

1 **Empowerment group therapy for refugees with affective disorders: results**
2 **of a multi-center randomized controlled trial**

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37

38 **Abstract**

39 **Background:** Against the background of missing culturally-sensitive mental health care
40 services for refugees, we developed a group intervention (*'Empowerment'*) for refugees at level
41 three within the stratified Stepped and Collaborative Care Model of the project *Mental Health*
42 *in Refugees and Asylum Seekers* (MEHIRA). We aim to evaluate the effectiveness of the
43 *Empowerment* group intervention with its focus on psychoeducation, stress management and
44 emotion regulation strategies in a culturally-sensitive context for refugees with affective
45 disorders compared to treatment-as-usual (TAU).

46 **Method:** At level three of the MEHIRA project, 149 refugees and asylum seekers with
47 clinically relevant depressive symptoms were randomized to the *Empowerment* group
48 intervention or TAU. Treatment comprised 16 therapy sessions conducted over 12 weeks.
49 Effects were measured with the Patient Health Questionnaire (PHQ-9) and the Montgomery
50 Asberg Depression Rating Scale (MÅDRS). Further scales included assessed emotional
51 distress, self-efficacy, resilience and quality of life.

52 **Results:** Intention-to-treat analyses show significant cross level interactions on both self-rated
53 depressive symptoms (PHQ-9; $F_{(1,147)}=13.32, p<.001$) and clinician-rated depressive symptoms
54 (MÅDRS; $F_{(1,147)}=6.91, p=.01$), indicating an improvement in depressive symptoms from
55 baseline to post-intervention in the treatment group compared to the control group. The effect
56 sizes for both scales were moderate ($d=0.68$, 95% CI 0.21 to 1.15 for PHQ-9 and $d=0.51$, 95%
57 CI 0.04 to 0.99 for MÅDRS).

58 **Conclusion:** In the MEHIRA project comparing an SCCM approach vs TAU, the
59 *Empowerment* group intervention at level three showed effectiveness for refugees with
60 moderately severe depressive symptoms.

61

62

63 Introduction

64 Estimates assume that in 2023, the number of people forcibly displaced will, for the first time
65 in history, cross the number of 117 million [1]. Studies show repeatedly higher prevalence rates
66 of mental distress in refugee populations compared to native-borns [2, 3] and economic
67 migrants [4], including rates for post-traumatic stress disorders and affective disorders [5].
68 Current group therapy approaches address different consequences of displacement-related
69 trauma in refugees by focusing on psychoeducation [6], stabilization [7], trauma narrative and
70 cognitive restructuring [8] or transdiagnostic processes such as impulsivity [9]. To our
71 knowledge, there is no manual targeting the treatment of depressive symptoms in refugees. We
72 developed the *Empowerment* manual, the first depression-specific intervention for refugees
73 [10]. The intervention comprises 16 sessions, each starting with a mindfulness or breathing
74 exercise. Sessions 1 to 5 focus on psychoeducation and behavioral activation in the context of
75 displacement. A culturally-sensitive explanatory model taking pre- and post-migration stressors
76 into account is developed [11]. Sessions 6 to 10 impart coping skills in dealing with migration-
77 related acute stress, disturbed sleep, and somatic pain. Sessions 11 to 14 focus on emotion
78 regulation strategies. Strategies for dealing with fear, anger and homesickness are imparted. In
79 the final two sessions, information about further treatment options within the German mental
80 health care system are given. Developing the manual according to the core dimensions of
81 cultural-sensitive psychotherapy [11] and in close cooperation with cultural mediators, we
82 aimed to develop a manual sensitive to the cultural background and needs of refugees. The
83 intervention was specifically developed for Arabic and Dari/Farsi speaking refugee population
84 groups coming from Syria, Afghanistan, Iraq and Iran. All four countries were represented in
85 Germany in 2014 among the 10 countries of origin with the highest inflow. Opportunities for
86 behavioral activation and sleep hygiene in mass shelters, the inclusion of religion and cultural
87 values (e.g., family cohesion), culturally sensitive group compositions of participants and the

88 use of linguistic and cultural mediators represent measures to make the intervention engaging
89 and helpful for refugees.

90 The Empowerment manual was implemented for the first time within the project *Mental Health*
91 *in Refugees and Asylum Seekers (MEHIRA)*, a trial developing and implementing a stratified
92 Stepped and Collaborative Care Model (SCCM) for refugees with depressive disorders [12].
93 Within the SCCM, refugees received culturally sensitive interventions, with the intensity of
94 treatment being tailored to the symptom burden. Treatment within the SCCM resulted in a more
95 effective and cost-effective improvement in depressive symptoms compared to a treatment-as-
96 usual group (TAU) control group [13]. Our study aimed to investigate the effectiveness of the
97 Empowerment intervention within the framework of the MEHIRA project. The group-based
98 therapy approach of the Empowerment intervention is presumably more cost-effective and
99 scalable than individual therapy (level 4 of the MEHIRA SCCM), yet possibly more effective
100 than peer-to-peer approaches (level 2 of the MEHIRA SCCM), making it an appropriate
101 therapeutic approach to be used as part of a stepped care model. Our primary hypothesis was
102 that the intervention is more effective in the reduction of self-rated severity of depressive
103 symptoms compared to routine care at the time of post intervention. Our secondary hypotheses
104 stated that group therapy is effective in improving clinician-rated depression severity, self-
105 efficacy, emotional distress, resilience and quality of life in comparison to routine care.

106

107 **Methods**

108 *Study design*

109 Patients with moderate depressive symptoms were randomly assigned on level three of the
110 SCCM to either the Empowerment intervention or TAU [12]. Randomization was carried out
111 in a 1:1 scheme with fixed block size using a computer-generated electronic case report form
112 (eCRF) generated by the Clinical Study Center Berlin. All procedures contributing to this work

113 comply with the Good Clinical Practice guidelines and with the Helsinki Declaration of 1975,
114 as revised in 2008. All procedures involving patients were approved by the ethics committee of
115 the Ludwig-Maximilians-University Munich (approval number 17-883) and the ethics boards
116 of all other study sites. The MEHIRA project was registered in ClinicalTrials.gov (registration
117 number: NCT03109028; registration date 11.04.2017).

118

119 ***Participants***

120 Inclusion criteria for participants of this analysis were a) legal status of an asylum seeker or
121 refugee [14], b) between 18 and 65 years of age, c) native speaking in Arabic or Dari/Farsi
122 and/or fluent in German or English and d) a screening sum score between 15 and 19 on the
123 Patient Health Questionnaire-9 [PHQ-9; 15], indicating moderate depressive symptoms.
124 Patients were not eligible to participate in a study with 1) a current or past psychotic or
125 degenerative disorder, 2) absent informed consent, and 3) a score of ≥ 4 on item 10 of the
126 Montgomery Åsberg Depression Rating Scale [MÅDRS; 16], indicating a current risk of
127 suicidality. Potential participants were recruited from refugee shelters, general practitioners'
128 practices and refugee educational facilities. Sample size calculation for the MEHIRA project
129 yielded a planned sample size of 476 participants (238 per arm) for the primary outcome from
130 baseline (t_0) to time of post-intervention [t_1 ; 12].

131

132 ***Procedures***

133 Potential participants were screened for relevant depressive symptoms and signs of emotional
134 distress using the PHQ-9 [15] and the Refugee Health Screener [RHS-15; 17]. Participants
135 needed to score “several days” or higher on at least five items of the PHQ-9 and attain a sum
136 score of ≥ 12 on items 1-14 or a distress thermometer score of ≥ 5 on the RHS-15. All study
137 related written content was provided in German, Arabic or Dari/Farsi. After written informed

138 consent was obtained, symptomatology at baseline was assessed using PHQ-9 [15], RHS-15
139 [17] and the MÅDRS [16]. Further outcome scales included were the Brief Resilience Scale
140 [BRS;181], the Generalized Self-Efficacy Scale [GSE; 19], the Strength and Difficulties
141 Questionnaire [SDQ; 20] and the World Health Organization Quality of Life Assessment
142 [WHOQoL-BREF; 21]. Participants were then randomly assigned to receive the Empowerment
143 intervention within the SCCM or to remain in existing routine care practices (TAU). All
144 outcome scales were assessed at baseline (t_0), at time of post-intervention after 12 weeks (t_1),
145 at follow-up 1 after 24 weeks (t_2) and at follow-up 2 after 48 weeks (t_3). Data measurements
146 were performed by independent raters blinded to the study condition while randomization,
147 communication of group condition and treatment were performed by unblinded study staff. To
148 ensure blinding, the scales collected were handed over to an unblinded colleague after a rating,
149 who then carried out the randomization in the eCRF and informed the study participants of the
150 result of the randomization.

151

152 ***Intervention***

153 The Empowerment group intervention is a manualized group therapy written in German,
154 designed to be carried out with the help of linguistic and cultural mediators. The manual is
155 based on well-established CBT principles and consists of four central components:
156 psychoeducation, behavioral activation, stress management and emotion regulation. The 16
157 Empowerment sessions were conducted over a period of three months. Participants attended
158 two sessions per week in the first four weeks of treatment and one session per week in the last
159 eight weeks of treatment. The session length was 90 minutes. Group assignment was based on
160 the same native language of the participants. In some groups, participants spoke the same
161 language but came from different countries of origin (e.g. Arabic speaking participants from
162 Syria and Iraq). The translations were in Arabic or in Dari/Farsi. All groups except for one were
163 implemented with the assistance of linguistic and cultural mediators. In this one group, the

164 therapist herself was a native speaker of Arabic. The duration of therapy in this group was
165 adjusted accordingly and reduced to 60 minutes per session. Groups were held with only
166 female, only male or mixed-gender participants. Group size was intended to be between four
167 and ten participants.

168 All study therapists had completed a master's degree and were in advanced practical post-
169 graduate training. In addition, all therapists had prior experience in therapeutic work with
170 refugees and culturally sensitive psychotherapy. All psychologists were trained for one day in
171 using the manual and working with linguistic and cultural mediators. Regular supervision
172 sessions in-person and via phone were conducted to ensure adherence to the treatment protocol
173 and therapy manual. Participants in the control condition received the available routine care
174 with no stipulations made regarding the treatment received (TAU).

175

176 ***Outcome measures***

177 *Primary outcome*

178 The primary outcome was self-rated depression severity at post-intervention assessed by the
179 PHQ-9. The self-rating instrument assesses depressive symptoms on a four-point likert scale
180 resulting in sum scores between 0 and 27 [15]. The scale provides a test-retest reliability of .84
181 and an internal consistency of $\alpha = .86 - .89$ [15]. Validated across different populations and
182 cultural settings [22], the PHQ-9 is recommended by the DSM-5 to be used as a general measure
183 of depression severity.

184

185 *Secondary outcomes*

186 In brief, secondary outcome measures were: the Montgomery Åsberg Depression Rating Scale,
187 assessing clinician-rated depression severity [16], the RHS-15 as a screening instrument for
188 depressive symptoms, anxiety and trauma-related disorders in refugees and asylum seekers
189 [17], the Brief Resilience Scale assessing the ability to recover from stress and adversity [18],

190 the General Self-Efficacy Scale assessing patients' sense of effective personal action control
191 [19], the Strengths and Difficulties Questionnaire assessing emotional and behavioral problems
192 [20] and the World Health Organization Quality of Life assessment assessing patient's quality
193 of life [21]. Further descriptions and characteristics of these measures are reported in the
194 Supplementary Material.

195

196 *Statistical Analysis*

197 The primary analyses were carried out on the intention-to-treat (ITT) sample, pre-specified as
198 all randomized participants for whom baseline data were available for the primary outcome.
199 All analyses were then run with the per protocol (PP) sample, which was pre-specified as all
200 randomized patients who attended 50% or more of the therapy sessions provided. We fitted
201 linear mixed models (LMM) with three hierarchical levels: time of measurement on level one,
202 nested within patient on level two, nested within study centers on level three. The model
203 included time (from t_0 to t_1) as a continuous growth factor on level one and condition
204 (intervention vs. TAU) as a predictor variable on level two to modulate cross-level interactions
205 (time*group). We did not impute missing values in any of the analyses.

206 Standardized effect sizes (Cohen's d) were computed for all comparisons between groups.
207 Using logistic regression models, response and remission rates were compared across both
208 groups for the two depression-specific outcomes PHQ-9 and MÅDRS. Response was defined
209 as a $\geq 50\%$ reduction of sum scores on both PHQ-9 and MÅDRS from baseline to post-
210 intervention [23, 24]. Respectively, participants with a sum score of < 5 on the PHQ-9 [25] and
211 ≤ 10 on the MÅDRS [26] at time of post-intervention were classified as remitters. χ^2 tests,
212 independent t-tests or Mann-Whitney-U-Tests were calculated to assess any differences
213 between treatment groups regarding sociodemographic data and outcome scores at baseline.
214 All tests were run using a two-sided alpha level of 0.05. Analyses were run with R version 4.0.5
215 [27].

216

217 **Results**218 ***Patient flow***

219 Between April 2018 and December 2019, 584 participants were included in the MEHIRA
220 project. The subsample for the analysis of MEHIRA level three (i.e. *Empowerment* vs TAU)
221 was obtained by extracting adult participants with moderately severe depressive symptoms
222 (PHQ-9 sum score: 15–19). In the ITT-sample, 149 participants were randomly assigned to the
223 intervention ($n=81$) or the control group ($n=68$). For the PP-sample, only patients who had
224 attended at least 50% of the therapy sessions were included in the analysis. Reasons why
225 participants did not receive the Empowerment intervention or dropped out of the intervention
226 early included having second thoughts about group therapy, deciding that they did not need
227 therapy, having to move due to regulatory requirements or the group not taking place due to
228 insufficient number of participants. Patient flow is presented in Figure 1.

229

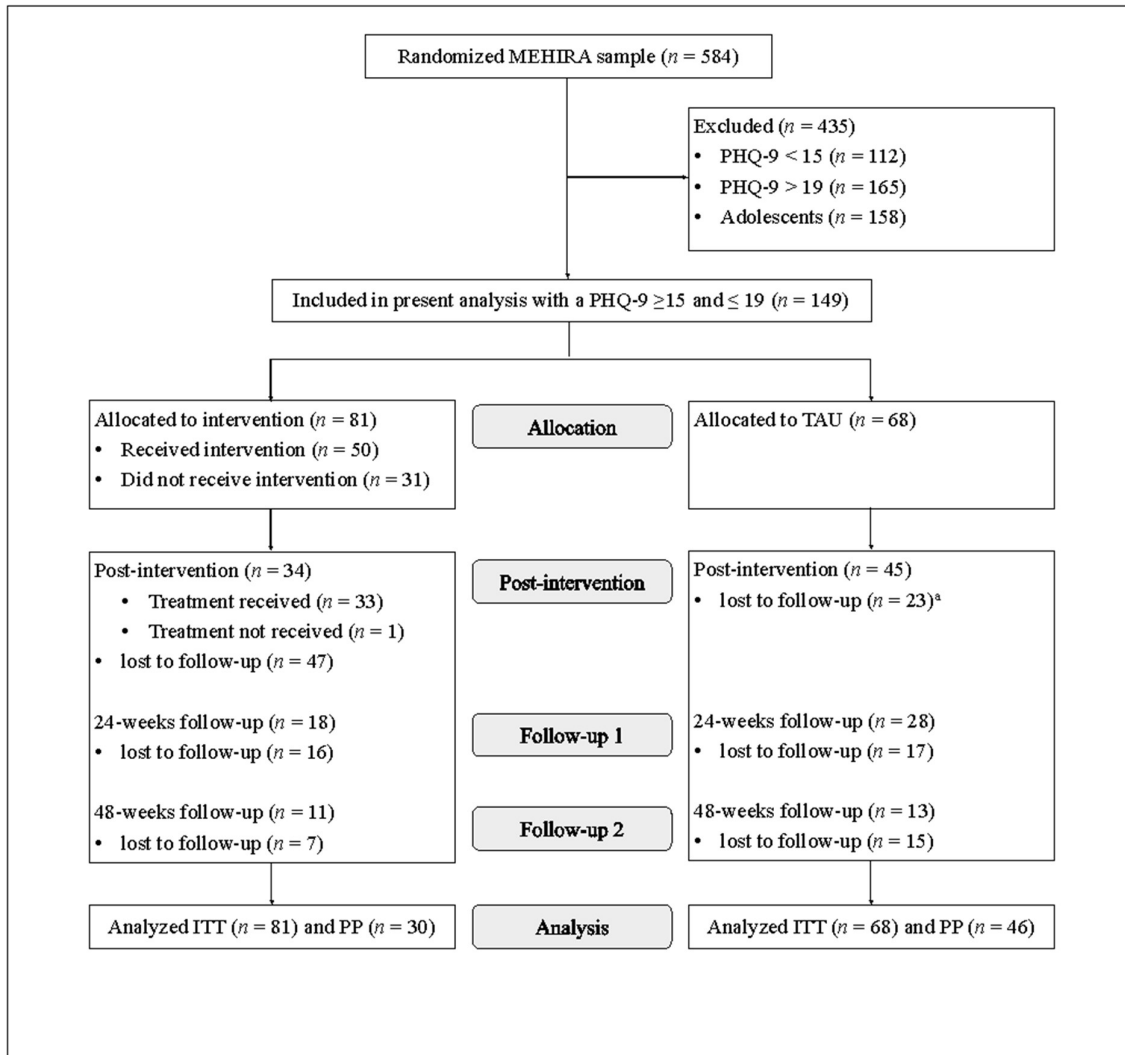
230 ***Drop-out analyses***

231 Drop-out rates between intervention and control group showed significant higher drop-
232 out rates in the intervention group at time of post-intervention, $\chi^2(1) = 4.97, p = .026$, and at
233 time of follow-up, $\chi^2(1) = 4.56, p = .033$. Drop-out rates between both groups did not differ at
234 time of follow-up 2, $\chi^2(1) = 0.46, p = .50$. No significant differences in age, sex, and baseline
235 PHQ-9 sum score were found between drop-outs and non-drop-outs at time at any measurement
236 time point (all $p > .05$). One reason for the high dropout rate in the intervention group was the
237 fact that 38% of subjects had not participated in the Empowerment intervention as planned. Of
238 those participants that had not received the intervention as indicated, all but one dropped out of
239 the study by the time of post-intervention. Reasons why participants did not receive treatment
240 included 1) having second thoughts about group therapy, e.g. the idea that the treatment offered

241 may not sufficiently address daily demands (e.g. poor living conditions), 2) the group not taking
 242 place due to an insufficient number of participants at the respective time point, and 3) having
 243 to move due to regulatory requirements or a rejected asylum application. Missing values were
 244 not imputed in any of the analyses.

245
 246
 247

Figure 1. CONSORT flow chart.



248
 249 Note. MEHIRA, “Mental Health in Refugees and Asylum Seekers”; PHQ-9 Patient Health Questionnaire-9;
 250 TAU treatment-as-usual; ITT intention-to-treat; PP per protocol. ^aNo post-intervention measurements but
 251 follow-up measurements were available for one control participant.
 252
 253

254

255 **Baseline characteristics**

256 Demographic and clinical data for both ITT and PP samples are presented in Table 1. The two
 257 study groups did not differ significantly from one another on any of the characteristics.

258 **Table 1. Demographic and clinical characteristics upon study admission.**

	ITT (n = 149)		PP (n = 76)	
	Intervention (n = 81)	TAU (n = 68)	Intervention (n = 30)	TAU (n = 46)
<i>Demographic characteristics</i>				
Age in years, mean (SD)	32.62 (9.08)	31.64 (9.84)	31.87 (8.98)	32.57 (10.80)
Female, N / total N (%)	35/81 (43.2)	22/68 (32.4)	14/30 (46.6)	13/46 (28.3)
Marital status, N / total N (%)				
Single	31/81 (38.3)	30/67 (44.8)	13/30 (43.3)	18/30 (60.0)
Married	38/81 (46.9)	23/67 (34.3)	12/30 (40.0)	17/30 (56.7)
Divorced	9/81 (11.1)	10/67 (14.9)	5/30 (16.7)	8/30 (26.7)
Widowed	3/81 (3.7)	4/67 (6.0)	0/30 (0.0)	3/30 (10.0)
Having children, N / total N (%)	42/81 (51.9)	31/65 (47.7)	14/30 (46.7)	23/46 (50.0)
Education, mean (SD)	8.8 (4.4)	8.8 (4.7)	7.7 (4.2)	8.3 (4.8)
Social status change, mean (SD)	-1.2 (1.2)	-1.1 (1.2)	-0.9 (1.2)	-1.1 (1.0)
Identification migrant, mean (SD)	1.7 (1.1)	1.7 (1.2)	1.6 (1.1)	1.7 (1.1)
Religious affiliation, n/n total (%)	67/79 (84.8)	55/67 (82.1)	27/30 (90.0)	38/46 (82.6)
Residence status, N / total N (%) ^a				
Permanent residence permit	3/81 (3.7)	3/66 (4.5)	1/30 (3.3)	2/46 (4.3)
Temporary residence permit	73/81 (90.2)	54/66 (81.8)	29/30 (76.7)	40/46 (87.0)
Permanent residence in the EU	1/81 (1.2)	4/66 (6.1)	0/30 (0.0)	2/46 (33.3)
No legal residence permit	3/81 (3.7)	3/66 (4.5)	0/30 (0.0)	1/46 (2.2)
Other	1/81 (1.2)	2/66 (3.1)	0/30 (0.0)	1/46 (2.2)
Living situation, N / total N (%)				
Private flat	32/81 (39.5)	19/66 (28.8)	12/30 (40.0)	13/45 (28.9)
Refugee accommodation ^b	40/81 (49.4)	35/66 (53.0)	16/30 (53.3)	26/45 (57.8)
Shared flat	8/81 (9.9)	10/66 (15.2)	2/30 (6.7)	5/45 (11.1)
Other	1/81 (1.2)	2/66 (3.0)	0/30 (0.0)	1/45 (2.2)
Current employment				
Unemployed	70/78 (89.7)	56/66 (84.8)	27/30 (90.0)	37/46 (80.4)
Employed	8/78 (10.3)	10/66 (15.2)	3/30 (10.0)	9/46 (19.6)
Reasons for migration, N / total N (%) ^c				
War	49/81 (60.5)	44/68 (64.7)	21/30 (70.0)	30/46 (65.2)
Natural disaster	0/81 (0.0)	1/68 (1.5)	0/30 (0.0)	0/46 (0.0)
Economic crisis	6/81 (7.4)	9/68 (13.2)	4/30 (13.3)	5/46 (10.9)
Individual situation	10/81 (12.3)	12/68 (17.6)	2/30 (6.7)	8/46 (17.4)
Persecution	28/81 (34.6)	28/68 (41.2)	9/30 (30.0)	17/46 (37.0)
Social situation	18/81 (22.2)	18/68 (26.5)	7/30 (23.3)	9/46 (19.6)
Other	6/81 (7.4)	0/68 (0.0)	1/30 (3.3)	0/46 (0.0)
<i>Clinical characteristics</i>				
Subtype of depression, n (%) ^d				
Unipolar depression	48/79 (60.8)	35/63 (55.5)	18/30 (60.0)	22/45 (48.9)
Recurrent depressive disorder	18/79 (22.8)	20/63 (31.7)	6/30 (20.0)	17/45 (37.8)
Dysthymia	1/79 (1.3)	3/63 (4.8)	0/30 (0.0)	2/45 (4.4)
Bipolar	1/79 (1.3)	0/63 (0.0)	0/30 (0.0)	0/45 (0.0)
No diagnosis according to M.I.N.I. ^e	11/79 (13.9)	5/63 (7.9)	6/30 (20.0)	4/45 (8.9)
Reported traumatic events, mean (SD)	10.05 (6.35)	10.53 (6.35)	10.48 (6.40)	10.50 (6.12)
One comorbid axis I disorder, n (%)	28/79 (35.4)	16/63 (25.4)	12/30 (40.0)	11/45 (24.4)
≥ 2 comorbid axis I disorders, n (%)	20/79 (25.3)	20/63 (31.7)	7/30 (23.3)	15/45 (33.3)
PTSD, n (%)	33/79 (41.8)	22/63 (34.9)	13/30 (43.3)	18/45 (40.0)

12

Substance use disorder, <i>n</i> (%)	5/79 (6.3)	4/63 (6.3)	0/45 (0.0)	2/45 (4.4)
Concomitant antidepressants, <i>n</i> (%)	31/80 (38.8)	28/67 (41.8)	14 (46.7)	22/46 (47.8)
Concomitant psychotherapy, <i>n</i> (%)	15/79 (19.0)	12/66 (18.2)	5/30 (16.7)	8/45 (17.8)

259 Abbreviations: ITT intention-to-treat, PP per protocol, *n* number; SD standard deviation, M.I.N.I. Mini-
 260 International-Psychiatric-Interview, PTSD Post-traumatic Stress Disorder. ^aResidence status upon study
 261 admission. Temporary residence status includes asylum seekers, asylum applicants, individuals under subsidiary
 262 protection, people under a ban on deportation and people with a tolerated right to stay. No information regarding
 263 residence status was obtained for two control participants. ^bRefugee accommodation includes initial reception
 264 centers, AnkER-centers, collective accommodation centers and decentralized accommodation. ^cMultiple answers
 265 possible. ^dNo M.I.N.I. was carried out with 7 subjects in the ITT sample and with one participant in the PP sample.
 266 ^e16 (10.7%) participants in ITT sample and 10 (13.2%) participant in the PP sample did not meet criteria for any
 267 affective disorder in the M.I.N.I.

268

269 **Primary outcome**

270 Within the ITT sample, primary outcome data were available for 149 participants at baseline
 271 (*t*₀) and for 77 participants at post-intervention (*t*₁). Analyses of the PHQ-9 sum scores revealed
 272 a significant time (*t*₀ vs. *t*₁) by group (intervention vs. TAU) interaction ($F_{(1,147)}=13.32, p<.001$).
 273 Post hoc analyses revealed that Empowerment group participants showed a significant
 274 improvement in severity of depressive symptoms from baseline to post-intervention ($\beta=-2.60,$
 275 $t_{(153.62)}=-3.59, p<.001$), whereas participants in the control group showed no change in the same
 276 period ($\beta=1.03, t_{(130.95)}=1.51, p=.133$). Calculation of Cohen's *d* revealed a moderate treatment
 277 effect of the intervention, $d=0.68$ (95% CI 0.21 to 1.15). PHQ-9 sum score trajectories from
 278 baseline to post-intervention are presented in Table 2. Figure 2 presents PHQ-9 scores as a
 279 function of group (intervention vs. TAU) and time (*t*₀ vs. *t*₁). Results of PP analyses on the
 280 primary outcome are presented in supplementary Table S1. Respectively for the PP sample,
 281 PHQ-9 scores as a function of group (intervention vs. TAU) and time (*t*₀ vs. *t*₁) are shown in
 282 supplementary Figure S1.

283

284 **Secondary outcomes**

285 For MÅDRS as secondary outcome, the ITT sample comprised 142 participants at *t*₀ and 78
 286 participants at *t*₁. Analyses reveal a main effect of time ($F_{(1,140)}=15.13, p<.001$), as well as a
 287 time (*t*₀ vs. *t*₁) by group (intervention vs. TAU) interaction ($F_{(1,140)}=6.91, p=.01$; Table 3).

288 Empowerment group participants showed a significant improvement in severity of clinician-
289 rated depressive symptoms in the same period ($\beta=-7.27$, $t_{(137.44)}=-4.43$, $p<.001$), whereas
290 MÅDRS scores in the control group showed no change from baseline to post-intervention ($\beta=-$
291 1.41, $t_{(107.28)}=-0.934$, $p=.352$). The intervention's effect size was moderate ($d=0.51$ (95% CI
292 0.04 to 0.99). At t_0 and t_1 , data on the RHS-15 were available for 148 and 77 participants. A
293 main effect of time indicated a reduction on RHS-15 sum scores between t_0 and t_1 across both
294 groups ($F_{(1,146)}=9.04$, $p=.003$). BRS scores were available at t_0 for 137 participants and at t_1 for
295 72 participants. We found a main effect of group, $F_{(1,135)} = 4.84$, $p=.029$, together with a time
296 (t_0 vs. t_1) by group (intervention vs. TAU) interaction, $F_{(1,135)} = 5$, $p=.028$. The interaction
297 indicated higher self-rated resilience in the group participants but not in the controls at post-
298 intervention. Analyses of the SDQ included 137 participants at t_0 and 71 participants at t_1 . We
299 found a main effect of time ($F_{(1,135)}=4.61$, $p=.035$), and a time (t_0 vs. t_1) by group (intervention
300 vs. TAU) interaction ($F_{(1,135)}=5.68$, $p=.02$). These results suggest a greater reduction in
301 interpersonal problems in the intervention condition compared to the control group. Analyses
302 of the WHOQoL-BREF were performed separately for the four domains physical,
303 psychological, social and environmental. In addition, the first two items were evaluated
304 separately as a general indicator of quality of life. WHOQoL-BREF scores were available for
305 136 participants at baseline and for 71 participants at post-intervention. For the psychological
306 domain, a main effect of time indicated a decline in psychological life quality from baseline to
307 time of post-intervention in both groups ($F_{(1,134)} = 14.34$, $p<.001$). Analyses of the other
308 domains yielded no results. Analyses of the GSE showed no significant effects. Sum score
309 trajectories of all secondary outcome scales from baseline to post-intervention are presented in
310 Table 2. Figure 2 presents secondary outcomes as a function of group (intervention vs. TAU)
311 and time (t_0 vs. t_1). Results of PP analyses on the secondary outcomes are presented in
312 supplementary Table S1. Respectively, secondary outcome scores for both groups (intervention
313 vs. TAU) and measurement times (t_0 vs. t_1) and time are presented in supplementary Figure S1.

314 Response and remission rates at t_1 for PHQ-9 and MÅDRS are shown in Table 2. The response
315 rates in the treatment group were significantly higher compared to the control group based on
316 PHQ-9 sum scores (OR=9, 95% CI 1.43 to 174.78, $p=.047$) and MÅDRS sum scores (OR=3.74,
317 95% CI 1.15 to 13.62, $p=.032$). Group participation lead to significant higher remission rates
318 compared to the control group based on MÅDRS sum scores (OR=13.55, 95% CI 2.51 to
319 118.77, $p=.006$).

320

321

322

323 **Table 2.** Trajectories of primary and secondary outcomes from baseline to post-intervention
 324 within ITT sample.

325

Outcome	Intervention		TAU		Group <i>F</i>	<i>p</i>	Time <i>F</i>	<i>p</i>	Time x Group <i>F</i>	<i>p</i>	ES <i>d</i>
	BL <i>M (SD)</i>	Post <i>M (SD)</i>	BL <i>M (SD)</i>	Post <i>M (SD)</i>							
PHQ-9	16.89 (3.1)	14.29 (6.11)	17.03 (1.32)	18.05 (4.81)	0.03	.857	2.48	.118	13.32	<.001	0.68 (0.21 to 1.15)
MÅDRS	23.32 (9.76)	16.12 (10.61)	24.56 (9.95)	23.8 (10.45)	0.81	.369	15.13	<.001	6.91	.01	0.51 (0.04 to 0.99)
RHS-15	34.98 (9.27)	29.97 (12.52)	35.21 (7.82)	33.98 (10.11)	0.02	.901	9.04	.003	3.39	.068	0.44 (-0.02 to 0.9)
BRS	2.7 (0.77)	2.93 (0.65)	2.94 (0.57)	2.76 (0.53)	4.84	.029	0.33	.567	5	.028	-0.42 (-0.89 to 0.06)
GSE	24.16 (7.16)	23.19 (6.3)	24.44 (7.16)	22.75 (5.66)	0.06	.814	2.84	.096	0.09	.76	-0.04 (-0.51 to 0.43)
SDQ	55.44 (7.16)	52.48 (4.77)	53.32 (8.26)	53.95 (4.9)	3.11	.08	4.61	.035	5.68	.02	0.58 (0.09 to 1.07)
WHOQoL- BREF (item 1+2)	10.76 (2.96)	11.78 (3.73)	11.65 (2.95)	11.05 (2.97)	2.64	.106	0.12	.726	2.71	.103	-0.26 (-0.76 to 0.25)
WHOQoL- BREF (phys.)	44.46 (16.64)	47.98 (20.73)	43.14 (14.11)	41.13 (12.76)	1.20	.274	0.01	.933	0.86	.357	-0.22 (-0.71 to 0.27)
WHOQoL- BREF (psych.)	47.74 (16.43)	40.53 (23.69)	47.54 (14.68)	38.23 (14.86)	0.01	.928	14.34	<.001	0.07	.791	0.06 (-0.43 to 0.56)
WHOQoL- BREF (social)	45.34 (21.63)	44.09 (27.15)	48.79 (23.17)	48.96 (20.92)	0.67	.415	0.01	.94	0.05	.826	0.08 (-0.41 to 0.57)
WHOQoL- BREF (environ.)	48.75 (16.84)	52.79 (19.23)	46.44 (15.38)	49.77 (13.11)	0.70	.403	2.67	.106	0.00	.954	0.08 (-0.41 to 0.56)

326 *Note.* TAU = treatment-as-usual; BL = Baseline; Post = Post-intervention; *M* = mean; *SD* = standard deviation;
 327 ES = effect size; *d* = Cohen's *d*; *OR* = odds ratio; *CI* = confidence interval; BL = baseline; PHQ-9 = Patient Health
 328 Questionnaire-9; MÅDRS = Montgomery Åsberg Depression Rating Scale; RHS-15 = Refugee Health Screener-
 329 15; BRS = Brief Resilience Scale; GSE = General Self-Efficacy Scale; SDQ = Strength and Difficulties
 330 Questionnaire; WHOQoL-BREF = World Health Organization Quality of Life questionnaire, brief version.

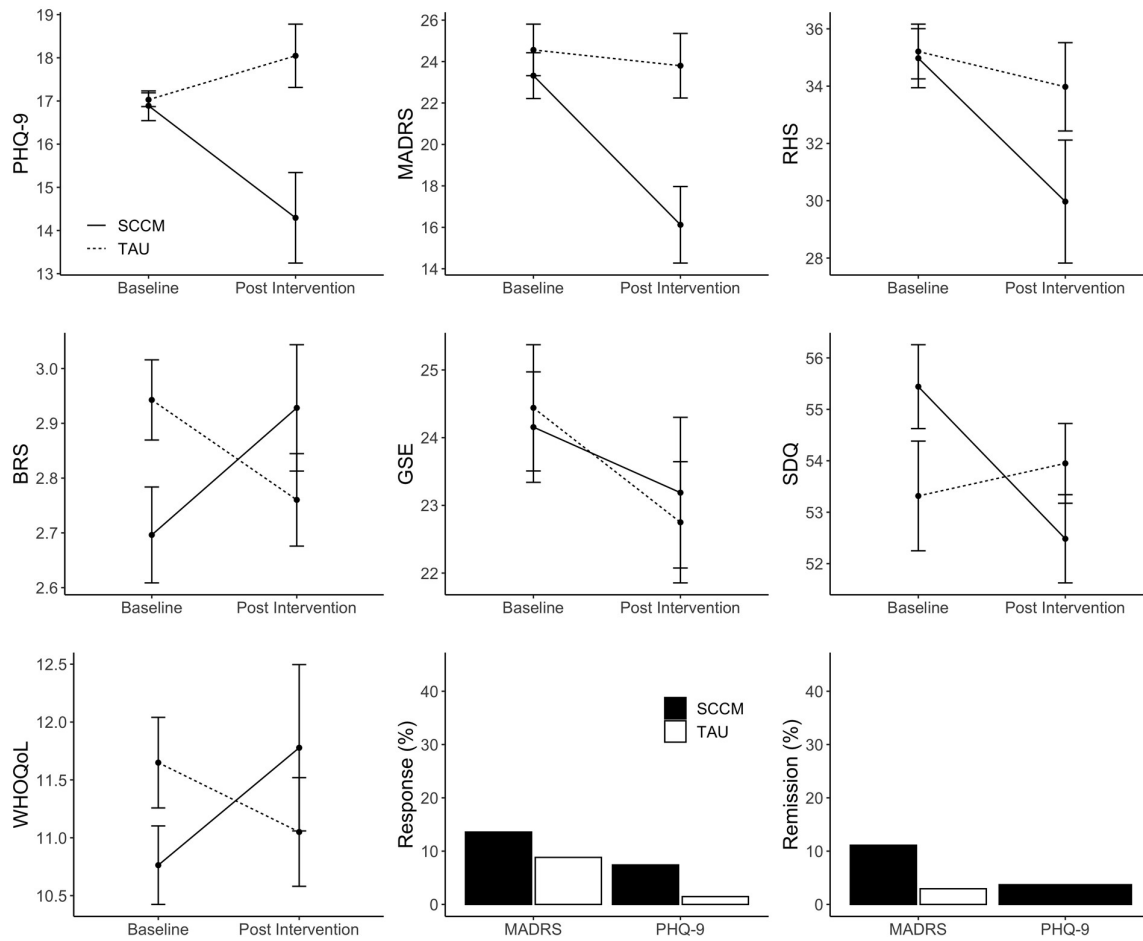
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334

335 **Figure 2.** Primary and secondary outcome variables as a function of time and group within the
 336 ITT sample.
 337



338 *Note.* TAU = treatment-as-usual; SCCM = Empowerment group intervention within the Stepped and Collaborative
 339 Care Model; PHQ-9 = Patient Health Questionnaire-9; MADRS = Montgomery Åsberg Depression Rating Scale;
 340 RHS = Refugee Health Screener-15; BRS = Brief Resilience Scale; GSE = General Self-Efficacy Scale; SDQ =
 341 Strength and Difficulties Questionnaire; WHOQoL = World Health Organization Quality of Life questionnaire,
 342 brief version, item 1 + 2. Error bars represent ± 1 standard error.
 343
 344

345 **Discussion**

346 We examined the effectiveness of a cultural-sensitive group intervention for refugees and
347 asylum seekers with moderate depressive symptoms within the multicenter MEHIRA project
348 that compares an SCCM approach vs TAU [12]. Our findings point towards the effectiveness
349 of the intervention compared to treatment-as-usual. Participating in the group intervention
350 resulted in a greater decrease in self-assessed and clinician-rated depressive symptomatology
351 compared to TAU. The within-intervention effect size for both scales was moderate. Group
352 participation resulted in significantly higher response and remission rates compared to the
353 control group. The results are comparable to mean effect sizes of a peer-provided problem
354 management group intervention (PM+) for refugees with depressive and stress-related
355 symptoms [28]. The preventive self-help group intervention SH+ developed by the WHO found
356 small positive effects on the development of current mental disorders two weeks, but not six
357 months, after the end of the intervention [29]. A meta-analysis evaluating the effectiveness of
358 different interventions, including NET, EMDR and culturally-adapted CBT found medium to
359 high effect sizes for PTSD symptoms and high effect sizes for depressive symptoms [30].
360 Compared to our results, a cognitive-behavioral therapy plus problem solving (CA-CBT+)
361 intervention for refugees greatly improved participants' overall psychological distress. The
362 results raise the question of whether refugee populations in particular benefit from problem-
363 solving skills training [31].

364 In our study, group participants reported fewer difficulties in interpersonal relationships (SDQ)
365 after the end of therapy, suggesting group participation to promote prosocial behavior and social
366 skills. It may also be the group context itself that is particularly well suited for refugee patients,
367 the majority of which have had experiences with dictatorial systems, betrayal or torture.
368 Throughout the course of the intervention, trusting relationships a sense of belonging and strong
369 cohesion in the groups often developed. Participating in the Empowerment group therapy
370 increased patients' resilience compared to the control group. Group participation had no effect

371 on the participant's quality of life. A possible explanation could be that the WHOQoL-BREF
372 assesses areas of life that remain unaffected by the intervention but have a major impact on the
373 life quality of people who have fled their homes (e.g. monetary needs, living conditions).

374

375 ***Strengths and limitations***

376 A key strength of our study is to include a large sample of refugees from four study sites within
377 a randomized controlled design. Another strength is the culturally sensitive treatment approach,
378 that specifically takes needs and values of refugee populations into account.

379 We would like to address the following limitations of our study. First, data at time of post-
380 intervention was only available for 53% of the participants. Refugee populations often represent
381 a very mobile group, leading to high dropout rates in clinical studies [32] and could therefore
382 benefit from interventions that are shorter or flexible in duration. The Empowerment
383 intervention with its 16 sessions could possibly be too long in its duration for the constantly
384 changing circumstances of refugees, which favor drop-out rates. Second, our group intervention
385 trial was conducted at university hospitals, a setting that is not representative for primary care
386 in mental health. In the future, however, the intervention would be scalable for various other
387 settings, e.g. delivered by trained health care workers in low-and-middle-income countries
388 (LAMICS) or provided as part of video-based services for outreach to rural areas. Such an
389 Empowerment video-based group intervention has already been developed by our research
390 team as part of a pilot study.

391

392 ***Conclusion***

393 Our study demonstrated the effectiveness of the Empowerment group intervention (i.e. level
394 three of the MEHIRA SCCM) as a new treatment approach for refugees and asylum-seekers
395 with depressive symptoms. The next step is ensuring that the intervention reaches populations
396 in LAMICS, where resources are limited and the demand for mental health interventions is

397 high. This implies networking with social and community health services in the respective
398 populations and may require an adaptation of the intervention's duration, to address the often
399 highly mobile living circumstances of refugees. A short version of the Empowerment
400 intervention has lately been developed for Ukraine refugees, an adaptation that could also be
401 helpful for refugee populations in LAMICS.

402 **Statements**

403 **Acknowledgements**

404 This work is part of the dissertation project of Dr. Maren Wiechers. The dissertation is titled
405 “Empowerment for refugees with affective disorders: Development of a culturally sensitive
406 group intervention within the multicenter MEHIRA trial”. The dissertation can be accessed
407 online via the following link: https://edoc.ub.uni-muenchen.de/29898/7/Wiechers_Maren.pdf.

408

409 **Conflicts of Interest**

410 Dr. Banaschewski served in a consultancy role for Lundbeck, Medice, Neurim
411 Pharmaceuticals, Oberberg GmbH, Takeda, and Infectopharm. He received conference support
412 or speaker's fee from Lilly, Medice, and Takeda. He received royalties from Hogrefe,
413 Kohlhammer, CIP Medien, Oxford University Press; the present work is unrelated to these
414 relationships. Alkomiet Hasan has been invited to scientific meetings by Lundbeck, Janssen,
415 and Pfizer, and he received paid speakerships from Desitin, Janssen, Otsuka, and Lundbeck.
416 He was a member of Roche, Otsuka, Lundbeck, and Janssen advisory boards. Paul Plener was
417 involved in clinical trials of Lundbeck and Servier. He received a speaker's honorarium from
418 Shire and Infectopharm. Frank Padberg is a member of the European Scientific Advisory Board
419 of Brainsway Inc., Jerusalem, Israel, and has received speaker's honoraria from Mag&More
420 GmbH and the neuroCare Group. His lab has received support with equipment from neuroConn
421 GmbH, Ilmenau, Germany, and Mag&More GmbH and Brainsway Inc., Jerusalem, Israel. The
422 other authors declare no competing interests.

423

424 **Ethics Statement**

425 The authors declare that procedures contributing to this work comply with the ethical standards
426 of the relevant national and institutional committees on human experimentation, the Good
427 Clinical Practice guidelines and with the Helsinki Declaration of 1975, as revised in 2008. All

428 procedures involving patients were approved by the ethics committee of the Ludwig-
429 Maximilians-University Munich (approval number 17-883) and the ethics boards of all other
430 study sites.

431

432 **Funding**

433 This project is funded by the Innovationsfond and German Ministry of Health [grant number
434 01VSF16061].

435

436 **Author Contributions**

437 Maren Wiechers: project management, project execution, investigation, development of
438 interventions, data collection, data analysis, data interpretation, writing, review and editin

439 Michael Strupf: project management, project execution, investigation, development of
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441 Malek Bajbouj: design, funding acquisition, investigation, development of intervention, project
442 supervision, original paper draft outline, review and editing throughout

443 Kerem Böge: project management, project execution, investigation, development of
444 interventions, data collection, data analysis, data interpretation, writing, review and editing

445 Carine Karnouk: literature review, project execution, data collection, development of
446 interventions, writing, review and editing

447 Stephan Goerigk: software, formal analysis, methodology, data interpretation, review and
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449 Inge Kamp-Becker: design, funding acquisition, investigation, project supervision

450 Tobias Banaschewski: design, funding acquisition, investigation, project supervision, review
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479

480 **Data Availability**

481 The trial data can be requested deidentified and anonymized by researchers for future usage in
482 independent scientific research projects. These requests should be addressed to the
483 corresponding author to negotiate a data-sharing agreement with the Ludwig-Maximilians-
484 University Munich.

485

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