis with high fatalities: Seven case reports  
*Shionoya K, Sasaki A, Moriya H, Kimura K, Nishino T, Kubota J, Sumida C, Tasaki J, Ichita C, Makazu M, Masuda S, Koizumi K, Kawachi J, Tsukiyama T, Kako M*
- 8695** Retinoblastoma in an older child with secondary glaucoma as the first clinical presenting symptom: A case report  
*Zhang Y, Tang L*
- 8703** Recurrent herpes zoster in a rheumatoid arthritis patient treated with tofacitinib: A case report and review of the literature  
*Lin QX, Meng HJ, Pang YY, Qu Y*
- 8709** Intra-abdominal ectopic bronchogenic cyst with a mucinous neoplasm harboring a *GNAS* mutation: A case report  
*Murakami T, Shimizu H, Yamazaki K, Nojima H, Usui A, Kosugi C, Shuto K, Obi S, Sato T, Yamazaki M, Koda K*
- 8718** Effects of intravascular photobiomodulation on motor deficits and brain perfusion images in intractable myasthenia gravis: A case report  
*Lan CH, Wu YC, Chiang CC, Chang ST*

- 8728** Spontaneous acute epidural hematoma secondary to skull and dural metastasis of hepatocellular carcinoma: A case report  
*Ly GZ, Li GC, Tang WT, Zhou D, Yang Y*
- 8735** Malignant melanotic nerve sheath tumors in the spinal canal of psammomatous and non-psammomatous type: Two case reports  
*Yeom JA, Song YS, Lee IS, Han IH, Choi KU*
- 8742** When should endovascular gastrointestinal anastomosis transection Glissonean pedicle not be used in hepatectomy? A case report  
*Zhao J, Dang YL*
- 8749** VARS2 gene mutation leading to overall developmental delay in a child with epilepsy: A case report  
*Wu XH, Lin SZ, Zhou YQ, Wang WQ, Li JY, Chen QD*
- 8755** Junctional bradycardia in a patient with COVID-19: A case report  
*Aedh AI*
- 8761** Application of 3 dimension-printed injection-molded polyether ether ketone lunate prosthesis in the treatment of stage III Kienböck's disease: A case report  
*Yuan CS, Tang Y, Xie HQ, Liang TT, Li HT, Tang KL*
- 8768** High scored thyroid storm after stomach cancer perforation: A case report  
*Baik SM, Pae Y, Lee JM*
- 8775** Cholecystitis-an uncommon complication following thoracic duct embolization for chylothorax: A case report  
*Dung LV, Hien MM, Tra My TT, Luu DT, Linh LT, Duc NM*
- 8782** Endometrial squamous cell carcinoma originating from the cervix: A case report  
*Shu XY, Dai Z, Zhang S, Yang HX, Bi H*
- 8788** Type 2 autoimmune pancreatitis associated with severe ulcerative colitis: Three case reports  
*Ghali M, Bensted K, Williams DB, Ghaly S*
- 8797** Diffuse uterine leiomyomatosis: A case report and review of literature  
*Ren HM, Wang QZ, Wang JN, Hong GJ, Zhou S, Zhu JY, Li SJ*

**LETTER TO THE EDITOR**

- 8805** Comment on "Posterior reversible encephalopathy syndrome in a patient with metastatic breast cancer: A case report"  
*Kunić S, Ibrahimagić OČ, Kojić B, Džananović D*

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Randomized Controlled Trial

# Application of unified protocol as a transdiagnostic treatment for emotional disorders during COVID-19: An internet-delivered randomized controlled trial

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## Abstract

### BACKGROUND

The coronavirus disease 2019 (COVID-19) pandemic has been an emotionally challenging time, especially for young adults. It is associated with a substantial increase in the prevalence of mental health problems, negative symptoms, and stressful experiences that compromise well-being. In low-income countries, internet-delivered psychological services could have a remarkable impact on the population's mental health, given the lack of mental health professionals.

### AIM

To investigate the efficacy of internet-delivered cognitive-behavior therapy (CBT)-transdiagnostic intervention for adults with emotional disorders.

### METHODS

In this internet-delivered randomized controlled trial, 102 students with an emotional disorder (mean age = 28.20 years, standard deviation = 5.07) were randomly allocated to receive unified protocol (UP) ( $n = 51$ ) or treatment as the usual intervention. Following a semi-structured clinical interview, participants completed an online survey including the Overall Anxiety Severity and Impairment Scale, Overall Depression Severity and Impairment Scale, Difficulties in Emotion Regulation Scale, Positive and Negative Affect Schedule, and Emotional Style Questionnaire.



## RESULTS

The participants showed a high degree of adherence. In total, 78% ( $n = 40$ ) of the experimental group participants completed the UP treatment. Considering the intention to treat procedure, the results of the analysis of covariance indicated that participants who received UP showed statistically significant changes in depression symptoms [Cohen's  $d = -1.50$  with 95% confidence interval (CI): -1.90 to -1.10], anxiety (Cohen's  $d = -1.06$  with 95%CI: -1.48 to -0.65), difficulties with emotion regulation (Cohen's  $d = -0.33$  with 95%CI: -0.7 to -0.06), positive affect (Cohen's  $d = 1.27$  with 95%CI: 0.85 to 1.68), negative affect (Cohen's  $d = -1.04$  with 95%CI: -1.46 to -0.63), and healthy emotionality (Cohen's  $d = 0.53$  with 95%CI: 0.09 to 0.13) compared with the control group.

## CONCLUSION

This study's findings highlight the potential value of transdiagnostic internet-delivered programs for young adults with an emotional disorder during the COVID-19 pandemic, and expand the research examining emotional well-being improvements resulting from CBT-transdiagnostic interventions. The findings suggest that UP, which generally concentrates on reducing negative effects, can increase positive effects.

**Key Words:** Unified protocol; COVID-19; Internet-delivered; Emotion regulation; Transdiagnostic; Depression; Anxiety

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**Core Tip:** Transdiagnostic treatments may optimize mental health services during the current pandemic. The findings of this study highlight the potential value of transdiagnostic internet-delivered programs for adults. The unified protocol is a promising transdiagnostic treatment for youth with emotional disorders during the coronavirus disease 2019 pandemic. The study's findings expand the body of research examining positive affect improvements resulting from cognitive-behavior therapy-transdiagnostic interventions.

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## INTRODUCTION

Depressive and anxiety disorders are highly prevalent conditions associated with significant impairments across all areas of life and great economic costs[1]. Before the coronavirus disease 2019 (COVID-19) outbreak, depressive and anxiety disorders were ranked as leading health burdens worldwide. Epidemiological studies have estimated a significant increase in the prevalence of major depressive disorders during the COVID-19 pandemic[2,3]. The COVID-19 outbreak has contributed to severe medical and mental health issues, particularly in vulnerable groups (*e.g.*, students and individuals with preexisting mental health problems)[4], with devastating morbidity and mortality[5,6]. Emotional disorders (*e.g.*, depression, anxiety, trauma-related, and somatic symptom disorders) are characterized by intense and unpleasant negative emotions and aversive reactions to these affective experiences, triggered by a reduced sense of emotion regulation[7]. These conditions are also comorbid and commonly coexist during the lifespan. For example, 45.7% of patients with major depressive disorder present one or more anxiety disorders[8]. The current pandemic has generated frequent and intense negative emotions[9]. Research indicates that psychiatric comorbidities or multiple co-occurring mental health problems are highly prevalent during the pandemic[10,11]. Traditional treatments or specific disorder protocols that target one diagnosis at a time (*e.g.*, major depressive disorder) may be difficult to rationalize when the clinical reality is suspected to be effective in cases with high rates of comorbidity[12]. Specific disorder treatments for primary depression are not equipped to handle comorbid conditions[13] and typically fail to produce significant outcomes in comorbid anxiety symptomatology[14]. As an alternative approach, the development of innovative transdiagnostic therapies reflects a shift from focusing on the distinctions between conditions to similarities and shared mechanisms[15].



The term transdiagnostic reflects an underlying psychological construct causally linked to the class of disorders mechanistically[16]. In the context of treatment approaches, transdiagnostic interventions focus on targeting the shared or common mechanisms implicated in the etiology or onset or maintenance of a group of disorders[17-19]. Neuroticism is a personality trait or temperamental characteristic closely linked to the emergence of anxiety and depression and the genetic risk of developing various mental and physical illnesses. Individual differences in neuroticism predict a broad range of adverse physical and psychological outcomes[20,21], such as depression[22], anxiety, and somatic symptoms[23]. Neuroticism has also been shown to be a strong predictor of internalizing symptomatology during the pandemic[24].

Additionally, emotion dysregulation is a core feature of almost every major form of psychopathology diagnosis with comorbidity[25]. Individuals with emotional disorders report higher impairment in emotion regulation, including maladaptive coping strategies and reduced awareness[26]. Other contributing factors with transdiagnostic relevance mechanisms are anxiety sensitivity, intolerance uncertainty, and rumination, observed in individuals during the pandemic[27]. The dissemination and implications of integrative transdiagnostic treatments are essential to target neuroticism or emotion dysregulation, particularly during the current pandemic[28].

The unified protocol (UP), a manualized, evidence-based, cognitive-behavior therapy (CBT)-transdiagnostic, emotion-focused treatment for emotional disorders[29,30], represents an intervention explicitly developed to address temperamental vulnerabilities, in this case, neuroticism and difficulties in emotion regulation comorbid conditions. UP, with its emphasis on common neurotic processes (*e.g.*, avoidance of effective experience)[31], has the potential to facilitate training programs and address issues regarding generalizability to everyday clinical settings. Evidence represents the equivalence between UP and gold standard protocols for patients with depression and anxiety[32]. An increasing number of studies have supported the effectiveness of UP in reducing anxiety[33] and depression symptoms[34]. With COVID-19 continuing to spread around the globe, scholars anticipate a substantial increase in the rates of depression and anxiety as individuals face emotional challenges. Concerning the substantial increase in the prevalence of depression and anxiety, psychological comorbidities, and negative affective experiences (*i.e.* related to unemployment, isolation) during the current pandemic, the application of UP could be beneficial by targeting the core features of emotional disorders such as neuroticism[35] and emotion dysregulation mechanisms[36]. As such treatments tackle multiple problems and can facilitate dissemination and training using a single set of intervention protocols, they provide a more parsimonious and practical approach[37,38]. However, there is a lack of experimental data on the UP and COVID-19.

Restricting policies (*e.g.*, physical distancing) to minimize the risk of infection have made it more difficult to seek treatment. However, individuals have difficulty accessing appropriate intervention, and the COVID-19 pandemic exacerbates this. Digital mental health services (*i.e.* internet-delivered) offer the possibility of expanding the accessibility of mental health care[39]. Nevertheless, meta-analysis findings have shown that internet-based therapies are effective for anxiety and depression[40-42], with moderate to high mean effect sizes. Recent research has demonstrated that internet-based cognitive-behavioral therapies are acceptable to college students and effectively lower anxiety and depression symptoms[43]. Compared with traditional face-to-face interventions, internet-delivered interventions provide widespread access and dissemination and increase cost-effectiveness. Evidence has revealed that internet-delivered interventions are as efficacious as traditional face-to-face treatments[44,45]. Transdiagnostic, emotion-focused cognitive-behavioral treatments, such as UP for Transdiagnostic Treatment of Emotional Disorders (UP), may be particularly well suited to address the challenges practicing psychologists and their patients face during the current COVID-19 pandemic[46-48].

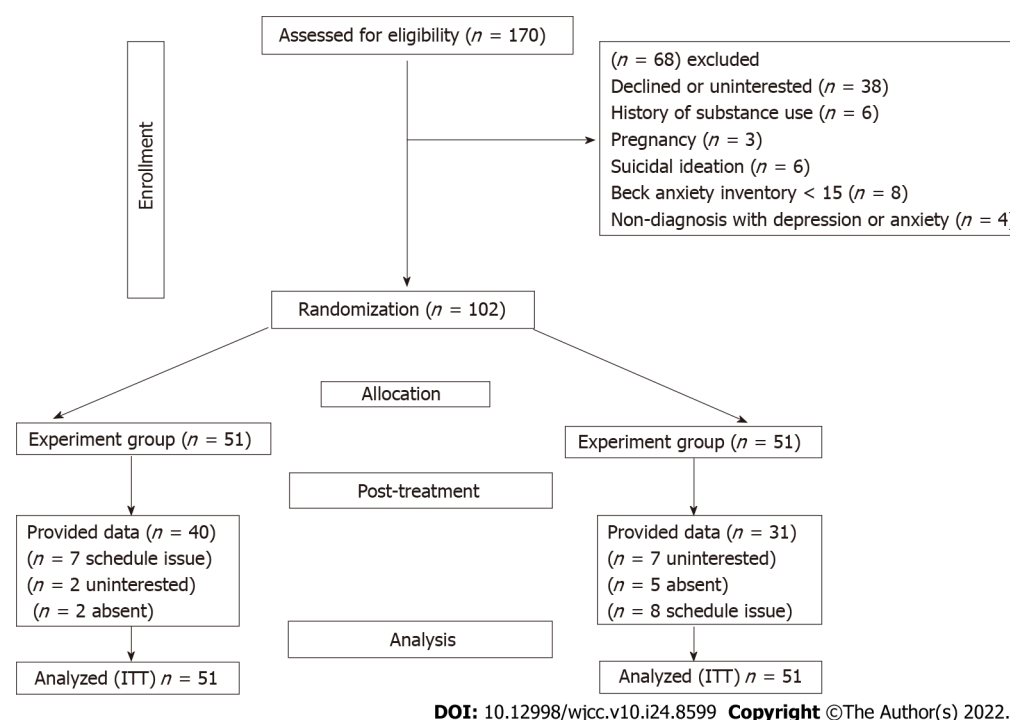
### Current study

This study was conducted to examine the application of an internet-delivered CBT-transdiagnostic intervention for adults with emotional disorders. It was hypothesized that participants randomly assigned to receive UP would demonstrate significant changes in depression, anxiety, affectivity (positive and negative affects), emotion dysregulation, and healthy emotionality compared with randomly assigned participants to the treatment-as-usual group (TAU). In addition, it was hypothesized that the experimental group participants would demonstrate significant changes in the dependent variable scores compared with baseline at post-intervention.

## MATERIALS AND METHODS

### Sample

A total of 170 students were screened, and 102 were eligible to participate in the trial. Sixty-eight individuals were excluded from this study. Of these, thirty-eight students declined or were uninterested (without a specific reason) in participating in the study. The consort diagram is shown in Figure 1. The CONSORT 2010 checklist of information was used to report a randomized trial (Supplementary material)[49]. Individuals were eligible if they met the following criteria: aged 18 years or older with no prior



**Figure 1** Participants flow chart diagram. ITT: Intent to treat.

experience with UP, were willing to participate and were randomly assigned to the control condition, had access to the internet and had an e-mail address, were fluent in Persian, and met the Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision (DSM-IV-TR) criteria for depression or anxiety disorders[50,51]. Individuals were excluded if they met the following criteria: Presence of a severe condition that would require prioritization for treatment (*e.g.*, schizophrenia, psychosis); pregnancy or breastfeeding; clear and current or history of substance dependence disorder or alcohol, and suicide; and unstable medication regimens (*e.g.*, complex medication regimens to manage their health; unstable dose of medication over the last 3 months). The study was reviewed and approved by the internal review board of Bamyan University (Bamyan, Afghanistan). Informed consent was obtained from all subjects involved in the study.

### Measures

The survey comprised the Overall Anxiety Severity and Impairment Scale (OASIS)[52], Overall Depression Severity and Impairment Scale (ODSIS)[53], Difficulties in Emotion Regulation Scale Short Form (DERS-SF)[54], Positive and Negative Affect Schedule (PANAS)[55], and (Emotional Style Questionnaire (ESQ[56]; Persian version[57]). The Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-IV-TR)[58] is a semi-structured interview that evaluates diagnostic criteria. At baseline, interviews were conducted to evaluate the participants to investigate the inclusion and exclusion criteria.

### Primary outcomes

**Anxiety:** The OASIS is a brief unidimensional transdiagnostic self-report scale developed to assess anxiety symptoms and impairment severity. Respondents rated the five items on a scale ranging from 0 (never) to 4 (extreme or all the time). Additionally, it can be used to measure anxiety disorders with comorbidities and sub-threshold anxiety symptoms. The scale had very good internal consistency (Cronbach's  $\alpha = 0.86$ ).

**Depression:** The ODSIS is a brief unidimensional transdiagnostic self-report scale. The ODSIS is a direct adaptation of the OASIS and has been modified to assess depression. The ODSIS is a brief, five-item questionnaire that assesses dimensional depression-related symptom severity and can be used across depressive disorders with varied comorbidities. Participants rated the five items on a scale ranging from 0 (never) to 4 (extreme or all the time). The scale had very good internal consistency (Cronbach's  $\alpha = 0.87$ ).

### Secondary outcomes

**Affectivity:** The PANAS was employed to determine the pleasant (ten descriptors) and unpleasant (ten descriptors) feelings experienced over the past month. Participants rated the items on a five-point scale,

ranging from very slightly (1) to extremely (5). The scale had very good internal consistency ( $\alpha = 0.83$ ).

**Difficulties in emotion regulation:** The DERS-SF was used to measure emotional dysregulation. The respondents rated the 18 items on a five-point scale, ranging from 1 (almost never) to 5 (almost always). Higher scores indicate greater difficulties in emotion regulation. The scale had very good internal consistency (Cronbach's  $\alpha = 0.81$ ).

**Healthy emotionality:** The ESQ was used to measure healthy emotionality. Respondents rated each 24-item item on a seven-point scale ranging from 1 (strongly disagree) to 7 (strongly agree). Raw scores range from 24 to 168, with higher scores indicating higher adaptive emotional functioning. The scale had very good internal consistency (Cronbach's  $\alpha = 0.89$ ).

### Procedure

The current study was an internet-based, two-armed, assessor-blinded, parallel randomized controlled trial (RCT) comparing the application of an online intervention (UP) with an online TAU control group. The study (*e.g.*, all assessments and treatments) was administered *via* the internet in a university setting, including an intervention platform. The study was conducted during the COVID-19 pandemic (August 2020 to January 2021). Over 3 mo, participants were recruited through online announcements, flyers, and referrals. Additionally, the link for the study was distributed and posted on online community platforms such as university forums. Potentially eligible individuals who applied to participate in the RCT were informed of the study's objectives, advantages, hazards, session numbers, confidentiality, assurances of anonymity, and the possibility of group assignment *via* e-mail or telephone. Participants were informed that they could withdraw their consent or stop participating at any point in the study. Also, they were free to skip specific questions and continue to participate.

Individuals who initially obtained a high score (greater than 15) on the Beck Anxiety Inventory[59] were requested to obtain informed consent. The consented participants underwent an interview to ensure that the eligibility criteria were fulfilled. Two clinical psychologists evaluated the participants' personal history, mental status, personal resources, and suicide risk through clinical interviews through 45 min of online video communication. Individuals who met the SCID-I-IV criteria for depression or anxiety disorders were requested to rate primary and secondary outcomes. The participants rated the primary and secondary outcomes at two time points: Time 1: Pre-treatment to allocation, including baseline; and Time 2: Immediately after the intervention, including posttreatment assessment. The intervention schedule is presented in Table 1.

### Sample size

Using G\*Power software[60], a power analysis was suggested in an analysis of covariance (ANCOVA) design assuming the desired  $\alpha$  level of 0.05, a power level of 0.8, two groups, and two measurement levels to detect a medium to large effect size[32,61]. The sample size was 82. Considering the reported dropout rate of 25%[62], the required sample size was 102.

### Randomization and blinding procedures

The participants were randomly allocated to the intervention groups using the permuted block technique. An independent statistician generated the allocation schedule. Random sequence block sizes were generated using a computer random number generator with an equal allocation ratio. The statistician informed the observer staff and participants of the random allocation results *via* e-mail. The psychological evaluators, statisticians, and assessors who measured and recorded the data were blinded to the conditions and the participants' groups. Participants were instructed not to share any assigned conditions or diagnostic status data.

### Interventions

**Experimental group:** The UP is typically delivered over 12 to 14 sessions in a group format[63]. UP is a modular intervention that was administered and structured based on manuals published by Barlow *et al* [29,30,32]. UP comprises eight different treatment modules delivered in twelve 2-h weekly sessions. The UP comprises five core modules: present-focused awareness, cognitive flexibility, changing emotional behaviors, awareness and tolerance of physical sensations, and emotional exposure. A module precedes these five core modules on motivation and readiness for change and treatment engagement. Also, the second introductory module provides psychoeducation and a framework for tracking emotional experiences. After the five core modules were completed, the final module for relapse prevention was provided. Table 2 presents an overview of each module's content and intervention schedule (Supplementary material for a more thorough explanation).

**Control group:** The control group received TAU as provided by the general practitioners. TAU is considered non-treatment and/or practical advice by general practitioners administered in normal care, focusing on reducing unpleasant feelings and negative emotional symptomatology. TAU was delivered in twelve 2 h weekly sessions. The participants who received the introductory modules of UP included four psychoeducation sessions. Specifically, the TAU comprises three parts: four sessions of psychoedu-

**Table 1 Study schedule of enrollment, intervention, and assessment**

	Enrollment	Pre-allocation	Allocation	Post-intervention
Duration	12 wk	1 wk	12 wk	
Eligibility	x			
Informed consent	x			
Clinical interview	x			x
Demographic question	x			
Intervention				
Unified protocol			-	
Treatment as usual			-	
Primary outcome				
OASIS		x		x
ODSIS		x		x
Secondary outcomes				
DERS		x		x
ESQ		x		x
PANAS		x		x

x: Completed at this stage; -: Intervention period. DERS: Difficulties in Emotion Regulation Scale; ESQ: Emotional Style Questionnaire; OASIS: Overall Anxiety Severity and Impairment Scale; ODSIS: The Overall Depression Severity and Impairment Scale; PANAS: Positive and Negative Affect Schedule.

**Table 2 Content and the number of sessions for each module**

Module	Schedule	Content and the number of sessions for each module
One <sup>1</sup>	Week 1	Setting goals and maintaining motivation (1 session)
Two <sup>1</sup>	Week 2	Understanding emotions (1 sessions)
Three <sup>2</sup>	Week 3 and 4 <sup>1</sup>	Mindful emotion awareness (2 sessions)
Four <sup>2</sup>	Week 5	Cognitive flexibility (2 sessions)
Five <sup>2</sup>	Week 6	Countering emotional behaviors (1 sessions)
Six <sup>2</sup>	Week 7	Understanding and confronting physical sensations (1 session)
Seven <sup>2</sup>	Weeks 8 to 11	Emotion exposures (5 sessions)
Eight <sup>3</sup>	Week 12	Recognizing accomplishments and looking to the future (1 session)

<sup>1</sup>The modules of three, four, five, six, and seven are core modules.

<sup>2</sup>The modules of one and two are introductory modules.

<sup>3</sup>The module of eight is the relapse introductory module.

cation, four sessions of COVID-19 consideration, and four sessions of sharing experiences.

### **Risk**

For participants with higher concerns related to psychological states, support was delivered by clinical psychologists and general practitioners *via* e-mail and telephone. Clinical team members received a comprehensive refreshment course in the context of psychological assessments, structured interviews, and ethics in clinical research.

### **Statistical analysis**

Data were analyzed using SPSS with a two-sided 5% significance level. Based on the intent-to-treat procedure, the data for all randomized participants were considered in the final analysis. The last observation-carried-forward method was considered the next point for dropping data to handle missing

data. Descriptive statistics were utilized to present the means and standard deviation for continuous variables and numbers or percentages for categorical variables. The parametric test of ANCOVA was performed to investigate UP efficacy compared with TAU, with the time1 (baseline) collected data as covariate scores to control preexisting group differences. The paired *t*-test was conducted to investigate within-group changes. Effect sizes are reported as partial eta-squared. Also, the standardized effect size (Cohen's *d*) was calculated for pretreatment and posttreatment changes based on the means and standard deviations. Effect size values were interpreted conservatively, with 0.2, 0.5, and 0.8 reflecting small, medium, and large treatment effects[64].

## RESULTS

### *Descriptive characteristics*

The baseline characteristics of the study participants are presented in Table 3. At baseline, independent *t*-tests showed no significant group differences in age, primary outcomes, or secondary outcomes ( $P > 0.05$ ), indicating successful randomization. The sample comprised 102 adults aged 20 years to 39 years. The mean age was 28.07 years [standard deviation (SD) = 5.07]. At the end of the study, 78% ( $n = 40$ ) of the experimental group participants completed UP treatment sessions and completed the assessment protocol. Additionally, 37% ( $n = 20$ ) of participants left the control group. In total, 70% ( $n = 71$ ) of the participants completed the course.

### *Treatment results*

Table 4 shows the results of the parametric test of ANCOVA to compare the effectiveness of the unified protocol intervention with TAU at posttreatment (Time 2). At the end of the study, the ANCOVA results revealed that students who received the UP intervention had a statistically significant reduction in ODSIS score compared with those who received TAU, Cohen's  $d = -1.50$  with 95%CI: -1.90 to -1.06; mean different = 4.08, standard error (SE) = 0.52,  $P < 0.001$ , with 95%CI: 3.05 to 5.11. ANCOVA results also revealed that students who received UP intervention demonstrated a statistically significant reduction in OASIS score compared with those who received TAU, Cohen's  $d = -1.06$  with 95%CI: -1.48 to -0.65; mean different = 2.47, SE = 0.56,  $P < 0.001$ , with 95%CI: 1.39 to 3.56.

At the end of the study, the results of ANCOVA revealed that students who received UP intervention demonstrated a statistically significant reduction in DERS score compared with those who received TAU, Cohen's  $d = -0.33$  with 95%CI: -0.7 to -0.06; mean different = 4.19, SE = 1.63,  $P = 0.01$ , with 95%CI: 0.95 to 7.43. ANCOVA results also revealed that students who received the UP intervention demonstrated a statistically significant increase in ESQ score compared with those who received TAU, Cohen's  $d = 0.53$ , 95%CI: 0.14 to 0.93; mean different = -0.876, SE = 2.44,  $P = 0.001$ , with 95%CI: -13.56 to -3.92.

At the end of the study, the results of ANCOVA also revealed that students who received UP intervention demonstrated a statistically significant increase in PANAS-PA score compared with those who received TAU; Cohen's  $d = 1.27$  with 95%CI: 0.85 to 1.68; mean different = -4.41, SE = 0.69,  $P < 0.001$ , with 95%CI: -5.79 to -3.04. ANCOVA results also revealed that students who received UP intervention demonstrated a statistically significant reduction in PANAS-NA score compared with those who received TAU, Cohen's  $d = -1.04$  with 95%CI: -1.46 to -0.63; mean different = 3.72, SE = 0.81,  $P < 0.001$ , with 95%CI: 2.14 to 5.37. Means and SDs are presented at Time 1 and 2 (Table 5).

The paired *t*-test was conducted to calculate the within-group effect size post-intervention compared with baseline. These findings revealed that the experimental group participants significantly demonstrated improvement in the dependent variable scores post-intervention (Table 6). The results showed no significant differences for the control group participants between Time 2 and Time 1.

## DISCUSSION

The outbreak of COVID-19 is an emotionally challenging time, especially for young adults, and is associated with a range of mental health problems, negative emotions, and stressful experiences that compromise a well-being. However, little evidence is available. The study was conducted to examine the application of an internet-delivered CBT-trans-diagnostic intervention for adults with emotional disorders. The study's findings show that an internet-delivered trans-diagnostic CBT protocol is an effective intervention for individuals with depression and anxiety during COVID-19. At posttreatment, the students who received the UP intervention showed significant changes in depression, anxiety, emotion dysregulation, affectivity, and healthy emotionality outcomes compared with those who participated in the TAU intervention. Our findings revealed significant changes in depression, anxiety, worry, emotion regulation, and affectivity measures in the unified protocol group posttreatment relative to baseline. There were no significant changes in the dependent variables in the control group at posttreatment relative to baseline. The stressful pandemic situations may have been a confounding factor that may have elevated mental health problems and higher than usual daily psychological life



**Table 3 Demographic characteristics of the sample, *n* = 102**

Item characteristic	Baseline value	Control group value	UP group value	Test	<i>P</i> value
Categorical variables					
Sex, <i>n</i> (%)					
Women	48 (47.1)	21	27	$\chi^2 = 0.35$	0.55
Man	54 (52.9)	30	24		
Principal diagnosis, <i>n</i> (%)					
Depressive disorder	45 (44.1)	22	23	$\chi^2 = 1.41$	0.23
Anxiety disorder	57 (55.9)	26	31		
Marital status, <i>n</i> (%)					
Single	34 (33.3)	20	14	$\chi^2 = 11.33$	0.001
In relationship	68 (66.7)	35	33		
Psychological disorders, <i>n</i> (%)					
MDD	40 (48.6)	18	22		
Dysthymia	5 (7.1)	4	1		
GAD	34 (31.4)	15	19		
SAD	23 (12.9)	11	12		
Continues variables (mean $\pm$ SD)					
Age, yr	28.07 $\pm$ 5.07	27.92 $\pm$ 4.67	28.18 $\pm$ 5.49	<i>t</i> (100) = 0.28	0.77
Anxiety	11.14 $\pm$ 1.88	11.35 $\pm$ 2.05	10.88 $\pm$ 1.69	<i>t</i> (100) = 1.26	0.21
Depression	10.97 $\pm$ 3.75	11.24 $\pm$ 1.75	10.71 $\pm$ 1.70	<i>t</i> (100) = 1.09	0.26
Emotion dysregulation	49.69 $\pm$ 7.82	49.08 $\pm$ 7.10	50.18 $\pm$ 8.04	<i>t</i> (100) = 0.80	0.4
Positive affect	26.49 $\pm$ 3.80	26.88 $\pm$ 3.92	26.10 $\pm$ 3.66	<i>t</i> (100) = 1.05	0.29
Negative affect	27.44 $\pm$ 3.42	26.59 $\pm$ 3.66	27.74 $\pm$ 3.01	<i>t</i> (100) = 1.48	0.14
Healthy emotionality	59.84 $\pm$ 8.82	60.33 $\pm$ 9.46	58.90 $\pm$ 11.35	<i>t</i> (100) = 1.67	0.09

GAD: Generalized anxiety disorder; MDD: Major depressive disorder; SAD: Social anxiety disorder; SD: Standard deviation; *t*: Independent *t*-test; UP: Unified protocol.

distress among the control group participants.

As an emotion-focused intervention, the core modules of UP are relevant to depression and anxiety. The improvement of emotion regulation can be associated with improved depression and anxiety symptoms[65,66]. A large body of evidence has examined the relationships and influences of emotional regulation in the treatment of depression[34,67,68], anxiety disorders[69,70], psychological distress[71], and rumination[72]. Depressed individuals lack emotional regulation skills, which results in higher rumination, avoidance, and suppression of positive emotion[73]. Individuals with higher depression report more ineffective coping strategies (*e.g.*, rumination, self-blame) and a lower prevalence of adaptive emotion regulation behaviors (*e.g.*, positive reappraisal, acceptance)[74] when experiencing negative emotions[75]. Moreover, psychological distress is associated with maladaptive or ineffective reappraisal functions and mood fluctuations, which contribute to depression, anxiety, and mental health problems[76].

The study revealed surprising findings. Large effect sizes were found in the negative and positive effects, with a greater effect on positive affect than negative affect. The decrease in negative affect scores confirms the UP protocol's theory that a mechanistically transdiagnostic treatment explicitly targets and reduces negative effects[19] as a psychopathology mechanism associated with the etiology of emotional disorders[77]. Despite the benefits of targeting positive emotions for physical and emotional well-being, most psychological interventions focus on targeting negative affect. Consequently, trans-diagnostic interventions for emotional disorders (*e.g.*, UP) remain focused on evaluating outcomes of reduced negative affectivity symptoms. While UP initially focuses on reducing negative affect. A few investigations have revealed that the UP application may also promote positive affect[33,78,79]. Anxiety and depression have also been associated with lower levels of positive affect (*i.e.* extraversion) and a lower tendency to experience the world in an energetic and sociable way[80]. The study's findings expand the

**Table 4 Analysis of covariance at Time 2 to compare the unified protocol with treatment as usual**

Measure	Condition	Adjusted mean		Levene's test		ANCOVA			
		TAU	UP	F (1, 100)	Sig	F (1, 99)	P value	$\eta^2p$	R <sup>2</sup>
Anxiety	Time 2	11.81	7.98	3.67	0.058	28.77	< 0.001	0.22	0.23
Depression	Time 2	12.11	8.03	3.43	0.07	62.02	< 0.001	0.38	0.37
Emotion dysregulation	Time 2	52.44	48.06	2.34	0.12	6.57	0.012	.06	0.07
Positive affect	Time 2	26.72	33.14	0.12	0.68	40.75	< 0.001	0.29	0.30
Negative affect	Time 2	27.01	23.28	1.87	0.17	21.35	< 0.001	0.18	0.16
Healthy emotionality	Time 2	58.83	65.68	0.19	0.68	12.90	0.001	0.12	0.14

ANCOVA: analysis of covariance;  $\eta^2p$ : Partial eta square; R<sup>2</sup>: Adjusted R square; TAU: Treatment as usual; Time 2: Immediately after treatment; UP: Unified Protocol.

**Table 5 Control group and intervention group**

Measure	Control group (TAU), n = 51		Intervention group (UP), n = 51	
	Time 1	Time 1I	Time 1	Time 1I
Anxiety	11.35 ± 2.05	11.75 ± 2.42	10.88 ± 1.69	8.54 ± 2.83
Depression	11.24 ± 1.75	12.08 ± 2.16	10.71 ± 1.70	8.14 ± 3.03
Emotion difficulties	49.07 ± 7.32	50.31 ± 8.40	50.18 ± 8.04	47.33 ± 9.41
Positive affect	26.88 ± 3.92	26.99 ± 4.22	26.10 ± 3.66	31.97 ± 3.59
Negative affect	26.59 ± 3.66	27.89 ± 3.74	27.74 ± 3.01	23.31 ± 4.92
Healthy emotionality	60.33 ± 9.46	59.47 ± 10.41	58.90 ± 11.35	65.12 ± 10.76

Data are presented as mean ± SD. Time 1I: Posttreatment; TAU: Treatment as usual; UP: Unified protocol.

body of research that examines positive affect improvements resulting from CBT-transdiagnostic interventions. The findings are promising, as they suggest that UP can promote positive affect and healthy emotionality, the constructs linked with emotional well-being and flourishing[81,82].

The current study could develop the UP, consisting of five core modules supported by the introductory modules, to teach clients how to accept and experience emotional distress while responding to them in more adaptive ways. As the treatment progresses, thoughts, physical feelings, and behaviors are examined in-depth, emphasizing the dysfunctional emotion regulation strategies that the patient has developed over time. Psychoeducational modules have increased patients' readiness and motivation for change and facilitated coping by developing knowledge about the components (*i.e.* behavioral, cognitive, and psychological) of emotions and their interaction. The UP core modules concentrate on skills and strategies to target deficits in emotion regulation and facilitate more adaptive responses[30]. Individuals with depression experience deficits in mindful awareness of their emotions and experiences, particularly for nonjudgmental awareness and allowing oneself to notice emotions without triggering a repetitive negative thinking process such as rumination[83,84]. There is also evidence that mindfulness is an effective strategy to facilitate inhibitory learning in exposure therapy. Mindfulness training is associated with decreased reliance on strategies such as rumination and over engagement and a greater ability to tolerate negative emotions[85]. Individuals affected by adverse events may misinterpret abnormal bodily sensations as severe condition warning signs[86]. Accurate knowledge concerning COVID-19 infection may inhibit an automatic fear response and suppress an



**Table 6 Paired *t*-test and within-group effect size at post-intervention**

Item	Treatment as usual group		Unified protocol group		
	<i>t</i> (50)	<i>P</i> value	<i>t</i> (50)	<i>P</i> value	Cohen's <i>d</i>
Anxiety	0.88	0.37	6.13	< 0.001	0.81
Depression	-1.89	0.06	4.38	< 0.001	0.75
Emotion difficulties	-0.98	0.33	5.45	< 0.001	0.54
Positive affect	0.12	0.8	-7.92	< 0.001	1.39
Negative affect	-0.36	0.72	4.43	< 0.001	0.83
Healthy emotionality	0.53	0.6	-2.16	0.03	0.39

initial emotional and bodily fear reaction[87,88]. The higher levels of self-awareness lead to a clear recognition of the triggering of negative effects and facilitate adaptive emotional functioning through mindful attention toward unpleasant bodily sensations[89]. As another UP component, interoceptive exposure (IE) was originally designed to target fearful reactions and anxious sensitivity toward bodily sensations linked with anxiety and fear generated by stressful experiences[90]. IE effectively reduces the fear of bodily sensations, treats anxiety sensitivity, and promotes self-regulated social interaction abilities[68].

The feasibility of the internet-delivered UP in a group setting was evaluated. While emotion dysregulation is linked to a lower desire to engage in the treatment, the sample is characterized as challenging to treat[91]. Overall, participants had a high degree of adherence, and the treatment was well tolerated. Previous studies have substantially improved patient engagement and clinical outcomes in the guided internet-delivered group interventions[92-94].

### Limitations

The trial's findings must be viewed in light of several limitations. The participants were students who were so well educated, which may have aided individuals' capacity to develop more UP and reduce generalizability. The next limitation was the anticipated dropout rate (25%), which was lower than the actual dropout rate (30%). With an interdisciplinary approach to attrition incorporating a range of technological, environmental, and individual factors, future studies may be required to explain participants' adherence comprehensively and improve retention in internet-delivered interventions. The next limitation was that the lack of follow-up made it difficult to assess prevention effects. Additionally, the study had no follow-up. Therefore, it was not easy to assess the long-term effects. Further studies with larger sample sizes and longer follow-up periods are required to replicate the findings of this study. The SCID-I-IV application at enrollment and the end of the study was a strength of this research.

## CONCLUSION

Despite the limitations, the findings developed the unified protocol as a promising transdiagnostic treatment for youth with emotional disorders during the COVID-19 pandemic. UP has the potential to simplify training efforts while also addressing concerns about generalizability to routine care settings. Addressing these current barriers to widespread dissemination and implementation of evidence-based practice treatments has implications for bridging the science-to-service gap. The present study's findings provide further evidence of internet-delivered CBT transdiagnostic interventions for improvements in depressive and anxiety disorders. In the challenging emotional events generated by the COVID-19 pandemic, the UP may be particularly well-suited to help individuals manage their experienced emotional problems. Additionally, from a global mental health perspective, a unified transdiagnostic treatment can potentially serve as a promising intervention approach that would be more cost-effective and may help to increase the availability of evidence-based treatments for emotional disorders, affordability of dissemination of a single protocol *vs* multiple protocols, and a decreased need for clinical observations by trained health professionals[95].

Further studies are required to assess the cost-effectiveness and economic evaluations of internet-delivered UP with larger samples, as this has not yet been formally evaluated. There would be value in adding qualitative components into future trials to establish the acceptance of unified protocol interventions for clinicians and clients. With an interdisciplinary approach to attrition incorporating a range of technological, environmental, and individual factors, future studies may be required to comprehensively explain participants' adherence and improve retention in internet-delivered interventions.

## ARTICLE HIGHLIGHTS

### Research background

Depressive and anxiety disorders represent one of the greatest burdens among human diseases worldwide. These emotionally difficult conditions often manifest as comorbidities. A growing body of evidence indicates that the trans-diagnostic approach for treating these disorders is safe, feasible, and efficient.

### Research motivation

Restricted policies (*e.g.*, physical distancing) to minimize the risk of infection have made it more difficult to seek and attend treatment. The majority of individuals with mental health problems remain untreated. Internet-based interventions can help to address existing barriers. Also, trans-diagnostic, emotion-focused cognitive-behavioral treatments, such as unified protocol (UP), may be particularly well suited to address the challenges practicing psychologists and their patients face during the current coronavirus disease 2019 (COVID-19) pandemic.

### Research objectives

This study was conducted to examine the application of an internet-delivered cognitive-behavior therapy (CBT)-transdiagnostic intervention for adults with emotional disorders.

### Research methods

In this internet-delivered two-armed, assessor-blinded, parallel randomized controlled trial, 102 students with an emotional disorder were randomly allocated to receive UP or treatment as the usual interventions. Following a semi-structured clinical interview, participants completed an online survey, including the Overall Anxiety Severity and Impairment Scale, Overall Depression Severity and Impairment Scale, Difficulties in Emotion Regulation Scale, Positive and Negative Affect Schedule, and Emotional Style Questionnaire.

### Research results

The findings of the current trial highlight the considerable potential of internet-delivered CBT programs, such as the UP, in improving access to online psychotherapy for affected adults by the pandemic. Our findings revealed significant changes in depression, anxiety, worry, emotion regulation, and affectivity measures in the unified protocol group posttreatment relative to baseline. There were no significant changes in the dependent variables in the control group at posttreatment relative to baseline.

### Research conclusions

Transdiagnostic treatments target shared mechanisms between disorders to facilitate change across diagnoses. Overall, the findings support that the unified protocol could be an additional efficient as a parsimonious, transdiagnostic treatment of emotional disorders for young adults with emotional disorders during the current pandemic.

### Research perspectives

From a global mental health perspective, a unified transdiagnostic treatment can potentially serve as a promising intervention approach that would be more cost-effective and may help to increase the availability of evidence-based treatments for emotional disorders, affordability of dissemination of a single protocol *vs* multiple protocols, and a decreased need for clinical observations by trained health professionals. With an interdisciplinary approach to attrition incorporating a range of technological, environmental, and individual factors, future studies may be required to comprehensively explain participants' adherence and improve retention in internet-delivered interventions.

## FOOTNOTES

**Author contributions:** Nazari N made significant contributions to the conceptualization and methodology of the study, and writing of the original draft; Yan K made significant contributions to the design, software, methodology, and supervision of the study; Yusufi MH made significant contributions to the preparation, data curation, writing, and revision of the draft. All authors wrote, reviewed, and edited the manuscript.

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