

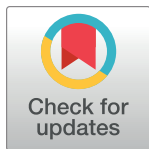
RESEARCH ARTICLE

Effects of a self-guided digital mental health self-help intervention for Syrian refugees in Egypt: A pragmatic randomized controlled trial

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OPEN ACCESS

Citation: Burchert S, Alkneime MS, Alsaod A, Cuijpers P, Heim E, Hessling J, et al. (2024) Effects of a self-guided digital mental health self-help intervention for Syrian refugees in Egypt: A pragmatic randomized controlled trial. *PLoS Med* 21(9): e1004460. <https://doi.org/10.1371/journal.pmed.1004460>

Academic Editor: Charlotte Hanlon, The University of Edinburgh, UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

Received: January 9, 2024

Accepted: August 14, 2024

Published: September 9, 2024

Peer Review History: PLOS recognizes the benefits of transparency in the peer review process; therefore, we enable the publication of all of the content of peer review and author responses alongside final, published articles. The editorial history of this article is available here: <https://doi.org/10.1371/journal.pmed.1004460>

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Data Availability Statement: The data collected for this study involves sensitive information obtained

Abstract

Background

Digital mental health interventions for smartphones, such as the World Health Organization (WHO) Step-by-Step (SbS) program, are potentially scalable solutions to improve access to mental health and psychosocial support in refugee populations. Our study objective was to evaluate the effectiveness of SbS as self-guided intervention with optional message-based contact-on-demand (COD) support on reducing psychological distress, functional impairment, symptoms of posttraumatic stress disorder (PTSD), and self-identified problems in a sample of Syrian refugees residing in Egypt.

Methods and findings

We conducted a 2-arm pragmatic randomized controlled trial. A total of 538 Syrians residing in Egypt with elevated levels of psychological distress (Kessler Psychological Distress Scale; K10 > 15) and reduced psychosocial functioning (WHODAS 2.0 > 16) were randomized into SbS + CAU ($N = 266$) or CAU only ($N = 272$). Primary outcomes were psychological distress (Hopkins Symptom Checklist 25) and impaired functioning (WHO Disability Assessment Schedule 2.0) at 3-month follow-up. Secondary outcomes were symptoms of PTSD (PTSD Checklist for DSM-5 short form, PCL-5 short) and self-identified problems (Psychological Outcomes Profiles Scale, PSYCHLOPS). Intention-to-treat (ITT) analyses showed significant but small effects of condition on psychological distress (mean difference: -0.15 ; 95% CI: $-0.28, -0.02$; $p = .02$) and functioning (mean difference: -2.04 ; 95% CI: $-3.87, -0.22$; $p = .02$) at 3-month follow-up. There were no significant differences between groups

Table 1. Demographic and baseline characteristics.

	CAU (n = 272)	SbS + CAU (n = 266)	Completer ¹ (n = 98)	Dropouts ² (n = 168)	Total (n = 538)
M (SD)					
Age	33.98 (10.54)	33.29 (11.20)	33.52 (10.13)	33.16 (11.81)	33.64 (10.87)
HSCL-25	2.39 (0.61)	2.46 (0.61)	2.42 (0.64)	2.49 (0.60)	2.42 (0.61)
WHODAS	30.77 (8.03)	31.94 (8.67)	31.90 (9.23)	31.96 (8.35)	31.35 (8.36)
PCL-5	14.84 (7.52)	15.18 (7.32)	14.50 (7.8)	15.58 (7.02)	15.01 (7.42)
PSYCHLOPS	15.40 (4.52)	15.02 (4.53)	14.96 (4.38)	15.06 (4.63)	15.21 (4.52)
% (n)					
Female	69.1% (188)	65.4% (174)	75.5% (74)	59.5% (100)	67.3% (362)
Marital status					
Never married	15.8% (43)	24.4% (65)	16.3% (16)	29.2% (49)	20.1% (108)
Married	70.2% (191)	64.3% (171)	77.6% (76)	56.5% (95)	67.3% (362)
Separated	4.4% (12)	3.8% (10)	4.1% (4)	3.6% (6)	4.1% (22)
Divorced	5.1% (14)	3.4% (9)	1.0% (1)	4.8% (8)	4.3% (23)
Widowed	4.0% (11)	2.6% (7)	1.0% (1)	3.6% (6)	3.3% (18)
Other	0.4% (1)	1.5% (4)	0% (0)	2.4% (4)	0.9% (5)
Education ³					
No education	6.6% (18)	7.5% (20)	9.2% (9)	6.5% (11)	7.1% (38)
Primary	35.7% (97)	27.8% (74)	23.5% (23)	30.4% (51)	31.8% (171)
Secondary	42.3% (115)	46.2% (123)	50.0% (49)	44.0% (74)	44.2% (238)
University	11.0% (30)	14.3% (38)	13.3% (13)	14.9% (25)	12.6% (68)
Technical	2.6% (7)	2.6% (7)	0% (0)	4.2% (7)	2.6% (14)
Other	1.8% (5)	1.5% (4)	4.1% (4)	0% (0)	1.7% (9)
Occupation					
Paid work	16.5% (45)	21.4% (57)	21.5% (21)	21.4% (36)	19.0% (102)
Self-employed	12.5% (34)	11.3% (30)	10.2% (10)	11.9% (20)	11.9% (64)
Unpaid work	0.4% (1)	0.8% (2)	0% (0)	1.2% (2)	0.6% (3)
Student	5.5% (15)	10.9% (29)	7.1% (7)	13.1% (22)	8.2% (44)
Homemaker	39.0% (106)	27.4% (73)	33.7% (33)	23.8% (40)	33.3% (179)
Retired	0.4% (1)	0.4% (1)	1.0% (1)	0% (0)	0.4% (2)
Unemployed	21.3% (58)	21.8% (58)	21.4% (21)	22.0% (37)	21.6% (116)
Other	4.4% (12)	6.0% (16)	5.1% (5)	6.5% (11)	5.2% (28)

¹At least 4 out of 5 SbS sessions completed.²Less than 4 SbS sessions completed.³Highest education level started.<https://doi.org/10.1371/journal.pmed.1004460.t001>

weekly phone calls to reduce this overhead and to increase the scalability of the approach. Intervention completion was defined as completion of a minimum of 4 out of 5 sessions because the fifth session essentially focused on repetition of previously learned techniques.

COD was provided by trained and supervised nonspecialist research assistants called “e-helpers”, using the in-app messaging system. The e-helper team consisted of male Syrian Arabic-native speakers with an educational background in psychology and were refugees. Participants could at any time reach out to e-helpers for help with the intervention, app functionality, technical issues, or other topics, including referral to other services. The in-app messaging feature was data efficient and incurred no additional costs, although it required an internet connection to send and receive messages. E-helpers responded within 48 hours, which means that

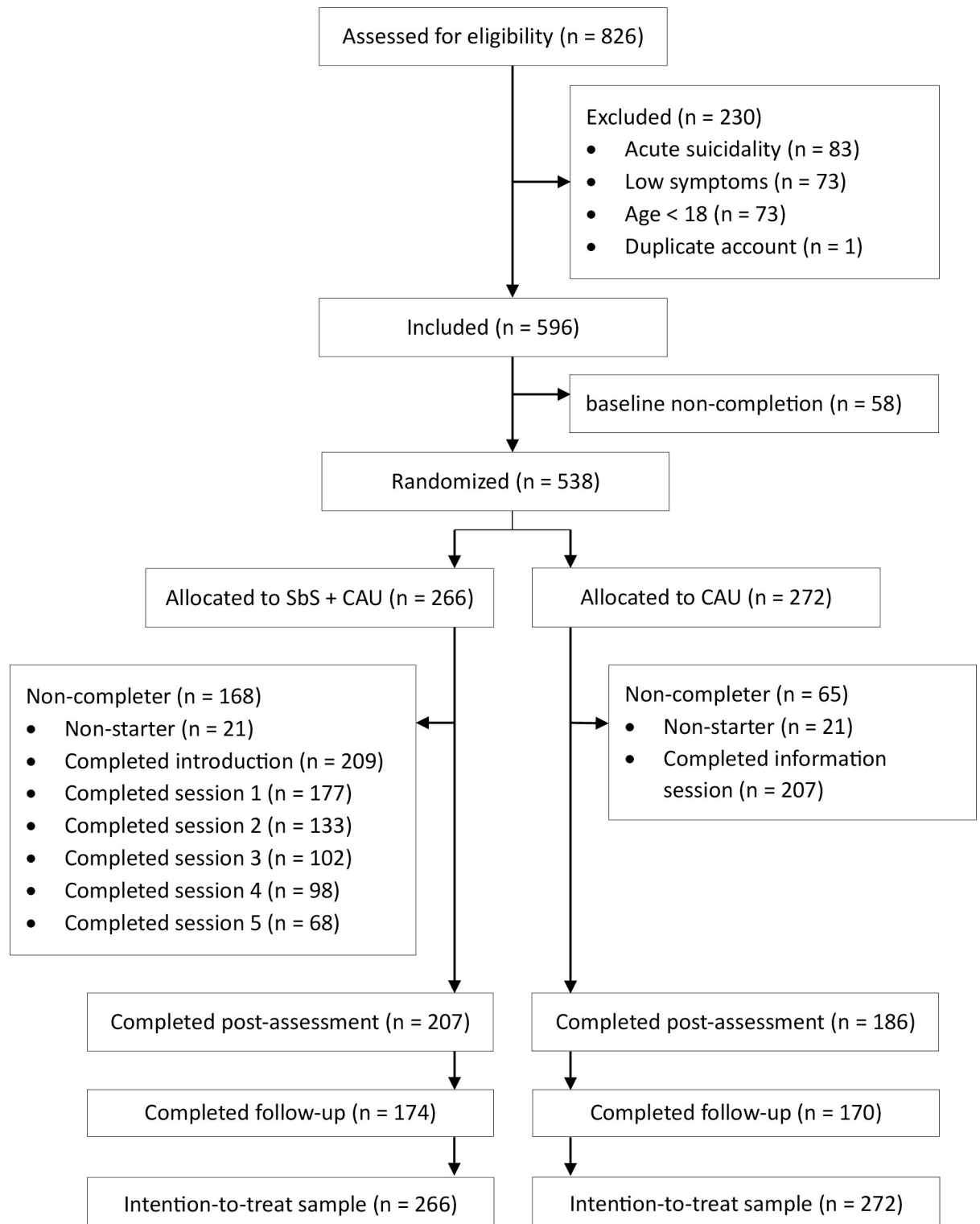


Fig 1. Flowchart.

<https://doi.org/10.1371/journal.pmed.1004460.g001>

Table 2. Pooled results from linear mixed models for primary and secondary outcomes ($N = 538$, based on multiple imputation).

		Descriptive statistics, Pooled ¹ <i>M</i> (<i>SD</i>)				Linear mixed model analysis ² , Pooled results ³		
Outcomes	Time point	SbS + CAU	<i>n</i>	CAU	<i>n</i>	Mean diff. (95% CI)	<i>p</i> -value	Effect size ⁴
Primary								
HSCL-25 (psych. distress)	Baseline	2.46 (0.61)	266	2.39 (0.61)	272			
	Post	2.29 (0.68)	207	2.36 (0.65)	186	−0.15 (−0.27, −0.02)	.021*	0.23
	Follow-up	2.18 (0.67)	174	2.26 (0.70)	170	−0.15 (−0.28, −0.02)	.022*	0.22
WHODAS (functioning)	Baseline	31.90 (8.67)	266	30.80 (8.03)	272			
	Post	29.80 (8.92)	207	30.90 (8.74)	186	−2.23 (−3.94, −0.53)	.011*	0.25
	Follow-up	29.40 (9.11)	174	30.30 (9.40)	170	−2.04 (−3.87, −0.22)	.023*	0.22
Secondary								
PCL-5 (short) (PTSD symptoms)	Baseline	15.20 (7.32)	266	14.80 (7.52)	272			
	Post	13.40 (7.78)	207	13.30 (7.65)	186	−0.19 (−1.51, 1.14)	.780	0.03
	Follow-up	12.70 (7.98)	174	13.10 (7.95)	170	−0.76 (−2.26, 0.74)	.320	0.10
PSYCHLOPS (self-defined problems)	Baseline	15.00 (4.53)	266	15.40 (4.52)	272			
	Post	12.80 (5.51)	207	14.00 (5.18)	186	−0.76 (−1.65, 0.14)	.099	0.14
	Follow-up	12.60 (5.43)	174	13.8 (5.33)	170	−0.85 (−1.78, 0.09)	.075	0.15

¹Pooled descriptive statistics across all imputed datasets.

²As covariates the models included: baseline score, gender, age, marital status, education, occupation, and postmigration living difficulties.

³Treatment effects were pooled based on multiple imputations (100), assuming missing at random, using progressive mean matching (PMM).

⁴Hedges' g effect sizes were derived by combining multiple imputation estimates using Rubin's rules.

<https://doi.org/10.1371/journal.pmed.1004460.t002>

of +3% in the HSCL-25 scores (indicating higher psychological distress) and +2% in the WHODAS scores (indicating lower functioning) were sufficient to render the results not significant.

Analyses on remission rates for the HSCL-25 were conducted for the subsamples of participants who scored above the cutoff for remission at baseline assessment, which was the case in 71.4% (SbS + CAU group) and 69.9% (CAU group) of the participants. In these subsamples, full remission on the HSCL-25 was found in 20.0% (SbS + CAU group) and 15.8% (CAU group) of participants. The study conditions did not differ in their remission rates, OR = 1.33; 95% CI 0.76, 2.35; $p = 0.35$. For the WHODAS, all participants scored above the cutoff for remission at baseline. Here, 9.8% (SbS + CAU group) and 7.1% (CAU group) were fully remitted, OR = 1.42; 95% CI 0.62, 3.38; $p = 0.44$.

Table 3 summarizes the types of services used by study participants in both conditions throughout the intervention period of 6 weeks. More than half (58.5%) of the participants reported using at least 1 type of service during this period. Participants mainly utilized primary healthcare services by visiting a general practitioner (30.5%) or going to a health worker/nurse (23.4%). A minority reported using specialized mental healthcare services and visited a psychologist (4.1%) or a psychiatrist (3.6%), as well as taking medication for mood problems (7.1%), anxiety (11.2%), and sleep problems (14.2%). During the trial, no serious adverse events were reported to the e-helper team. Upon trial completion, analysis of the service use questionnaire indicated that 4.8% of the participants were in contact with external CAU crisis services. Hospitalization in a psychiatric hospital or a psychiatric ward in a public hospital was reported by 3 participants (0.8%). Outpatient services at a hospital were utilized by 1.5%, while 0.8% indicated a visit to an emergency room. There were no substantial differences in CAU utilization between the SbS + CAU and the CAU conditions. However, there were statistically significant differences in baseline, post, and follow-up symptom severity on the HSCL-25,