Efficacy of a Six-week Therapist-Guided Online Therapy Versus Self-Help Internet-based Therapy on COVID-19 Invoked Anxiety and Depression Among Individuals in Oman During the COVID-19 pandemic: An Open Label, Pragmatic Randomized Controlled Trial.

Mohammed Al Alawi, Roopa K McCall, Alya Sultan, Naser Al Balushi, Tamadhir Al-Mahrouqi, Abdullah Al Ghailani, Hilal Al Sabti, Abdullah Al-Maniri, Sathiya M. Panchatcharam, Hamed Al Sinawi

Submitted to: JMIR Mental Health
on: December 21, 2020

Table of Contents

Efficacy of a Six-week Therapist-Guided Online Therapy Versus Self-Help Internet-based Therapy on COVID-19 Invoked Anxiety and Depression Among Individuals in Oman During the COVID-19 pandemic: An Open Label, Pragmatic Randomized Controlled Trial.

Mohammed Al Alawi[1] MRCPsych; Roopa K McCall[2] PhD; Alya Sultan[3] PhD; Naser Al Balushi[1] PhD; Tamadhir Al-Mahrouqi[4] MD; Abdullah Al Ghailani[4] MD; Hilal Al Sabti[4] FRCSc; Abdullah Al-Maniri[4] PhD; Sathiya M. Panchatcharam[4] MSc; Hamed Al Sinawi[1] FRCPsych

[1]Department of Behavioral Medicine, Sultan Qaboos University Hospital, Muscat, Sultanate of Oman. Muscat OM
[2]Al Harub Medical Center, Muscat, Sultanate of Oman Muscat OM
[3]Euonia Clinic, Muscat, Sultanate of Oman Muscat OM
[4]Oman Medical Specialty Board, Muscat, Sultanate of Oman. Muscat OM

Corresponding Author:
Mohammed Al Alawi MRCPsych
Department of Behavioral Medicine, Sultan Qaboos University Hospital, Muscat, Sultanate of Oman.
Muscat
Muscat
OM

Abstract

Background: The coronavirus (COVID-19) pandemic has led to a notable increase in psychological distress, globally. Oman is no exception to this, with several studies indicating high levels of anxiety and depression among the Omani public. There is a need for adaptive and effective interventions aiming at improving the increased levels of psychological distress arising from the COVID-19 pandemic.

Objective: This study aimed at assessing the efficacy of therapist guided Online-Therapy versus self-help, e-mail delivered, therapy focusing on COVID-19-induced symptoms of anxiety and depression among individuals living in Oman during the COVID-19 pandemic.

Methods: This was a 6-week pragmatic randomized controlled trial involving 60 participants who were recruited from a study sample surveyed for symptoms of anxiety/depression among the public in Oman amid the COVID-19 pandemic. The participants in the intervention group were allocated to receive 1 online session per week for 6 weeks from certified psychotherapists in Oman in Arabic or English. The Psychotherapists utilized Cognitive Behavioral Therapy (CBT) and Acceptance and Commitment Therapy (ACT) interventions. The participants in the control group received an automatic weekly newsletter via e-mail containing self-help information and tips to cope with distress associated with COVID-19. The information mainly consisted of behavioral tips revolving around the principles of CBT and ACT. The primary outcome was measured by comparing the change in the mean Patient Health Questionnaire-9 (PHQ-9) and General Anxiety Disorder-7 (GAD-7) scores from baseline to the end of the study (after six sessions) between the two arms. The secondary outcome was comparing the proportions of participants with depression and anxiety in the two groups.

Results: Data from 46 participants were analyzed (22 in intervention arm and 24 in control arm). There was no statistical difference in baseline characteristics between both arms. Analysis of covariance indicated a significant reduction in the GAD scores ($F(1,43) = 7.307$; $P = 0.010$) between the two arms after adjusting for baseline scores. The intervention arm GAD scores reduced more than those of the control arm ($B = -3.27$; $P = 0.010$). The intervention arm had a greater reduction in PHQ-9 mean scores ($F(1,43) = 8.298$; $P = 0.006$) when compared to the control arm ($B = -4.311$; $P = 0.006$). While the levels of anxiety and depression reduced in both study arms, the reduction was higher in the intervention group (P values of <0.049 and <0.022, respectively).

Conclusions: This study provides a preliminary evidence to support the efficacy of Online-Therapy for improving the symptoms of anxiety and depression during the COVID-19 crisis in Oman. Therapist guided Online-Therapy was noted to be superior to

self-help Internet-based therapy, however, both therapies could be considered as viable options. Clinical Trial: ClinicalTrials.gov NCT04378257

(JMIR Preprints 21/12/2020:26683)
DOI: https://doi.org/10.2196/preprints.26683

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**
Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v
Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

Efficacy of a Six-week Therapist-Guided Online Therapy Versus Self-Help Internet-based Therapy on COVID-19 Invoked Anxiety and Depression Among Individuals in Oman During the COVID-19 pandemic: An Open Label, Pragmatic Randomized Controlled Trial.

Mohammed Al Alawi[1*], MRCPsych; Roopa K McCall [2], PhD; Alya Sultan[3], PhD; Naser Al Balushi[1], MRCPsych; Tamadhir Al-Mahrouqi [4], MD; Abdullah Al Ghailani[3], MD; Hilal Al Sabti[4], FRCSc; Abdullah Al-Maniri [4], PhD; Sathiya M. Panchatcharam[4], MSc; Hamed Al Sinawi[1] FRCPsych
[1]Department of Behavioral Medicine, Sultan Qaboos University Hospital, Muscat, Sultanate of Oman.
[2]Al Harub Medical Center, Muscat, Sultanate of Oman
[3] Euonia Clinic, Muscat, Sultanate of Oman
[4] Oman Medical Specialty Board, Muscat, Sultanate of Oman.

*Corresponding Author:
Mohammed Al Alawi MD
Department of Behavioral Medicine,
Sultan Qaboos University Hospital,
Sultan Qaboos University,
Muscat, Sultanate of Oman
P.O. Box 35
Al-Khoudh 123
Phone: + 96892281145
Email: alalawim@squ.edu.om

Authors' emails
Hamed Al Sinawi [drhamed@hotmail.com]
Naser Al Balushi [naser.albalushi@hotmail.com]
Tamadhir Al-Mahrouqi [omcf13095@nu.edu.om]
Abdullah Al Ghailani [ayghailani@gmail.com]
Roopa K McCall [roopakoshy08@gmail.com]
Alya Sultan [alya.r.sultan@gmail.com]
Hilal Al Sabti [alsabti@omsb.org]
Abdullah Al-Manir [almaniri@gmail.com]
Sathiya M. Panchatcharam [sathiya.m@omsb.org]
Mohammed Al Alawi [alalawim@squ.edu.om]

Abstract

Background: The coronavirus (COVID-19) pandemic has led to a notable increase in psychological distress, globally. Oman is no exception to this, with several studies indicating high levels of anxiety and depression among the Omani public. There is a need for adaptive and effective interventions aiming at improving the increased levels of psychological distress arising from the COVID-19 pandemic.

Objectives: This study aimed at assessing the efficacy of therapist guided Online-Therapy versus self-help, e-mail delivered, therapy focusing on COVID-19-induced symptoms of anxiety and depression among individuals living in Oman during the COVID-19 pandemic.

Methods: This was a 6-week pragmatic randomized controlled trial involving 60 participants who were recruited from a study sample surveyed for symptoms of anxiety/depression among the public in Oman amid the COVID-19 pandemic. The participants in the intervention group were allocated to receive 1 online session per week for 6 weeks from certified psychotherapists in Oman in Arabic or English. The Psychotherapists utilized Cognitive Behavioral Therapy (CBT) and Acceptance and

Commitment Therapy (ACT) interventions. The participants in the control group received an automatic weekly newsletter via e-mail containing self-help information and tips to cope with distress associated with COVID-19. The information mainly consisted of behavioral tips revolving around the principles of CBT and ACT. The primary outcome was measured by comparing the change in the mean Patient Health Questionnaire-9 (PHQ-9) and General Anxiety Disorder-7 (GAD-7) scores from baseline to the end of the study (after six sessions) between the two arms. The secondary outcome was comparing the proportions of participants with depression and anxiety in the two groups.

Results: Data from 46 participants were analyzed (22 in intervention arm and 24 in control arm). There was no statistical difference in baseline characteristics between both arms. Analysis of covariance indicated a significant reduction in the GAD scores (F(1,43) = 7.307; *P*=.010) between the two arms after adjusting for baseline scores. The intervention arm GAD scores reduced more than those of the control arm (B = -3.27; *P*=.010). The intervention arm had a greater reduction in PHQ-9 mean scores (F(1,43) = 8.298; *P*=.006) when compared to the control arm (B = -4.311; *P*=.006). While the levels of anxiety and depression reduced in both study arms, the reduction was higher in the intervention group (*P* values of .049 and .022, respectively).

Conclusion This study provides preliminary evidence to support the efficacy of Online-Therapy for improving the symptoms of anxiety and depression during the COVID-19 crisis in Oman. Therapist guided Online-Therapy was noted to be superior to self-help Internet-based therapy, however, both therapies could be considered as viable options.

Trial registration ClinicalTrials.gov NCT04378257.

Keywords: COVID-19; Depression; Anxiety; Oman; Online-Therapy; randomized controlled trial; Telehealth

Introduction

In order to contain and minimize the impact of the coronavirus (COVID-19) pandemic, countries across the world have resorted to physical distancing, quarantining and social isolation. This has remodeled healthcare services through the implementation of online and/or remote treatment [1, 2]. This transition has also applied to mental healthcare services, and has been a highly recommended service as a result of the expected rise in psychological distress during the pandemic [3]. This rise in the use of online services catering to patients' psychological well-being has also occurred in Oman, where these services are generally provided in government hospitals or in the private sector. However, there is a dearth of literature regarding the efficacy of this treatment model globally, including Oman.

On January 20 2020, the World Health Organization declared COVID-19 to be a 'global pandemic'. More literature is now arising detailing the impact of the pandemic on mental health, even among the non-infected or less-at-risk individuals.[4] The pandemic has meant that all members of society are now considered to be 'vulnerable'. As such, there is now a rise in ethical practice education regarding Online-Therapy services, despite it having been available for the last two decades. It has been noted that mental health practitioners were previously resistant to implementing this system as a lot of stock has been placed in the value of face-to-face healthcare practice [5]. However, contrary to this popular belief, online psychotherapy or e-therapy guided by a psychotherapist has shown favorable outcomes, particularly in cases of anxiety or clinical depression [6, 7]. In fact, there is a growing need for guided Online-Therapy, particularly catering to populations in regions where access to treatment facilities for mental health care is limited [2, 8].

Conversely, Online-Therapy can also be inaccessible to large populations, owing to insufficient network connectivity, lack of economic feasibility, personal and social stigma and the lack of awareness of accessing or availability of such facilities. Considering these factors, more and more online self-help applications (apps) and websites are now providing free, basic mental and physical healthcare remedies and strategies to cope with the psychological distress that accompanies the COVID-19 pandemic. Previous studies have indicated that the outcomes of face-to-face interventions (in-person or online) and self-help online resources have yielded effective results [9, 10]. However, these trends are yet to be explored in Oman and in the Middle East, in general.

Studies in Oman have indicated that there is a high risk of experiencing psychological distress during the COVID-19 pandemic [11]. Marital status, gender, pre-existing health conditions and financial status have been found to play a significant role in enhancing the risk variables of developing psychological distress during this time [11]. On April 10, 2020, the Omani government issued a lockdown in order to manage the outbreak of COVID-19 in the country. At the time of writing this paper, 7770 COVID-19 cases have been confirmed in Oman [12]. Mental health sectors across Oman have launched various self-help and online services to be able to provide healthcare from a distance. It is of value to understand the efficacy of these services in enhancing the mental health status in order to assist the health authorities in Oman to provide focused and high-quality mental health services to vulnerable populations. Additionally, this tool, if well-developed, would have far-reaching potential, particularly among those in Oman who are unable to access mental health services.

The authors designed this study to investigate the efficacy of therapist guided Online-Therapy versus Internet-based, emailed-delivered self-help materials for the symptoms of depression and anxiety caused by the COVID-19 crisis. The findings of this study can assist mental health practitioners in Oman to effectively provide their services virtually to vulnerable populations and also provide policy makers with insight into the utility of online-delivered mental health aids during the COVID-19 pandemic, and any potential future crises, in Oman.

Hypothesis

We hypothesized that compared to Internet-based self-help email delivered therapy, therapist guided Online therapy is more efficient in reducing COVID-19 induced symptoms of anxiety and depression among individuals in Oman during the COVID-19 pandemic.

Objective

To assess the efficacy of a six-week therapist-guided Online-Therapy versus self-help therapy e-mails focusing on COVID-19 symptoms of anxiety and depression among a sample of individuals in Oman, during the COVID-19 pandemic.

Methods

Design and study site

In this 6-week, open-label, comparative trial, participants were randomized to receive either therapist guided Online therapy or self-help therapy, using a fixed randomization schedule allocating participant between the two treatment arms in a 1:1 ratio. This study was conducted virtually using a secure encrypted video conference platform to deliver the Online-Therapy to participants in the intervention arm, across Oman.

Allocation, concealment, and randomization

A software randomizer generated block randomization sequence (block size is 6) in a 1:1 ratio to balance the number of the subjects in each arm. Participant allocation to either the intervention or control arm was concealed from the study participants and the researchers before the trial started to

avoid selection bias and done through a centralized service at the Department of Behavioral Medicine, Sultan Qaboos University, Muscat, Oman. Each coded, sealed opaque envelope which contained the participant's treatment allocation was opened by research personnel not involved in the study or the process of data collection. All participants had a code number allocated to them. As this was an open label trial, the participant and therapist who conducted the therapy were aware of the intervention status after the randomization process finished. However, the outcome assessor, the person who received the outcome assessment e-mails, was blind to the participant's allocation.

Sample Size

The sample size was calculated using nMaster 2.0 (Department of Biostatistics, CMC, Vellore). The Superiority hypothesis parallel clinical trial model was adopted to calculate the required sample size in each arm to achieve a mean effect size of Glass's $\Delta = 0.75$, according to the published literature. [13]Taking the power as 80% and 5% rate of type one error, the needed sample size was 30 participants in each arm, after considering a 20% attrition rate.

Participants selection and eligibility

Inclusion criteria:

- All Omanis and non-Omanis living in Oman, male or female, aged 18–65 years, with *Patient Healthcare Questionnaire* (PHQ-9) total scores ≥ 12 or *Generalized Anxiety Disorder*-7 (GAD-7) total scores ≥ 10;
- Access to the internet and video conferencing;
- Able to participate in the trial and adhere to the trial protocol;
- Can provide written informed consent to participate in the trial.

Exclusion criteria:

- Pre-existing mental health disorders;
- Diagnosis of moderate to severe intellectual disability;
- Presence of alcohol or other substance use disorders (except for nicotine or caffeine);
- Those who does not meet the inclusion criteria;
- Those with suicidal or homicidal ideation at baseline.

Intervention arm: Therapist Guided Online-Therapy

The participants in this group were allocated to receive weekly sessions from a trained and licensed psychologist in Oman via Zoom (Zoom Video Communications, Inc.). The psychologist sent an invitation e-link to the participant via email prior to the scheduled meeting. The link directed the participant to a screen where they would be able to see and interact with the psychologist once a week. The sessions were conducted either in Arabic or English, as per the participant's preference.

The initial sessions focused on building rapport and psychological first aid. Following sessions used principles of Cognitive Behavioral Therapy (CBT) and Acceptance and Commitment Therapy (ACT) interventions based on the therapist's training background and best fit for the participant. Ongoing supervision was provided in 1-hr weekly online group meetings, as well individual sessions with each therapist, if required. No treatment manuals were used, instead therapists were asked to use therapy models in which they are trained in. Skills, such as active listening, empathy, providing focus and structure, goal setting, and providing feedback, were determined to be relevant. Behavioral interventions were considered applicable to treatment, including behavior activation, exposure, homework, and skills training. Components designated as unique to CBT, such as discussion of automatic thoughts, core beliefs, and schemas, identification of cognitive distortions and cognitive restructuring were also applied. Unique ACT components, such as experiential acceptance and willingness, de-fusion, mindfulness training, encouragement of value-driven living, were also

applied by therapists while ensuring adhering to the same orientation throughout the sessions.

The final sessions primarily focused on relapse prevention and terminating the therapeutic relationship. After the six sessions, participants received an email to complete the post-intervention outcome assessment.

Control arm

The participants in the control group were allocated to receive an automatic weekly newsletter via e-mail containing self-help information and tips to cope with distress associated with COVID-19. The information mainly consisted of behavioral tips from principles of CBT and ACT focusing on positive cognitive reinforcement, strengthening relationships and mindfulness practice. The participants were requested to use this information to manage any distress that they might experience. After finishing the sixth week, the participants in the control group were assessed on their mood and anxiety symptoms via email-linked questionnaires.

Outcome Measures

The PHQ-9 is a self-administered measure used to make a tentative diagnosis of depression and monitor its severity. The PHQ-9 has been validated in a number of studies from different populations.[14, 15, 16] Al-Ghafri et al examined the applicability and psychometric characteristics of the PHQ-9 among an Omani sample.[17] A cut-off score of 12 gave the best trade-off between a sensitivity of 80.6% and a specificity of 94.0%. In this study, a cut off 12 was used to indicate the presence of significant depression.

The GAD-7 consists of a self-reported questionnaire that allows for the rapid detection of GAD.[18] Participants are asked if they were bothered by anxiety-related problems over the past two weeks by answering seven items on a 4-point scale. The total scores ranged from 0 to 21. At a cutoff score of 9, the GAD-7 had a sensitivity of 89% and a specificity of 82% for detecting GAD compared with a structured psychiatric interview.[18] However, the validation of an Arabic version of the GAD-7 indicated that a cutoff score of 10 had the best trade-off between sensitivity and specificity.[19, 20] In the current study we took a total score of 10 and above as the cut-off for significant anxiety.

Data related to age, gender, marital status, number of children, highest qualification, studying abroad, occupation, working in health care, financial strains, physical health problems, mental health problems, self-quarantine, coping with illicit drugs, and e-mail addresses were collected

The primary endpoint was comparing the change in the mean scores of PHQ-9 and GAD-7 from baseline to the end of the study (after six sessions) between the intervention and the control arms. The secondary endpoint was comparing the proportion of participants with significant psychological distress (PHQ-9 total score ≥ 12 or GAD-7 total score ≥ 10) between the two arms

Recruitment, recruitment period and consent procedure

Recruitment occurred between 14 April and 30 May 2020. Participants were recruited from a list of online survey respondents with significant psychological distress in Oman during the COVID-19 pandemic.[4] This survey was conducted by the current trial team during the first two weeks of April 2020 and included 1539 respondents from different regions Oman. The prevalence of psychological distress among the trial sample was 30%. The research assistant contacted eligible participants by email and interested participants were briefed about the trial protocol. Potential participants received a thorough explanation of the objectives, procedures, and risks of the trial protocol. Based on the autonomy principle, the subject had the right to decline to participate or to withdraw from the study at any time without prejudice. After the consent was read and discussed with their family, if

participants wished to get the family opinion, the participants signed an electronic informed consent. All interaction with the subjects, including explanation and consenting process, happened over private tele/video interviews.

Follow up visits and assessment procedures and data management

After baseline assessment and receiving 6 sessions of therapist guided Online-Therapy or self-help therapy, participants were assessed for outcome measures at week 6 by sending them email links containing the GAD-7 and PHQ-9. Over the first 6 weeks, each virtual visit included checking the consent, compliance with protocol and if any adverse effects like the worsening of anxiety or depression symptoms. Checking side effects, consent and compliance with protocol were carried out for both arms. In the self-help arm we asked the participant, weekly, via email to confirm receipt of the therapy material by sending an email to research assistant. Additionally, we asked them to report any adverse events by contacting the research assistant through a phone number provided to them at the beginning of the study.

Data of each participant was assigned a unique code (serial number). All data was entered initially into a specified file for each subject in every visit and then transferred to the Epi data sheet at the end of the virtual visits.

Statistical analysis

The data were double entered into an electronic database EpiData, V.2.2, Denmark,[21] to ensure accuracy and then exported to the Statistical Package of Social Science Software (SPSS) version 20, IBM Corp., Chicago, USA).[22] Continuous variables were summarized as means and standard deviation (SD) and categorical variables were presented as frequency. Analysis of covariance (ANCOVA) was used in examining pre- and post-differences in the mean values of the PHQ-9 and GAD-7 between the intervention and control arms while considering the influence of the uncontrolled independent variables, such as pre-intervention scores. Categorical variables and proportions of participants with anxiety or depression were investigated using the chi-square test or Fisher's exact test, when appropriate. Significance level was set at P <0.05.

Ethics

The study followed the guidelines of the Declaration of Helsinki, 2001.[23]Written informed consent was obtained from each participant. Participation was voluntary, and each participant had the right to withdraw from the trial at any time for any reason and their withdrawal did not affect them in any way. This study was granted ethical approval by the research ethics committee at the College of Medicine and Health Science, Sultan Qaboos University, Muscat, Oman (MREC#2103). This trial was registered at ClinicalTrials.gov, registration number NCT04378257.

Results

Table 1: Baseline characteristics of the participants in this trial (N = 46)

Variables	Intervention group (n = 22)	Control group (n = 24)	Total (n = 46)	P value*
Age (Mean ± SD)	27.0 ± 8.72	29.96 ± 8.63	28.51 ± 8.70	.142[#]
Gender, n (%)				
Male	2 (9.1)	8 (33.3)	10 (22)	.074
Female	20 (90.9)	16 (66.7)	36 (78)	
Marital status, n (%)				
Single	15 (68.2)	11 (45.8)	26 (57)	.149

Married	7 (31.8)	13 (54.2)	20 (43)	
Do you have children? n (%)				
Yes	17 (77.3)	14 (58.3)	15 (33)	.217
No	5 (22.7)	10 (41.7)	31 (67)	
Education level, n (%)				
Finished secondary school	8 (36.4)	4 (16.7)	12 (26)	.183
College and above	14 (63.6)	20 (83.3)	34 (74)	
Employment status, n (%)				
Employed	9 (40.9)	14 (58.3)	23 (50)	.376
Unemployed	13 (59.1)	10 (41.7)	23 (50)	
Are you a healthcare worker? n (%)				
Yes	7 (31.8)	8 (33.3)	15 (33)	.931
No	15 (68.2)	16 (66.7)	31 (67)	
Are you financially stable? n (%)				
Yes	15 (68.2)	18 (75.0)	33 (72)	.746
No	7 (31.8)	6 (25.0)	13 (28)	
Are you diagnosed with chronic illness? n (%)	2 (9.1)	-	2 (4)	.223
Yes	20 (90.9)	24 (100.0)	44 (96)	
No				
Did you self-quarantine yourself during COVID 19 pandemic, n (%)				
Yes	16 (72.7)	14 (58.3)	30 (65)	.364
No	6 (27.3)	10 (41.7)	16 (35)	
Are you in quarantine now because of COVID 19 pandemic? n (%)				
Yes	15 (68.2)	12 (50.0)	27 (59)	.245
No	7 (31.8)	12 (50.0)	19 (41)	
Disorder, n (%)				
Anxiety	7 (31.8)	8 (33.3)	15 (33)	.965
Depression	5 (22.7)	6 (25.0)	11 (24)	
Anxiety and Depression	10 (45.5)	10 (41.7)	20 (43)	

*Chi-square test, #Mann-Whitney Test
SD = standard deviation

As shown in Table 1, data related to the 46 participants in this trial were analyzed. Of the total, 22 participants belonged to the intervention arm and 24 were in the control arm. The mean age was 28.51 ± 8.70 years (78% female). Most were single (26 out of 46; 57%) and about one-third had children. Most had achieved a college education and 15 out of 46 participants (33%) were working in healthcare. Financial instability was noted in 13 out of 46 participants (28%) of the study participants. The majority (30 out of 46; 65%) of the participants were self-quarantining because of the pandemic. The difference in baseline scores and proportions of anxiety and depression in the two arms were not statistically significant. Additionally, there was no statistically significant difference in the baseline characteristics of the two arms. Attrition rate was 26% for the intervention arm and 20% for the control arm. Overall, the characteristics of participants who lost follow up did not differ from the remainder of the participants. Regarding adverse events, one participant who was allocated to the intervention arm showed safety concerns before starting the therapy. The participant was immediately referred for psychiatric assessment at Sultan Qaboos university hospital.

Table 2: Adjusted post-anxiety score[a] and treatments using ANCOVA test

Parameter	B	95% CI of B	't' value	*P* value
Intercept	6.79	2.97 to 10.62	3.59	<.001
Pre-GAD-7 score	0.02	-0.24 to 0.27	0.15	.885
Intervention group	-3.27	-5.71 to -0.83	-2.70	.010

[a]dependent variable

ANCOVA = analysis of covariance; CI = confidence interval; GAD-7 = Generalized Anxiety Disorder-7

Table 3: Adjusted post-depression score[a] and treatments using ANCOVA test

Parameter	B	95% CI of B	't' value	*P* value
Intercept	5.25	0.80 to 9.71	2.38	.022
Pre-PHQ-9 score	0.23	-0.03 to 0.49	1.77	.084
Intervention group	-4.31	-7.33 to -1.29	-2.88	.006

[a]dependent variable

ANCOVA = analysis of covariance; CI = confidence interval; PHQ-9 = Patient Health Questionnaire-9

A univariate ANCOVA was conducted to compare the effectiveness of the intervention between the two study arms, while adjusting for the pre-intervention scores (covariant). Levene's test and normality checks were carried out and the assumptions met. There was a significant difference in GAD score reduction (F(1,43) = 7.307; *P*=.010) between two arms. Parameter estimates showed that the intervention group GAD scores were significantly reduced (B = -3.27; *P*=.010), with an adjusted R squared of 0.106. There was a significant difference in PHQ score reduction (F(1,43) = 8.298; *P*=.006) between the intervention and control groups. Parameter estimates showed that the intervention group PHQ scores were significantly reduced (B = -4.311; *P*=.006) with an adjusted R squared of 0.173. (Tables 2 and 3)

Figure 1: Comparison of the post-intervention proportions of anxiety between the two arms Using Chi-square test

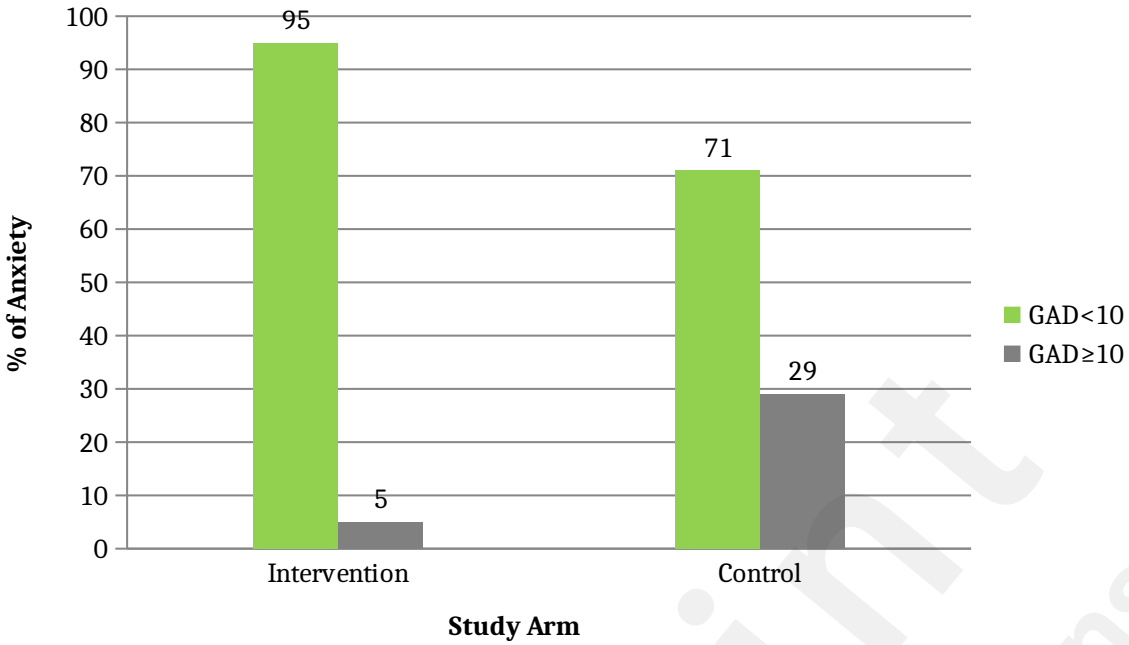
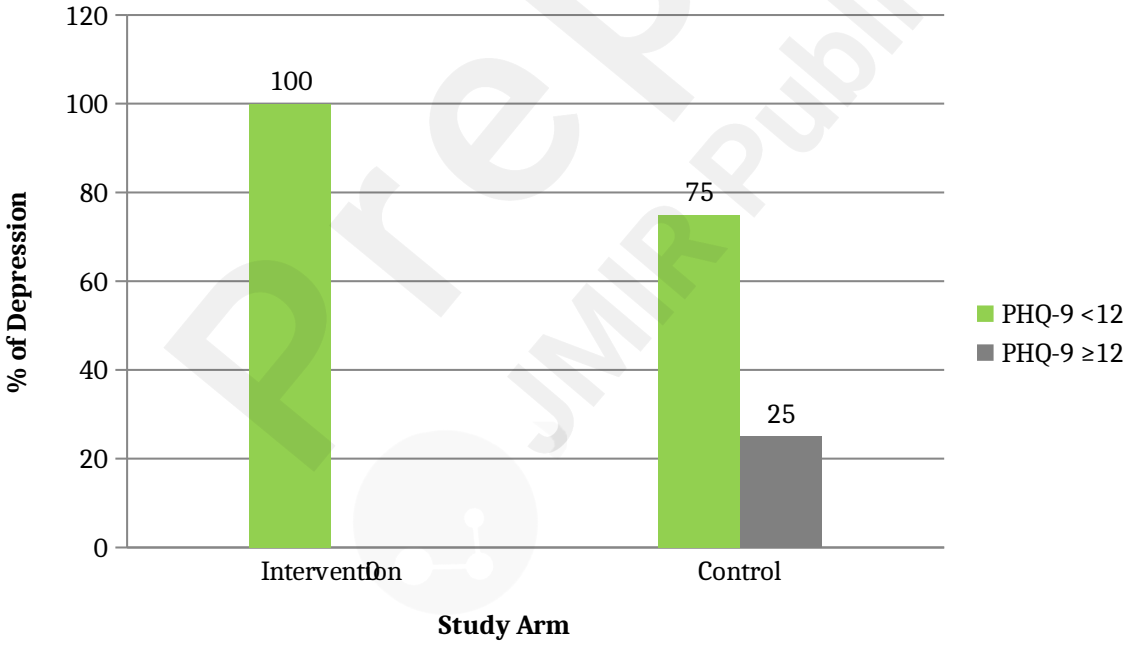


Figure 2: Comparison of the post-intervention proportions of depression between the two arms using Chi-square test.



Figures 1 and 2 show the comparisons of the proportions of post-intervention anxiety and depression between the two arms. While the levels of anxiety and depression had reduced in both study arms, the proportions of participants with anxiety and depression were significantly lower in the intervention arm compared to control arm (*P* values of .049 and .022, respectively). The difference is more pronounced with regards to the impact of the intervention on depression, none of the participants in the intervention arm met the cut-off score for depression after they received the

intervention.

Discussion

The primary purpose of the present study was to measure the efficacy of therapist guided e-treatment protocols versus self-help emailed delivered-therapy in a sample of the Omani community during the COVID-19 pandemic. In our sample of 46 participants, we found that therapist guided Online-Therapy led to a significant reduction in psychological distress as identified by the participants' experience of depression or anxiety. This evidence supports previous literature which stated that Online-Therapy is efficient and provides increased access to treatment for people suffering from anxiety and depression [6, 7]. The results of the present align with the existing literature with regards to this alternate mode of delivery of psychotherapy services.

With the expansion of the COVID-19 pandemic globally, the social systems have had to adapt to a changed society, marked with physical distancing, working from home and the rise in uncertainty and fear [1, 2]. The pandemic has acted as a catalyst for change in the delivery of healthcare services. The remote delivery of psychological treatment services has been researched and, in previous studies prior to the pandemic, it has been found that the efficacy of this platform is as high as face-to-face treatment programs [9, 10].

The second aim of the present study was to compare the effectiveness, as defined by proportions of anxiety or depression, of therapist guided e-treatment protocol compared to a self-help control group. Overall, improved therapeutic outcomes were noted for both treatment approaches. However, the strength of these associations varied. In both conditions, effect sizes were large, and most participants demonstrated clinically significant improvements as a function of treatment. Nevertheless, therapist-guided treatment resulted in a larger reduction of anxiety and depression compared to the control group. These findings support the notion that therapist guided Online-Therapy and self-help materials are functionally distinct from one another [24].

The randomized allocation ensured balancing baseline characteristics of the participants in the two arms to control for and monitor factors that potentially could contribute to differential outcomes. Therefore, there were no differences found for participant expectations of efficacy for the two treatment approaches. Nevertheless, the control group did improve due to the efficacy of the self-help materials, presumably due to the regression of the mean and the natural progression of these conditions with time [24].

In addition to the role of the therapist-client relationship via electronic medium, there are other factors that could contribute to the existing results. The reduction in distress levels may have been impacted by the role of the community in times of crisis in a collectivistic society [25], the predicted adjustment to the 'new normal' through increased resilience [26] and a decline in media related information about the pandemic [27].

Strengths and Limitations

The present study has a number of notable strengths. To the best of our knowledge, this is the first study in the region to evaluate the efficacy of the therapist guided Online-Therapy services that have been implemented in the region since the onset of the pandemic. Secondly, treatments were non-manualized, therefore allowing therapists to individualize the delivery of each treatment-specific intervention for each participant as they deemed appropriate. Nonetheless, non-manualized therapy limits the reproducibility of the study.

A limitation of the study is the generalizability of the results. Our participants were relatively well-educated and could be classified as “younger-adults”, limiting the conclusions with respect to feasibility. In addition, although participation only required basic email skills, not all households in Oman have a broadband internet connection, making our sample less generalizable to the general public. While it can be argued that most internet users are female [28], it is also worth noting that an overall stigma towards seeking mental health services is evident in Oman. [29] Furthermore, males may be less open to discussing emotional difficulties in Oman and in Eastern culture [30]. Another limitation is that the design of this study did not allow for adequate follow-up of participants, and it is therefore unknown whether the treatment effects will be similarly maintained in the long term. Further, the compliance to self-help therapy could not be ascertained fully and this may limit the interpretation of the findings.

Conclusions

The findings of the study are consistent with a growing body of the literature demonstrating the effectiveness of Online-Therapy on the psychological impact of COVID-19. Furthermore, results indicate that therapist support makes a substantial difference in terms of effectiveness of online interventions. Therefore, it can be useful to integrate internet-delivered services with traditional mental health services using a stepped care model starting with e-guided self-help and moving to therapist-guided therapy. Clients identified as being suitable for online interventions could be directed to therapist-guided programs, whilst those deemed unsuitable can be provided with face-to-face interventions or a hybrid approach. Long-term follow-up may be more valuable and is needed to identify the effects of Online-Therapy on anxiety and depression levels. Finally, a more direct investigation of the extent of training and supervision is required to train effective therapists, as well as a plan for further specialized services in Oman. There is a limited number of qualified therapists in Oman, with current services focusing predominantly on a medical model for treatment. Further studies on therapist compatibility and training in evidence-based interventions are needed to make Online-Therapy a more abundant and acceptable option in Oman.

Acknowledgments

The authors would like to acknowledge the individuals who participated in the study and the therapists who provided the guided online therapy to all the participants.

Author contributions

Study design and conceptualization: MA, HA, HA, RK, AS, AA. Data collection, statistical analysis and interpretation: SP, TA, NA, AG, MA, RK, AS. Validation of the statistical analysis: SP, MA, HA. Drafting of the manuscript: MA, HA, TA, NA, HA, RK, AS. Intellectual contributions in the interpretation of the findings, edition of the initial version, and critical revision of the manuscript: MA, HA, AG, AA, HS. Approval of the final version for publication: all co-authors.

Funding

This work was funded by The Research Council, Sultanate of Oman. The funding institution had no role in the study design, collection, analysis and interpretation of the data, or in the preparation, revision or approval of the present manuscript. Thus, the views expressed in this publication are the views of the authors.

Competing interests

None

Ethics approval and consent to participate

This study was granted ethical approval by research ethics committee at college of medicine and health science, Sultan Qaboos University MREC#2103. All participants provided written informed consent to participate in the study.

Data availability statement

Data are available upon reasonable request directed to MA (alalawim@squ.edu.om).

References

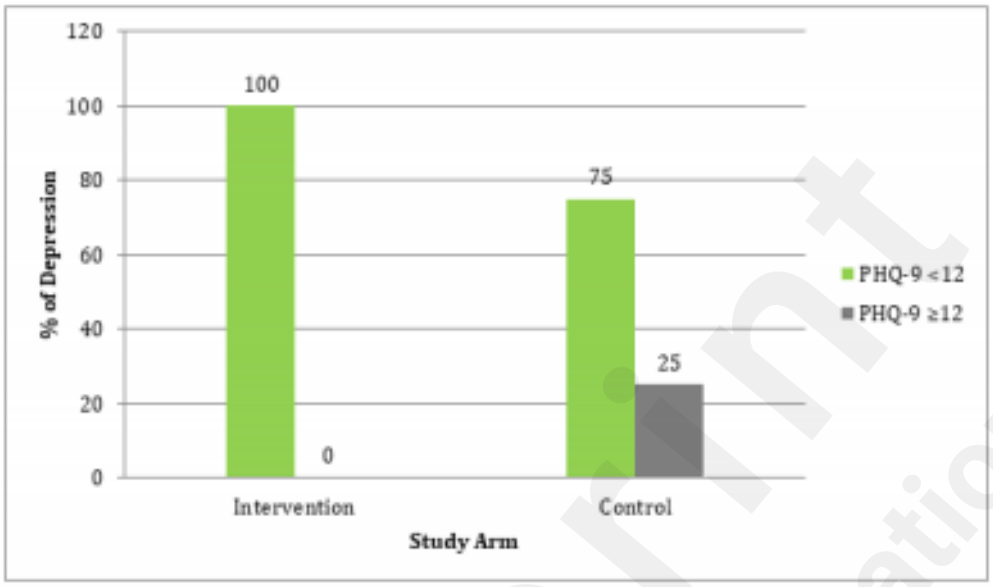
1. Greenhalgh T, Wherton J, Shaw S, Morrison C. Video consultations for covid-19. British Medical Journal Publishing Group; 2020. PMID: 32165352
2. Wind TR, Rijkeboer M, Andersson G, Riper H. The COVID-19 pandemic: The 'black swan'for mental health care and a turning point for e-health. Internet interventions. 2020. PMID: 32289019
3. Ho CS, Chee CY, Ho RC. Mental health strategies to combat the psychological impact of COVID-19 beyond paranoia and panic. Ann Acad Med Singapore. 2020;49(1):1-3. PMID: 32200399
4. Sinawi HA, Al Balushi N, Al-Mahrouqi T, Al Ghailani A, McCall RK, Sultan A, et al. Predictors of psychological distress among the public in Oman amid coronavirus disease 2019 pandemic: a cross-sectional analytical study. Psychology, Health & Medicine. 2020:1-14. PMID: 33151748
5. Berger T. The therapeutic alliance in internet interventions: a narrative review and suggestions for future research. Psychotherapy research. 2017;27(5):511-24. PMID: 26732852
6. Berryhill MB, Culmer N, Williams N, Halli-Tierney A, Betancourt A, Roberts H, et al. Videoconferencing psychotherapy and depression: a systematic review. Telemedicine and e-Health. 2019;25(6):435-46. PMID: 30048211
7. Karyotaki E, Ebert DD, Donkin L, Riper H, Twisk J, Burger S, et al. Do guided internet-based interventions result in clinically relevant changes for patients with depression? An individual participant data meta-analysis. Clinical psychology review. 2018;63:80-92. PMID: 29940401
8. Torous J, Myrick KJ, Rauseo-Ricupero N, Firth J. Digital mental health and COVID-19: Using technology today to accelerate the curve on access and quality tomorrow. JMIR mental health. 2020;7(3):e18848. PMID: 32213476
9. Wright JH, Caudill R. Remote treatment delivery in response to the COVID-19 pandemic. Psychotherapy and Psychosomatics. 2020;89(3):1. PMID: 32213775
10. Wright JH, Mishkind M, Eells TD, Chan SR. Computer-Assisted Cognitive-Behavior Therapy and Mobile Apps for Depression and Anxiety. Current psychiatry reports. 2019;21(7):62. PMID: 31250242
11. Badahdah AM, Khamis F, Al Mahyijari N. The psychological well-being of physicians during COVID-19 outbreak in Oman. Psychiatry Research. 2020;289:113053. PMID: 32388173
12. Strauss A, Corbin J. Basics of qualitative research: Newbury Park, CA: Sage; 1990.
13. Hadlaczky G, Hökby S, Mkrtchian A, Carli V, Wasserman D. Mental Health First Aid is an effective public health intervention for improving knowledge, attitudes, and behaviour: A meta-analysis. International Review of Psychiatry. 2014;26(4):467-75. PMID: 25137113
14. Adewuya AO, Ola BA, Afolabi OO. Validity of the patient health questionnaire (PHQ-9) as a screening tool for depression amongst Nigerian university students. Journal of affective disorders. 2006;96(1-2):89-93. PMID: 16857265
15. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. Journal of general internal medicine. 2001;16(9):606-13. PMID: 11556941
16. Becker S, Al Zaid K, Al Faris E. Screening for somatization and depression in Saudi Arabia: a validation study of the PHQ in primary care. The International Journal of Psychiatry in Medicine. 2002;32(3):271-83. PMID: 12489702

17. Al-Ghafri G, Al-Sinawi H, Al-Muniri A, Dorvlo AS, Al-Farsi YM, Armstrong K, et al. Prevalence of depressive symptoms as elicited by Patient Health Questionnaire (PHQ-9) among medical trainees in Oman. Asian journal of psychiatry. 2014;8:59-62. PMID: 24655629
18. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Archives of internal medicine. 2006;166(10):1092-7. PMID: 16717171
19. AlHadi AN, AlAteeq DA, Al-Sharif E, Bawazeer HM, Alanazi H, AlShomrani AT, et al. An arabic translation, reliability, and validation of Patient Health Questionnaire in a Saudi sample. Annals of general psychiatry. 2017;16(1):32. PMID: 28878812
20. Terkawi AS, Tsang S, AlKahtani GJ, Al-Mousa SH, Al Musaed S, AlZoraigi US, et al. Development and validation of Arabic version of the Hospital Anxiety and Depression Scale. Saudi journal of anaesthesia. 2017;11(Suppl 1):S11. PMID: 28616000
21. Lauritsen J. EpiData data entry, data management and basic statistical analysis system. Odense: EpiData Association. 2008.
22. Nie N, Hull C, Bent D. IBM statistical package for the social sciences (SPSS Version 20). Computer Software Chicago, IL: SPSS. 2011.
23. Association WM. World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. Bulletin of the World Health Organization. 2001;79(4):373. PMID: 11357217
24. Bennett SD, Cuijpers P, Ebert DD, McKenzie Smith M, Coughtrey AE, Heyman I, et al. Practitioner Review: Unguided and guided self-help interventions for common mental health disorders in children and adolescents: a systematic review and meta-analysis. Journal of Child Psychology and Psychiatry. 2019;60(8):828-47. PMID: 30775782
25. Ahmen D, Buheji M, Fardan SM. Re-emphasising the future family role in “care economy” as a result of covid-19 pandemic spillovers. American Journal of Economics. 2020;10(6):332-8.
26. Chen S, Bonanno GA. Psychological adjustment during the global outbreak of COVID-19: A resilience perspective. Psychological Trauma: Theory, Research, Practice, and Policy. 2020;12(S1):S51. PMID: 32538658
27. Depoux A, Martin S, Karafillakis E, Preet R, Wilder-Smith A, Larson H. The pandemic of social media panic travels faster than the COVID-19 outbreak. Oxford University Press; 2020. PMID: 32125413
28. Al-Qaysi N, Mohamad-Nordin N, Al-Emran M. What leads to social learning? Students’ attitudes towards using social media applications in Omani higher education. Education and Information Technologies. 2019:1-18.
29. Al-Mashrafi S, Al-Saadi S, Al-Ruzaqi W, Al-Alawi M, Al-Huseini S, Panchatcharam SM, et al. Determinants Affecting the Perception toward Mental Health Problems among Residents at Oman Medical Specialty Board; Across Sectional Correlative Study. Clinical and Experimental Psychology. 2020;6(1):1-4.
30. Razzak HA, Harbi A, Ahli S. Depression: Prevalence and associated risk factors in the United Arab Emirates. Oman Medical Journal. 2019;34(4):274. PMID: 31360314

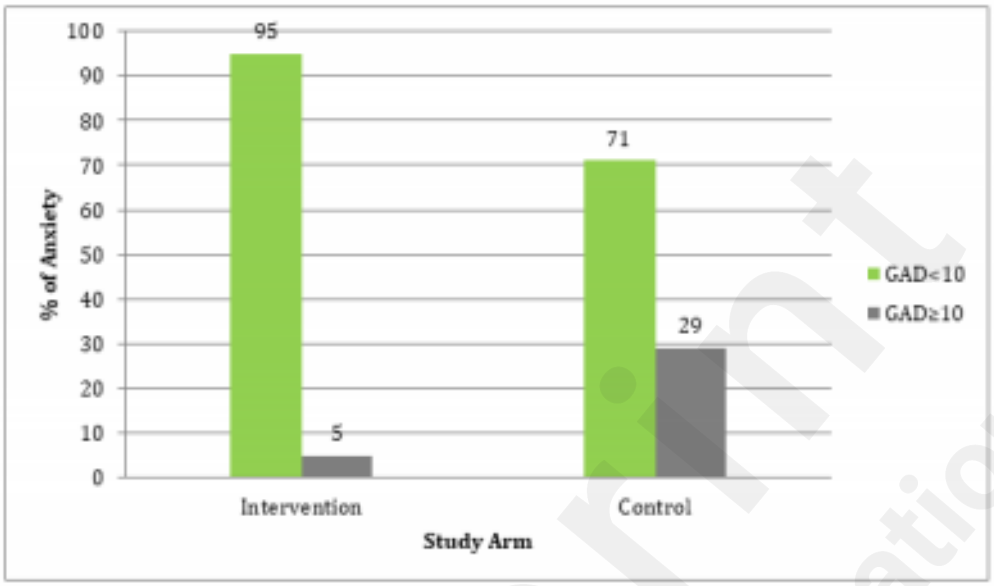
Supplementary Files

Figures

Comparison of the post-intervention proportions of depression between the two arms using Chi-square test.



Comparison of the post-intervention proportions of anxiety between the two arms using Chi-square test.



CONSORT (or other) checklists

Revised CONSORT-EHEALTH (V 1.6).
URL: https://asset.jmir.pub/assets/295e7a73c4792066de18e5b1341840b9.pdf

Revised CONSORT Flow Diagram COVID 19.
URL: https://asset.jmir.pub/assets/8aaf46784cd9449153ef965b1b35224a.pdf