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ORIGINAL RESEARCH

Guided digital health intervention for depression in Lebanon: randomised trial

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ABSTRACT

Background Most people with mental disorders in communities exposed to adversity in low-income and middle-income countries (LMICs) do not receive effective care. Digital mental health interventions are scalable when digital access is adequate, and can be safely delivered during the COVID-19 pandemic.

Objective To examine the effects of a new WHO-guided digital mental health intervention, Step-by-Step, supported by a non-specialist helper in Lebanon, in the context of concurring economic, humanitarian and political crises, a large industrial disaster and the COVID-19 pandemic.

Methods We conducted a single-blind, two-arm pragmatic randomised trial, comparing guided Step-by-Step with enhanced care as usual (ECAU) among people suffering from depression and impaired functioning. Primary outcomes were depression (Patient Health Questionnaire 9 (PHQ-9)) and impaired functioning (WHO Disability Assessment Schedule-12 (WHODAS)) at post-treatment.

Findings 680 people with depression (PHQ-9>10) and impaired functioning (WHODAS>16) were randomised to Step-by-Step or ECAU. Intention-to-treat analyses showed effects on depression (standardised mean differences, SMD: 0.71; 95% CI: 0.45 to 0.97), impaired functioning (SMD: 0.43; 95% CI: 0.21 to 0.65), post-traumatic stress (SMD: 0.53; 95% CI: 0.27 to 0.79), anxiety (SMD: 0.74; 95% CI: 0.49 to 0.99), subjective well-being (SMD: 0.37; 95% CI: 0.12 to 0.62) and self-identified personal problems (SMD: 0.56; 95% CI 0.29 to 0.83). Significant effects on all outcomes were retained at 3-month follow-up.

Conclusions Guided digital mental health interventions can be effective in the treatment of depression in communities exposed to adversities in LMICs, although some uncertainty remains because of high attrition.

Clinical implications Guided digital mental health interventions should be considered for implementation in LMICs.

Trial registration number ClinicalTrials.gov NCT03720769.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Depression is a major public health problem in communities exposed to adversity.
⇒ Digital interventions for depression have been found to be effective in high income settings, but have not been extensively examined in communities exposed to adversity in low-income and middle-income countries (LMICs).

WHAT THIS STUDY ADDS

⇒ This study shows that a guided digital smartphone intervention can be effective in communities exposed to adversity.
⇒ The intervention has also positive effects on other outcomes, such as impaired functioning, post-traumatic stress, anxiety and subjective well-being.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE AND/OR POLICY

⇒ Guided digital interventions can be considered for dissemination in communities exposed to adversity in LMICs.

INTRODUCTION

According to the latest global estimates, almost 1 billion people in the world suffer from a mental disorder.[1] Although depression is a leading cause of disability,[1] the vast majority of affected people do not receive treatment. This is especially true in low-income and middle-income countries (LMICs) where only 1 in 27 people with depression are likely to receive evidence-based treatment.[2] Major mental health system transformations are needed to address this enormous public health challenge.[3]

One country that seeks to strengthen its mental health system is Lebanon, a middle-income country in the Middle East with 6.8 million citizens. Lebanon is affected by a history of conflict and adversity. In 2020, the country faced five co-occurring emergencies: a collapsing economy, severe political turmoil, an ongoing, massive refugee crisis (involving 1.5 million displaced Syrians), an explosion of neglected ammonium nitrate destroying large parts of the capital Beirut and the impact of the COVID-19 pandemic.[4]

There is no recent national study on mental disorders in Lebanon. Data from 2002 to 2003 indicated that 17% of the population suffered from a mental disorder.[5] This is in line with WHO estimates, suggesting that 22% of people exposed to conflict

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in the previous 10 years suffer from a mental disorder, including 11% suffering from depression.[6] These rates do not take into account the COVID-19 pandemic that has compounded the mental health crisis in Lebanon.[7–9] Lebanon's National Mental Health Programme aims to scale up mental healthcare. However, the circumstances in Lebanon complicate the provision and implementation of services considerably. There are limited resources, many well-trained clinicians have left the country, and because of the pandemic it is a challenge to offer care safely.

One possible strategy to scale up services involves digital interventions, an option already indicated in the country's national mental health strategy.[10] Most people in Lebanon have access to mobile phones (92%), and research from high income-countries suggests that mobile apps can be effective for reducing symptoms of depression and other mental disorders.[11] Digital interventions can be either unguided, or guided by a trained helper who supports participants in their use of self-help materials. While unguided interventions are less effective, guided self-help interventions are no less effective than face-to-face treatments.[12] There is also considerable evidence that individual, group, telephone based and guided digital interventions have moderate-to-large effects on depression,[12] and psychological therapies for mental disorders in LMICs affected by humanitarian crises have also been found to be effective.[13] Thus far, no studies on guided digital mental health interventions have been conducted in communities exposed to adversity in LMICs.

A new digital mental health intervention, 'Step-by-Step', was developed by the WHO for the treatment of depression.[14] It is based on behavioural activation and includes additional therapeutic techniques such as stress management, a gratitude exercise, positive self-talk, strengthening social support and relapse prevention. It can be delivered with guidance from lay helpers. The current study examines the effects of guided 'Step-by-Step', compared with enhanced care as usual (ECAU) in Lebanon.

METHODS

Design

This single-blind, two-arm pragmatic randomised clinical trial examined the effectiveness of a digital health intervention for depression compared with ECAU in people residing in Lebanon. The study was conducted together with an identical study among Syrian refugees in Lebanon, which will be reported elsewhere. The trial was registered at ClinicalTrials.gov. The trial protocol, an open pilot trial and a feasibility randomised controlled trial (RCT) have been published.[15–17]

Procedures

Any person above 18 residing in Lebanon was eligible to participate if they understood and spoke Arabic or English and had access to an internet-connected device. Participants were required to have moderate or severe depressive symptoms (Patient Health Questionnaire 9 (PHQ-9>10))[18] and experience functional impairment (WHO Disability Assessment Schedule-12 (WHODAS>16)).[19] Participants at imminent risk of suicide (based on a question on serious thoughts or a plan to end one's life in the past month) were excluded and referred to the national suicide prevention helpline.

Participants were recruited through online advertisements and social media, keeping with the online nature of the intervention. Interested participants could access the web version or download the mobile app, where information was given about the intervention and the study, including an animated video explaining key points. After completing informed consent and the baseline self-screening instruments, participants who met inclusion criteria were asked to complete additional baseline questionnaires. As remuneration for completing all the questionnaires, users received US$20 phone credit.

Participants were randomised to the intervention or ECAU, using a permuted block randomisation with 1:1 allocation ratio within blocks of random length between 2 and 8. The random numbers table and randomisation process were built into the app.

Study arms

Intervention

Step-by-Step is a five-session intervention, designed to treat depression through an internet-connected device.[14] It provides psychoeducation and training in behavioural activation through an illustrated narrative, with additional therapeutic techniques such as stress management, a gratitude exercise, positive self-talk, strengthening social support and relapse prevention.

The narrative was adapted to the local context, considering gender, linguistic and cultural nuances among populations residing in Lebanon.[20] It has a female and male version, each with two versions, one for married people with children and one for unmarried people. Participants can also choose the appearance of the character, broadly reflecting the main cultural groups. The intervention was provided as a hybrid app for iOS, Android and web browsers using technical infrastructure developed by the Freie Universität Berlin.[21] Users who accessed the intervention received email or phone-based notifications, covering reminders of assessments due or upcoming, new sessions available and gratitude for study participation. They could opt out of notifications any time.

Users are expected to complete one session per week; noting that each session is divided into two or three smaller parts that can be done either at one-go or across several days of the week. The next session would only unlock after completion of the previous session. This is to allow users to practice the tips and techniques they learnt throughout the story. On doing the activities, users can input them in the 'toolbox' interactive part of the app. So, in between sessions, they can practice the exercises of the sessions completed in the toolbox and input their feedback in the interactive part and can also insert a daily mood tracker.

Users of the intervention were supported by trained non-specialists ('e-helpers') who offered weekly phone or message-based contact with users to provide support (maximum 15 min per week). E-helpers were Lebanese citizens who had no previous experience in delivering mental healthcare. While the content of the intervention was delivered through the app, the e-helpers were trained to provide technical and emotional support to strengthen users' motivation, to assess and refer participants at high risk of suicide, child abuse or gender-based violence, and to support participants in acute distress, using preset protocols. E-helpers passed a competency test after the training to be involved in the trial. A treatment fidelity checklist was used and 5% of the guidance calls and messages were rated. Training was delivered over 5 days with ongoing weekly group supervision—and, on demand, individual meetings—being provided by one local clinical psychologist.

Enhanced care as usual

ECAU consisted of one page of basic psychoeducation and a referral list to evidence-based care, which was administered online right after allocation. Psychoeducation on depression and anxiety was delivered through the app or website. The text

for the psychoeducational messages was taken from the first session of Step-by-Step to ensure identical information. After the psychoeducation, users received a list of primary healthcare facilities with non-specialised staff trained in evidence-based mental healthcare.[22]

Outcomes

Primary outcomes were depressive symptoms measured by the PHQ-9,[18] and functional impairment measured by the WHODAS-12 V.2.0[19] at post-treatment. The PHQ-9 is a 9-item instrument measuring severity of depression, with a cut-off score of ≥10 indicating moderate or severe depression, which has also been validated in Lebanon.[23] The WHODAS assesses functional impairment across six domains (cognition, mobility, self-care, getting along, life activities and participation).

Secondary outcomes included subjective well-being, anxiety and post-traumatic stress assessed by the 5-item WHO-5 Well-Being Index[24]; the 7-item Generalised Anxiety Disorder 7 (GAD-7)[25]; and the 8-item Post-Traumatic Stress Disorder Checklist for Diagnostic and Statistical Manual 5; Post-Traumatic Stress Disorder Checklist 5 (PCL-5),[26] respectively. The Psychological Outcomes Profile (PSYCHLOPS) instrument was used to identify and rate self-described problems.[27] Satisfaction with the intervention was measured with the Client Satisfaction Questionnaire.[28]

Outcomes were measured at baseline, post-treatment (8 weeks after baseline) and follow-up (3-month post-treatment). The reliabilities (Cronbach's alpha at post-test) of the PHQ-9, WHODAS, WHO-5, GAD-7, PCL-5 and PSYCHLOPS were respectively 0.85, 0.87, 0.92, 0.90, 0.88 and 0.78). All outcome measures were already available in Arabic (PHQ-9, WHODAS, WHO-5) or were translated by the research team.

All participants in the intervention and control group were contacted by e-helpers via email or phone contact (according to preference) once their post-assessments and follow-up assessments were due. In case they did not complete the assessment within 3 days of contacting them, they received a maximum of 2 additional contact attempts (after 3 days and after 6 days).

Analyses

The RCT was designed to have >90% power with $\alpha=0.05$ to detect a 0.5 standardised mean difference (SMD) between the intervention and control group. Assuming 70% dropout,[29] we planned to recruit 568 participants to show that the intervention was effective. We compared the intervention and control group on demographic and clinical characteristics with χ^2 and variance analyses. The main outcomes were examined with intention-to-treat analysis (ITT). Per protocol analyses were secondary analyses.

For ITT analyses, regression models were estimated with treatment assignment status as principal predictor. To address potential bias concerns due to selective attrition, missing outcome observations were calculated using multiple imputation exploiting prescores and prespecified background characteristics (gender, age, education and symptom severity). Given we consider continuous outcomes, multivariate normal regression imputation with an iterative Markov Chain Monte Carlo method was used based on initial treatment assignment. The prespecified covariates and baseline measurement of primary endpoint were added to the baseline model for improved precision. Effect sizes calculated are Hedges' g by combining the multiple imputation estimation results using Rubin's rules. Effect sizes of 0.2 were considered as small, 0.5 as moderate and 0.8 as large.[30]

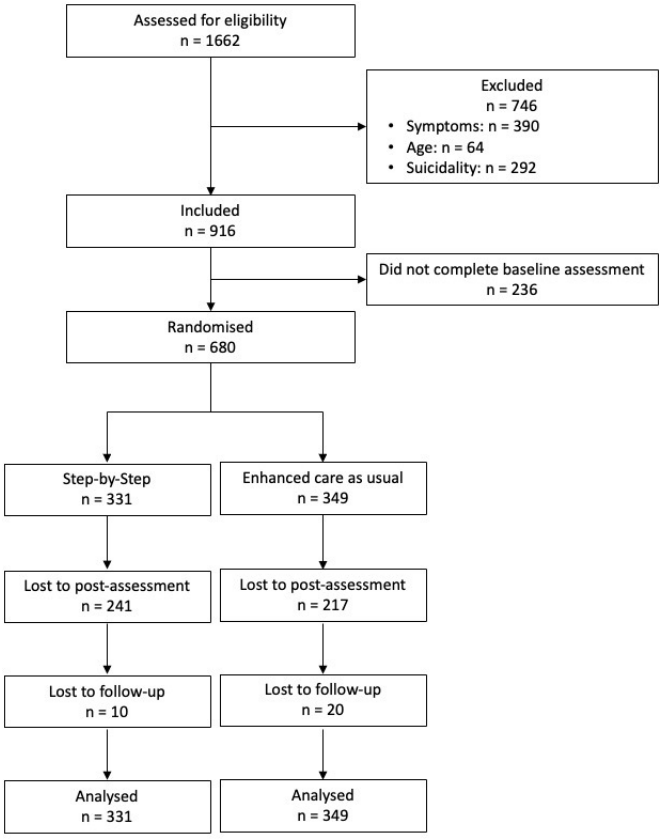

Figure 1 Flowchart.

To examine the robustness of the results to differential non-random attrition across treatment arms, Random Forest Lee bounds (RFLBs) were estimated.[31] This bounding approach applies extreme worst-case and best-case assumptions about the impact of differential selective attrition on the estimated effect for never-attriters.

To guide clinical interpretation, we calculated the proportion of participants who responded (>50% reduction of PHQ-9 symptoms) and completely remitted (<5 on the PHQ-9).

Concerns of multiple testing error were addressed by maintaining an experiment-wise type 1 error of 5%. To address potential heterogeneity, treatment effects were estimated for subgroups (eg, based on prescores). Finally, average treatment effects on the treated were estimated, and corresponding measures of clinically meaningful change and numbers needed to treat (NNT) were explored.

RESULTS

Participants

Of 1662 persons assessed for eligibility, 680 met inclusion criteria and were randomised (figure 1). A total of 331 participants were randomised to the intervention and 349 to ECAU. The post-treatment assessment was returned by 34.9% of respondents (ie, 65.1% dropout). The recruitment started at 9 December 2019 and ended at 9 July 2020. The original plan was to start recruitment in November 2019; however, due to the eruption of protests in Lebanon and political unrest in 2019, it was postponed for 1 month. The completion of data collection was also delayed for about 2 months. No other deviations from the protocol occurred.

Among users in the intervention group, 60% of participants completed the introduction and proceeded to session 1. Among

Table 1 Demographic and baseline characteristics*

	Intervention (n=331)	Control (n=349)	Total (n=680)
Age, M (SD)	27.0 (8.4)	27.1 (8.1)	27.02 (8.3)
Female gender	240 (72.5)	235 (67.3)	475 (69.9)
Marital status			
Never married	218 (65.9)	229 (65.6)	447 (65.7)
Married	84 (25.4)	96 (27.5)	180 (26.5)
Other	29 (8.8)	24 (6.9)	53 (7.8)
Nationality			
Lebanese	305 (92.1)	314 (90.0)	619 (91.0)
Syrian	1 (0.3)	1 (0.3)	2 (0.3)
Other	25 (7.6)	34 (9.7)	59 (8.8)
Education			
Primary/elementary	20 (6.0)	23 (6.6)	43 (6.3)
Secondary	66 (19.9)	68 (19.5)	134 (19.7)
Undergraduate/BSc	141 (42.6)	173 (49.6)	314 (46.2)
Graduate/MSc	86 (26.0)	77 (22.1)	163 (24.0)
Other	18 (5.4)	8 (2.3)	26 (3.9)
Employment status			
Paid work	122 (36.9)	133 (38.1)	255 (37.5)
Non-paid work	17 (5.1)	27 (7.7)	44 (6.5)
Student	97 (29.3)	94 (26.9)	191 (28.1)
Unemployed	94 (28.4)	90 (25.8)	184 (27)
Other	1 (0.3)	5 (1.4)	6 (0.8)

*All cells indicate n (%), unless otherwise indicated.

those, the mean number of completed sessions was 1.72. In total, 40% of participants in the intervention group completed session 1, 31% completed session 2, 27% completed session 3, 24% completed session 4 and 19% completed session 5.

The sociodemographic characteristics of the participants are summarised in table 1. The average age was 27.0 years. The majority was female (69.9%) and most were never married (65.7%). Only 26.0% had only primary or secondary education, while 70.2% had an undergraduate or graduate degree. A total of 37.5% had a paid job, 28.1% was a student and 27.0% was unemployed. There were no significant differences between intervention and control group. Among users in the intervention group, 12 (3.6%) saw a psychiatrist, 11 (3.3%) a psychologist, 15 (4.5%) took medication for mood problems, 9 (2.7%) for anxiety problems and 14 (2.4%) for sleep problems.

Primary outcome

The ITT analyses showed significant treatment effects for both primary outcomes, depression (b=−2.18; SE=0.78; p<0.01) and functional impairment (b=−3.95; SE=1.04; p<0.01). Effect sizes (SMDs) were large for depression (g=0.71; 95% CI: 0.45 to 0.97) and moderate for functional impairment (g=0.43; 95% CI: 0.21 to 0.65) (tables 2 and 3).

At 3-month follow-up, the intervention effect was maintained for depression (b=−3.73; SE=0.90; p<0.01) with a moderate SMD (g=0.52; 95% CI: 0.22 to 0.82), but no significant effect for functional impairment (b=−1.57; SE=1.22, p=0.20; g=0.17; 95% CI: −0.09 to 0.43). Estimating worst-case and best-case scenarios for the potential impact of selective differential attrition yielded RFLBs for never-attriters (model 2 in table 3). In the RFLB analyses, the effects of the intervention on depression were still significant, but the effects in quality of life were not.

Secondary outcomes

In the ITT analyses, all secondary outcomes at post-test indicated significant results (p<0.01) with moderate-to-large SMDs: 0.37 for subjective well-being (WHO-5), 0.74 for anxiety (GAD-7), 0.53 for post-traumatic stress (PCL-5), 0.56 for personal problems (PSYCHLOPS) and (tables 2 and 3). In the strict RFLB analyses, the effects on anxiety, post-traumatic stress and on personal problems were still significant, but the effects on well-being were not (model 2 in table 3).

At 3-month follow-up, the intervention continued to be more effective than ECAU for well-being (SMD=0.44; 95% CI: 0.17; 0.71; p<0.01), anxiety (SMD=0.49; 95% CI: 0.22 to 0.76; p<0.01), post-traumatic stress (SMD=0.35; 95% CI: 0.06 to 0.64; p=0.02) and personal problems (SMD=0.47; 95% CI: 0.19 to 0.75; p<0.01). In the strict RFLB analyses, effects were still significant for well-being, anxiety and personal problems.

Response and complete remission

For the ITT sample, almost half of the treated people showed a treatment response (46.5%) versus 1 in 7 (14.3%) in the control group (table 4). Furthermore, approximately 1 in 4 (26.0%) treated people completely remitted versus about 1 in 20 (4.6%) in the control group. The NNTs were three for response and five for complete remission for the ITT sample as well as for the completers sample.

Table 2 Inferential statistics of treatment outcome measures for complete cases: means, SD and N

	Baseline		Post-treatment		3-month follow-up	
	Intervention	Control	Intervention	Control	Intervention	Control
N	331	349	96	141	81	113
Primary						
PHQ-9	16.47 (4.12)	16.29 (4.10)	9.34 (6.10)	13.57 (5.51)	9.11 (5.57)	12.09 (5.83)
WHODAS	31.92 (8.44)	31.73 (8.06)	24.40 (8.57)	28.02 (9.07)	25.20 (9.30)	26.64 (9.28)
Secondary						
WHO-5	6.49 (3.99)	7.02 (4.33)	10.42 (5.73)	8.50 (5.47)	11.31 (5.48)	8.82 (5.23)
GAD-7	15.92 (4.71)	15.92 (4.64)	10.08 (5.62)	14.30 (5.64)	9.99 (5.35)	12.89 (5.94)
PCL-5	19.88 (6.19)	20.18 (6.27)	13.88 (7.34)	17.81 (6.92)	13.05 (7.91)	16.41 (8.33)
PSYCHLOPS	16.69 (3.54)	16.74 (3.39)	10.08 (4.84)	13.75 (4.64)	9.21 (5.06)	11.96 (5.63)

GAD-7, Generalised Anxiety Disorder 7; PCL-5, Post-Traumatic Stress Disorder Checklist 5; PHQ-9, Patient Health Questionnaire 9; PSYCHLOPS, Psychological Outcomes Profile; WHODAS, WHO Disability Assessment Schedule-12.

Table 3 Step-by-Step treatment effect estimates

	Post-treatment					Follow-up				
	Model 1 MI			Model 2 RFLB		Model 1 MI			Model 2 RFLB	
	B MI (SE)	P value	Effect size (95% CI)	B Lower bound (SE)	B Upper bound (SE)	B MI (SE)	P value	Effect size (95% CI)	B Lower bound (SE)	B Upper bound (SE)
Primary										
PHQ	−4.18 (0.78)	<0.01	0.71 (0.45 to 0.97)	−6.73 (1.14)	−1.57 (0.94)	−3.07 (0.90)	<0.01	0.52 (0.22 to 0.82)	−5.17 (1.28)	−0.36 (1.15)
WHODAS	−3.95 (1.04)	<0.01	0.43 (0.21 to 0.65)	−7.79 (1.68)	0.99 (1.76)	−1.57 (1.22)	0.20	0.17 (−0.09 to 0.43)	−5.03 (2.01)	2.64 (1.97)
Secondary										
WHO-5	2.01 (0.68)	<0.01	0.37 (0.12 to 0.62)	−0.47 (1.05)	4.74 (0.94)	2.42 (0.76)	<0.01	0.44 (0.17 to 0.71)	0.31 (1.11)	4.81 (1.04)
GAD-7	−4.14 (0.71)	<0.01	0.74 (0.49 to 0.99)	−6.98 (1.03)	−1.50 (1.08)	−2.86 (0.79)	<0.01	0.49 (0.22 to 0.76)	−5.30 (1.25)	−0.50 (1.27)
PCL-5	−3.86 (0.94)	<0.01	0.53 (0.27 to 0.79)	−7.31 (1.28)	−0.77 (1.32)	−2.70 (1.15)	0.02	0.35 (0.06 to 0.64)	−6.54 (1.74)	0.31 (1.86)
PSYCHLOPS	−2.79 (0.67)	<0.01	0.56 (0.29 to 0.83)	−5.34 (0.97)	−0.88 (0.92)	−2.64 (0.81)	<0.01	0.47 (0.19 to 0.75)	−5.33 (1.24)	−0.64 (1.24)

*Treatment effects in model 1 are derived through multiple (150) imputations, assuming missing at random, applying multivariate normal regression, imputation by experimental group and accommodating arbitrary missing outcome value patterns using an iterative Markov Chain Monte Carlo method. Prescore and background controls (gender and a dummy for whether a participant had missing values on 1 or more of these characteristics) are included for improved precision of the regression point estimates reported in model 1. Effect sizes reported in model 1 are Hedges g, combining MI estimation results using Rubin's rules. Treatment effects in model 2 are derived through RFLBs procedure, assuming missing not at random for the differential attrition between treatment arms.
GAD-7, Generalised Anxiety Disorder 7; MI, multiple imputation; PCL-5, Post-Traumatic Stress Disorder Checklist 5; PHQ, Patient Health Questionnaire; PSYCHLOPS, Psychological Outcomes Profile; RFLBs, Random Forest Lee Bounds; WHODAS, WHO Disability Assessment Schedule-12.

Table 4 Response and complete remission rates*

	ITT			Completers		
	Treatment	Control	NNT	Treatment	Control	NNT
Response	46.5% (154/331)	14.3% (50/349)	3	46.9% (45/96)	14.2% (20/141)	3
Complete remission	26.0% (86/331)	4.6% (16/349)	5	25.0% (24/96)	2.8% (4/141)	5

*Response was defined as a 50% reduction in depressive symptoms on the Patient Health Questionnaire 9 (PHQ-9) from baseline to post-treatment; complete remission was defined as a score of <5 on the PHQ-9.
ITT, intention-to-treat analysis; NNT, needed to treat.

Other outcomes

Of 331 participants in the intervention condition, 199 (60.1%) finished the introduction session, 88 (26.6%) finished at least 4 of 5 sessions and 64 (19.3%) finished all sessions. Of the 90 participants who completed the post-assessment, approximately half indicated that most or almost all of their needs were met (44.4%).

All participants in the intervention group were invited to complete the user satisfaction questionnaire. Of the participants who completed the questionnaire, 74% have completed the intervention, and 88% have completed four out of five sessions. A large majority responded that they were mostly or very much satisfied (91.1%), and that they would come back to the programme if they were to seek help again (92.2%). Fidelity checks revealed 6% minor deviations from the treatment protocol, such as a helper not reviewing the story with a user or not reviewing practice exercises. During the trial, one serious adverse event occurred (a hospitalisation in the intervention group, which was unrelated to the intervention).

DISCUSSION

This study supports the value of digital self-help, in a setting where people were subjected to a range of co-occurring adversities. The fact that the study was able to rapidly complete recruitment during the COVID-19 pandemic shows the value of digital health at a time when physical distancing is required. We found that this new WHO digital mental health intervention Step-by-Step is effective in reducing mental health problems among people living in Lebanon. Moderate-to-large effects on depression were found at post-treatment and 3-month follow-up. These remained significant in a very strict sensitivity analysis. The intervention also had significant effects on impaired functioning, anxiety, post-traumatic stress, well-being and personal problems, and these effects were also maintained at follow-up. With NNTs of 3 (response) to 5 (complete remission) in the ITT sample, the clinical relevance of this intervention is considerable.

These results are consistent with previous findings showing that e-health in general,[12] as well as mobile health apps,[11] can effectively reduce mental health problems. However, most of this research has been conducted in high-income countries. This study shows that mobile interventions can be also effective in people with mental health problems in a lower resourced country, among people exposed to severe adversity. This study also shows that participants can be well recruited through online advertisements and social media, and these strategies can also be used in other countries and settings. It may also be considered to disseminate Step-by-Step through health authorities, local medical centres and employers.

Strengths of this study include the implementation in a country exposed to multiple crises, adaptation to the local context, the

large sample size, automated randomisation shielding against researcher bias, automated assessment ensuring blinded data collection, the overall strict design and analyses and the central involvement of Lebanon's National Mental Health Programme, positioning it to scale up this intervention nationally.

One important problem of this study is that the dropout rate was very high. This is inherent to e-mental health interventions and research,[32] and for which we had powered the study, but still makes the findings uncertain. At the same time, the recruitment went very fast, probably reflecting the shortage of evidence-based and accessible mental health services in Lebanon. Exit surveys in those who dropped out after 3 weeks suggested that the high dropout rate may also be related to technical issues, such as problems with WiFi, the phones and login details. Others indicated that dropout was related to changes in their lives and competing priorities. Further research is needed how such dropout can be prevented or reduced.

Further limitations included the fact that we did not conduct clinical diagnostic interviews. Furthermore, we only examined the effects at 3-month follow-up, though effects were maintained at least over that period. We also offered the intervention in different formats (through the smartphone or through a web browser) and the support could also be given in different format (phone calls, email). It is not known whether this may have affected the outcomes. Finally, the intervention itself is limited, because it requires digital access, which is inequitably distributed in populations.

Despite these limitations, we conclude that Step-by-Step had a statistically significant and meaningful effect on depression, functional impairment, anxiety, post-traumatic stress, subjective well-being and self-identified problems among people living in Lebanon. This study is the first to show that a digital intervention supported by human helpers can contribute considerably to improving mental health among people in communities exposed to adversity in a low-resourced setting.

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