Mindfulness-Based Trauma Recovery for Refugees (MBTR-R): Randomized Waitlist-Control Evidence of Efficacy and Safety

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Abstract

Background. Worldwide, refugees and asylum seekers suffer at high rates from trauma- and stress-related mental health problems. We thus developed Mindfulness-Based Trauma Recovery for Refugees (MBTR-R) – a 9-week, mindfulness- and compassion-based, trauma-sensitive and socio-culturally adapted, group intervention for refugees and asylum seekers. **Aims.** We assessed whether MBTR-R is an efficacious and safe mental health intervention for traumatized asylum seekers. **Method.** We conducted a randomized waitlist-control trial of MBTR-R among a community sample of 158 Eritrean asylum seekers (46.2% female, 53.8% male) with severe trauma history and ongoing post-migration stress. **Results.** Eighty-three of 98 participants randomized to MBTR-R and 48 of 60 randomized to waitlist-control condition were prospectively retained and completed pre- and post-intervention assessment. Relative to waitlist-controls, MBTR-R intervention completers (> 4 sessions attended) demonstrated significantly reduced rates and symptom severity of PTSD, depression, anxiety and multi-morbidity – at post-intervention and at 5-week follow-up; as well as improved well-being at post-intervention, but not follow-up. Intent-To-Treat sample effects were identical, though smaller in magnitude. Second, intervention effects were not dependent on key demographic factors, post-migration living difficulties or trauma history severity. Finally, no MBTR-R participant demonstrated lasting clinically significant deterioration in any of the monitored symptoms or well-being. Importantly, MBTR-R appears to be efficacious and safe for highly traumatized and chronically stressed asylum seekers in an urban post-displacement setting. High attendance and low study attrition suggest that MBTR-R may be a feasible and acceptable mental health intervention among asylum seekers. Due to its brief intervention format and group-based delivery, MBTR-R may be readily implemented and well-suited for scaling. Considering fast-growing human rights and mental health crisis of forced

displacement, and extensive barriers to mental health intervention delivery among refugees and asylum seekers, observed MBTR-R efficacy and safety are promising.

Keywords: Adverse Effect, Asylum Seekers, Anxiety, Compassion, Depression, Forcibly Displaced People, Meditation, Mindfulness, PTSD, Post-Migration Stress, Randomized Controlled Trial, Refugees, Stress, Trauma

Today, an unprecedented 71 million people, among them refugees and asylum seekers, are forcibly displaced from their homes by conflict, persecution, and other forms of human brutality [1]. Following traumatic events and chronic stressors post-displacement (e.g., insecurity of residential status, rupture of family structure and roles, discrimination), refugees and asylum seekers suffer at high rates from various trauma- and stress-related mental health problems including posttraumatic stress, depression, and anxiety [2-5]. The personal suffering of the forcibly displaced, fracturing of families and communities, and inter-generational transmission of trauma will challenge re-settlement communities, aid organizations, policy makers, and practitioners around the world for many years to come [2, 6-8].

This crisis has led to global calls for the development and delivery of mental health interventions that are effective, safe, generalize to diverse individuals and populations (e.g., gender, education), yet are also brief, cost-effective, disseminable, transportable, readily implemented, and scalable [9-13]. Developing and implementing intervention programs that meet these demanding criteria is a, if not the, seminal challenge facing the field of global mental health in the coming decade [8, 14-16]

Field-wide efforts are under way. First, intensive, typically individual, trauma-focused exposure-based therapies, such as exposure-base therapies like Narrative Exposure Therapy (NET), have demonstrated moderate efficacy and effectiveness among diverse refugee populations [16-20]. Notably, intensive exposure-based therapy interventions may not be readily implemented in, nor therapeutically indicated for, increasingly uncertain and stressful post-displacement realities. Post-displacement settings are increasingly characterized by insecure visa or unrecognized asylum status, economic instability, ongoing threat, lack of physical safety and the large majority (~70%) of refugees and asylum seekers in the current crisis reside in urban post-

displacement settings [21-24]. Second, emerging mental health interventions for refugees and asylum seekers entail low-intensity cognitive-behavior therapy, focused on coping with here-and-now post-migration stressors, that may be delivered by paraprofessionals and via mobile e-health platforms. For example, Problem Management Plus (PM+) and e-health Self Help Plus (SH+) have demonstrated promising feasibility, fidelity, and adherence [25, 26]. Preliminary evidence of SH+ effectiveness has been recently reported although documented therapeutic effect sizes are modest [27]. Third, other commonly implemented mental health intervention approaches include individual psychotherapy, such as cognitive-behavioral therapy and the common elements treatment approach (CETA), have demonstrated evidence of modest efficacy [28-30]. Likewise, psychosocial interventions typically targeting community-level resilience and -support are commonly implemented although only a small number of studies have tested their therapeutic efficacy [2, 31-33].

These early therapeutic models represent seminal building blocks of a public refugee mental health intervention portfolio [14, 15]. Clinical science and public health scholars as well as policy makers and global health service organizations have thus made urgent calls for the development and study of novel mental health interventions for refugees. Specifically, stake-holders are calling for interventions tailored to the complex, uncertain and stressful contexts and post-migration realities of forcibly displaced persons, and in particular, asylum seekers [8, 14, 19]. These populations may be least likely to access or benefit from intensive, individual or trauma-focused exposure therapies, yet may be particularly burdened by a range of mental health problems linked to chronic ongoing post-migration stressors [2, 14, 19]. It may therefore be useful to draw on therapeutic approaches with a strong clinical evidence-base relevant to the trauma- and stress-related mental health needs of refugees, that are also pragmatically well-suited to the

implementation challenges facing refugee mental health intervention efforts, but have yet to be adapted for or tested among refugees and asylum seekers [8]. Work over the past number of years led to us speculate that mindfulness-based interventions (MBIs) may represent one such promising approach [15, 34-37].

MBIs are a family of mental training interventions, the most common of which are Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn [38], Kabat-Zinn [39]) and Mindfulness-Based Cognitive Therapy (MBCT; Segal, Williams [40]). MBIs entail practice in formal mindfulness meditation as well as informal practice of mindfulness in daily living to cultivate present moment attention and awareness characterized by a number of attitudinal qualities (e.g., acceptance, non-judgment, self-compassion) [41]. MBIs have varied applications and implementation in various sectors, contexts, and populations [35, 41, 42].

Central features of MBIs may be well-suited to some of the implementation challenges facing refugee mental health intervention efforts. First, there is a growing body of evidence documenting robust stress-buffering effects of MBIs [43-46] including increased subjective well-being, reduced severity, persistence and relapse of common mental health problems, and enhanced coping [42, 47-50], and protective effects on physiological markers of chronic stress and trauma including hyperarousal, numbing and psychosomatic symptoms [51-53]. Furthermore, emerging evidence has linked MBIs to trauma recovery in Western Educated Industrialized Rich Democratic (WEIRD) populations and contexts [49, 54-61].

Second, the training targets and techniques, format, modes of MBI delivery, and the potential cost-effective reach and scalability of MBIs are well-suited to address common barriers to implementation of mental health interventions for asylum seekers and refugee populations [22, 62-65]. Indeed, mainstream or secularized MBIs target and train psychological processes that, to

varying degrees, transcend cultures, such as attention, neurocognitive executive functions, awareness, and compassion [66, 67]. Moreover, relative to more linguistically-mediated psychotherapeutic interventions, MBIs require relatively less verbal interactions between trainers and participants; MBIs are relatively brief and can be delivered by trained para-professionals under supervision, regardless of geographic distance/isolation [41, 68, 69]; and may be delivered via a number of formats including groups, self-help audio recordings, text, and web- or mobile-supported platforms [70-72]. MBIs may be readily scaled-up even in under-resourced health systems, as they are brief, group-based, low cost, and beneficial to participants with a range of stress-related distress and personal goals [12, 13, 15]. Likewise, MBIs, and specifically meditation practices, may be adapted to be trauma-sensitive for vulnerable participants with a traumatic stress history or posttraumatic stress symptoms [51]. Finally, contemporary secularized MBIs have been successfully adapted to a variety of populations and contexts (e.g., schools, organizations, clinics) in ways that are socio-culturally sensitive to diverse backgrounds, belief systems and languages [73, 74].

To-date, the potential for MBIs to promote well-being, trauma recovery, and coping with post-migration stressors among refugees and asylum seekers has been preliminary – explored via qualitative studies and via non-randomized, uncontrolled intervention studies of small samples [74-77]. Yet, to the best of our knowledge: (1) no MBI has been specifically designed to care for stress- and trauma-related mental health needs of refugees and asylum seekers; and (2) we do not yet have any experimental evidence of the efficacy or safety of a MBI among refugees or asylum seekers. In light of the global public health urgency, significance and expected longevity of the current humanitarian and mental health crisis, as well as challenging barriers to effective mental health intervention implementation, such research is timely and much needed.

Present Study & Aims

The present study reports efficacy and safety outcomes of a randomized waitlist-control study of a novel specialized MBI – Mindfulness-Based Trauma Recovery for Refugees (MBTR-R) – among N=158 (55.7% women) Eritrean asylum seekers residing in an urban post-migration setting in the Middle East (Israel). MBTR-R is a 9-session mindfulness-based group intervention that is trauma-sensitive and socio-culturally adapted for diverse populations of refugees and asylum seekers. The premise of MBTR-R is to train refugees and asylum seekers to experience moments of (inner) refuge and safety from which recovery may begin.

Efficacy

First, we tested whether, relative to a waitlist-control, MBTR-R led to significantly reduced rates of stress- and trauma-related mental health problems including post-traumatic stress, depression, anxiety, and wellbeing – at 1-week and 5-weeks post-intervention. Due to the residential insecurity of asylum seekers in this population [78], it was critical to limit follow-up (5-weeks post-intervention) to ensure prospective retention [79]. Second, we tested whether expected therapeutic effects of MBTR-R were moderated by key demographics of the studied population or pre-existing vulnerability factors at pre-intervention. The potential impact of MBTR-R depends on the degree to which expected therapeutic benefits of MBTR-R generalize to diverse forcibly displaced people from various backgrounds and are not circumscribed to narrow, specific sub-groups (e.g., more educated, less vulnerable) [8, 14].

Safety

Third, we tested whether, relative to the waitlist-control condition, MBTR-R was safe and thus not associated with participant-level clinically significant deterioration in any of the monitored primary mental health outcomes at post-intervention or at follow-up [80]. In the event

of adverse responding, we planned to test candidate contraindications for MBTR-R including key demographic factors or pre-existing vulnerability factors at pre-intervention that may predict participant-level deterioration or adverse responding to the intervention [81-83].

Method

Study Design & Participants

This study was a single-site randomized control trial examining MBTR-R versus a waitlist-control in a community sample of Eritrean asylum seekers residing in the Middle East (Israel). The study received human subjects' research ethics approval by a University of Haifa Institutional Review Board committee. Participants were recruited via public flyers, community recruitment and via local NGOs and municipal organizations working with refugees. Over the course of one year, male and female Eritrean asylum seekers were recruited in three cohorts, and randomized to either MBTR-R or waitlist-control. Exclusion criteria were (a) active suicidality, (b) current psychotic symptoms, (c) current mental health treatment (psychiatrist, psychotherapy, psycho-social support group). Randomization was conducted via random number generation in blocks of 2 conditions with a ratio of three MBTR-R participants to two waitlist-control participants. This was done based on a power analysis to, first, ensure sufficient number of participants to detect medium size between-group effects; and, second, to ensure sufficient power to detect moderate effects in planned within-group analyses among the MBTR-R group [84, 85].

The selected population of Eritrean asylum seekers are representative of a large and fast-growing forcibly displaced population in the current global refugee crisis [24]. First, members of this community were exposed to a large number of severely traumatizing events including serious violations of human rights, arbitrary detention, torture, sexual and gender-based violence, religious

and political persecution [86, 87]. Second, members of this community have not received refugee or formal residential status or protections such that their future remains unpredictable and uncertain due to threat of detention or deportation [88, 89]. Third, members of this community are struggling with chronic and often severe post-migratory life-stressors implicated in stress-related mental health problems that interfere with trauma recovery yet only a tiny fraction receive any mental health care let alone evidence-based care [90-93]. See Supplementary Materials (SM) for more details.

Procedure

Following assessment for eligibility to participate in the study through a phone screening, consent and randomization to condition (see Consort Diagram), participants completed the pre-intervention assessment including self-report questionnaires and behavioral/cognitive-experimental tasks. All self-report measures of vulnerability and mental health are included in the present report. Only one additional measure related to sensitivity to traumatic experiences and posttraumatic stress symptoms was not included in analyses as it is part of a larger psychometric study involved in the methodological development of a new measure.

MBTR-R participants also completed brief weekly assessments of targeted change processes before and after each intervention session. Following the 9-week intervention or identical waitlist-control period, participants completed assessments at one-week post-intervention. MBTR-R participants also completed a follow-up assessment five weeks after the post-intervention assessment. Waitlist-control participants only completed the 1-week post-intervention assessment – to ensure that we did not unnecessarily withhold treatment for asylum seekers in the waitlist-control condition [94].

MBTR-R Intervention Condition

See Table 1 in SM for a session-by-session overview of MBTR-R. MBTR-R is a mindfulness-based group (10-20 participants) intervention consisting of nine 2.5-hour weekly sessions. MBTR-R format and structure parallel common MBIs [41] including MBSR and MBCT [39, 95]. MBTR-R includes systematic training in formal and informal mindfulness practices (e.g., body scan, sitting meditation, mindful movement, 3-minute breathing space) although with key trauma-sensitive adaptations [51]; experiential inquiry-based discussions of all in-session practices [96]; and home practice via web-based audio recordings and handouts [41]. Critically, trauma-sensitive adaptations to mindfulness meditation practices were included to reduce risk of adverse responding and to optimize salutary benefits from MBTR-R [51]. First, a "safe place" practice was practiced in which participants trained bringing attention to objects of awareness that feel neutral, safe, or calm when feeling overwhelmed or numb during mindfulness meditation [51]. Second, psychoeducation about posttraumatic stress, stress reactivity, and depression is integrated in the intervention to normalize and de-stigmatize, trauma- and stress-related mental health problems [97, 98]. Third, loving-kindness and self-compassion practices are taught as ways of coping with fear, self-judgement, guilt, shame, and hostility, common to trauma- and stress-related mental health problems [99].

To provide optimal conditions for participants to learn mindfulness and key intervention principles and to benefit from the group format, delivery of MBTR-R was socio-culturally adapted. First, a cultural mediator from the refugee community that was personally familiar with mindfulness practice worked alongside the mindfulness instructor (See SM for instructor and cultural mediator qualifications and training). Cultural mediators conducted real-time linguistic translation (Tigrinya) of guided practices and group discussions [100-102]. Second, socio-culturally specific metaphors and idioms were integrated in the intervention protocol to

communicate key ideas [14, 102, 103]. Third, MBTR-R groups were conducted for men and women separately, and led, respectively, by male and female instructors and cultural mediators. Fourth, MBTR-R was delivered in a geographically accessible, familiar and "safe space" in the local asylum seeker community [101]. Fifth, group meetings included a shared mid-session meal consisting of traditional Eritrean food, during which mindfulness was also practiced to encourage adoption of mindfulness into daily living [97]. Finally, to reduce obstacles for session attendance, female participants were offered free child care [97].

Waitlist-control Condition

Following the 9-week waitlist period and 1-week post-intervention assessment, participants randomized to waitlist-control were offered an equivalent group intervention (i.e., 22.5 total hours, group instructor and cultural mediator, psychoeducation and low-intensity cognitive behavior therapy skill training, relaxation techniques). We chose this waitlist-control intervention primarily due to ethical considerations [94]. Critically, as this is the first trial of MBTR-R, we did not yet know safety or efficacy outcomes of MBTR-R, and were committed to provide participants seeking assistance randomized to wait-list control mental health care that would not involve exposing them to any unnecessary risk [94]. When participants were randomized, MBTR-R and the waitlist-control interventions were described nearly identically – in terms of purpose, total number of hours, compensation, etc. – so as to ensure similar expectancy effects and motivation between conditions.

Measures

All measures were translated and back-translated, and psychometrically evaluated and validated for this study or in earlier research – either in our or other research groups' studies of these specific African refugee populations [36, 37, 93, 104-106]. All translated measures were

pilot-tested and revised, in an iterative process, which included cognitive interviewing with translators and Eritrean asylum seekers to ensure linguistic as well as socio-cultural meaning [107, 108].

The *Harvard Trauma Questionnaire* (HTQ; [109] was used to measure traumatic stress exposure as well as PTSD symptoms. HTQ was developed to be used and adapted across socio-cultural groups and languages, and thus is a well-established instrument to measure traumatic stress and PTSD symptoms in diverse forcibly displaced populations, including E. African populations specifically [36, 110-112]. HTQ mean cut-off score ≥ 2 is commonly used to identify categorical (diagnostic) symptom status of PTSD [113-115]. The HTQ has three subscales, measuring re-experiencing, avoidance and arousal. In addition, a subscale of items measuring idioms of post-traumatic distress specific to East African refugees was included (e.g. "feeling isolated because of loss of social role") [105].

The *Brief Patient Health Questionnaire* (PHQ-9; [116] was used to measure symptom levels of depression. PHQ cut-off score ≥10 is commonly used to identify categorical (diagnostic) symptom status of depression [117]. The PHQ-9 is a commonly used measure of depression in diverse populations and refugee populations [118].

The *Beck Anxiety Inventory* (BAI; [119, 120]) was used to measure levels of anxiety symptoms. BAI has been commonly used as a self-report tool to measure anxiety, also among refugee populations [121, 122]. BAI total cut-off score ≥ 16 is commonly used to identify categorical (diagnostic) symptom status of anxiety disorder [123, 124]. For an initial sub-sample of 49 participants, we used an adapted version of the Overall Anxiety Impairment Scale (OASIS) and a sum score > 8 was used as a cut-off to diagnose anxiety [120]. OASIS was discontinued because of low comprehensibility of item content among participants.

Using the categorical (diagnostic) symptom status for PTSD, depression, and anxiety, we computed a *comorbidity index* (0 = no elevated psychiatric symptomatology, 1 = uni-morbid or diagnostic symptom levels in one condition, 2 = co-morbid or diagnostic symptom levels in two conditions, 3 = multi-morbid or diagnostic symptom levels in all three conditions).

The *Brief Inventory of Thriving* (BIT; [125]) was used to measure subjective well-being. The *BIT* has been commonly used as a self-report tool to measure thriving and wellbeing.

Finally, the *Post-Migration Living Difficulties Scale* [126] was used to measure current post-migration stressors. The *PMLDS* has been widely applied to measure post-migration stressors across a variety of refugee and migrant populations [92, 127].

Statistical Analysis

Randomization

To test randomization, we applied t-tests and logistic regression to compare MBTR-R to waitlist-control for all demographic variables as well as mental health measures at pre-intervention.

Aim 1. MBTR-R Efficacy

We tested MBTR-R efficacy relative to waitlist-control for 1-week and 5-weeks post-intervention outcomes using ANCOVAs for continuous symptom severity scores and logistic regression for categorical (diagnostic) symptom status. We controlled for pre-intervention levels of each outcome in each respective ANCOVA and logistic regression. To test the therapeutic efficacy of MBTR-R among participants who received an adequate dose of the intervention, and so may be expected to benefit from the intervention, primary analyses were conducted among intervention completers – participants who attended more than half (> 4) of the MBTR-R sessions [128, 129]. This definition of completion is aligned with MBCT trials [128, 130] as well as

reasonable expectations due to real-world constraints on regular attendance of refugees and asylum seekers due to post-migration environmental instability and stressors [131, 132]. Analyses were thus conducted among intervention completers with elevated symptoms at baseline pre-intervention as well as among all intervention completers regardless of levels of baseline symptomatology. Likewise, we ran identical parallel analyses among the more inclusive Intent-To-Treat (ITT) sample (see Consort Diagram in Figure 1).

Aim 2. Generalizability of MBTR-R Efficacy: Moderated Therapeutic Effects of MBTR-R

To test, whether expected therapeutic effects of MBTR-R (Aim 1) were dependent on key demographics of the studied population (gender, age, level of education), trauma stress history severity, or current post-migration living difficulties, we conducted a test of moderation per outcome (Aim 1) using PROCESS [133] in SPSS.

Aim 3. Safety & Adverse Effects of MBTR-R

To identify individual participants who experienced clinically significant deterioration over the course of the intervention, we calculated a Reliable Change Index (RCI) [80]. The RCI reflects change from baseline pre-intervention levels to 1-week and to 5-weeks post-intervention, for each mental health outcome, per participant, by group. RCI is an established and frequently used method to determine clinically significant, participant-level change in medical and mental health research [134-138]. To maximize the sensitivity of this analysis and likelihood of identifying individual participant(s) who experienced deterioration, we calculated RCI among all participants (N=158).

Results

Sample & context: Demographics, trauma history, post-migration stress, & mental health symptomatology

See Consort Diagram for details on screening and randomization (Figure 1). Two-hundred adult Eritrean asylum seekers in Israel were screened for participation, 158 were randomized to either MBTR-R intervention or waitlist-control and completed the pre-intervention assessment. We randomized 98 participants (47.9% men) to MBTR-R Intervention and 60 (63.3% men) to waitlist-control (see Consort Diagram for more details).

Participants' were 20-48 years old (*M(SD)* = 31.8(5.21) years), 53.8% were men, and education levels varied between 1-6 years (23.5% men, 32.9% women), 7-12 years (65.9% men, 57.5% women), 13-16 years (9.4% men, 8.2% women) and > 16 years (1.2% of men, 1.4% of women). Participants reported severe trauma history including experiencing torture, rape or sexual abuse and the murder of a family member or friend (M(SD) = 6.16 (4.28) number of traumatic event types). Likewise, participants reported high rates of post-migration living difficulties including fear of deportation to their home country, not having enough money for food or rent, and worries about being homeless (M(SD) = 5.44 (2.58) number of reported post-migration living difficulties). See Table 1 for rates of post-migration living difficulties and trauma exposure history at pre-intervention.

See Table 2 for continuous mental health outcomes by group and Table 3 for point-prevalence rates of mental health outcomes by group. Finally, 66.7 % of participants demonstrated diagnostically elevated symptom levels of either PTSD, depression, or anxiety disorder at baseline. Among all participants, 16% demonstrated unimorbidity of PTSD, depression or anxiety, 19.2% comorbidity, and 31.4% multi-morbid elevation of PTSD, depression and anxiety symptomatology.

Intervention Attendance & Study Attrition

See Figure 1 Consort Diagram for details regarding study attrition. Eighty-three of 98 (83% men, 86.3% women) participants randomized to MBTR-R and 48 of 60 (84.2% men, 72.7% women) participants randomized to waitlist-control condition were prospectively retained in the study and completed pre- as well as post-intervention assessment. Among the ITT sample, 67.5% (63.4% men, 70.3% women) attended five or more sessions ($M(SD)_{\text{Sessions Attended}}$ = 5.83(2.84)) and were classified as intervention completers. Participants classified as intervention completers attended $M(SD)$ = 7.63(1.21) sessions and those classified as non-completers attended only $M(SD)$ = 2.23 (1.31) sessions. Critically, neither gender, age, level of education, post-migration living difficulties, trauma history, PTSD, depression, anxiety nor well-being at pre-intervention predicted number of sessions attended or likelihood of intervention completion (see Table 2 in SM).

Test of Randomization at Pre-Intervention

Consistent with successful randomization, there were no differences between participants randomized to MBTR-R or wait-list control with respect to post-migration living difficulties, trauma exposure history, anxiety, or well-being. However, there were significant, albeit small, differences in levels of PTSD severity ($t(156) = 2.84$, $p = .005$) and point-prevalence of PTSD ($\chi2(1) = 2.72$, $p < .01$) as well as in levels of depression severity ($t(155) = -2.65$, $p = .009$) and point-prevalence of depression ($\chi2(1) = 7.55$, $p = .006$) between conditions wherein symptomatology was slightly higher in waitlist-control than in MBTR-R. Consequently, when coding PTSD symptom cluster using DSM-5 criteria (i.e., 3-cluster vs. 4-cluster), findings were nearly identical to those reported for DSM-IV criteria in all analyses [139, 140].

Aim 1: MBTR-R Efficacy

Continuous Symptom Severity Outcomes

See Table 2. Relative to waitlist-controls, participants randomized to MBTR-R demonstrated significantly lower levels of (1) total PTSD, re-experiencing, and hyper-arousal symptoms, as well posttraumatic stress measured via cultural idioms, (2) depression symptoms, (3) anxiety symptoms as well as (4) co- and multi-morbidity at post-intervention and 5-week follow-up. In addition, MBTR-R demonstrated marginally significant higher levels of (5) subjective well-being at post-intervention but not at follow-up. Effect sizes were moderate to large (η^2 = .05 to .29). Inconsistent with prediction, MBTR-R was not associated with lower levels of PTSD avoidance symptoms at post-intervention or follow-up. In the parallel ITT sample, all observed therapeutic effects of MBTR-R remained significant, although with smaller magnitude (see Table 3 in SM). Second, among all treatment completers, including participants without elevated symptoms of psychopathology, the same curative effects of MBTR-R on mental health outcomes were observed, with the exception of depression and well-being. Significant improvement in depression symptoms were observed at 5-weeks follow-up but not immediately following the intervention (see Table 4 in SM). In the parallel ITT sample, the same effects were observed for PTSD and anxiety outcomes but not for depression symptoms or subjective well-being at post-intervention (see Table 3 in SM). Finally, when re-coding PTSD symptom cluster using DSM-5 criteria (i.e., 3-cluster vs. 4-cluster), findings were nearly identical to those reported for DSM-IV criteria in all analyses [139, 140].

Diagnostic-Level of Symptoms: Categorical Status

See Table 3. Whereas 90.9% of the waitlist-control who demonstrated categorical (diagnostic) symptom status of PTSD at pre-intervention still presented PTSD at post-intervention, a significantly smaller 48.3% of MBTR-R participants still did so at post-intervention and 62% at follow-up. Likewise, whereas 88.5% of waitlist-controls with categorical (diagnostic) symptom

status of depression at pre-pre-intervention still presented with depression at post-intervention, a significantly smaller 58.8% of MBTR-R participants did so at 5-weeks follow-up but a smaller, though non-significantly lower, 70.6% still presented with depression at 1-week post-intervention. Finally, whereas 90% of waitlist-controls who demonstrated categorical (diagnostic) symptom status of anxiety at pre-intervention still presented with anxiety at post-intervention, a significantly smaller, albeit still elevated, 66.7% of MBTR-R participants did so at post-intervention and a non-significantly lower 78.3% at follow-up.

Aim 2: Generalizability of MBTR-R Efficacy: Moderation of Therapeutic Effects

See Table 5 in SM. None of the observed reported therapeutic effects of MBTR-R on tested mental health and wellbeing outcomes at post- intervention or 5-weeks follow-up (Aim 1) were moderated by age, gender, education, post-migration living difficulties or traumatic stress history.

Aim 3: Safety & Adverse Effects of MBTR-R

Among all participants for whom we have any post-intervention or follow-up data (N=131, 82.9% overall prospective study retention) (see Consort Diagram Figure 1), we found that only one participant randomized to MBTR-R demonstrated clinically significant deterioration in depression symptoms (>1.96 *SD*s change) at post-intervention; although, at 5-weeks follow-up, this participant's levels of depression symptoms returned to pre-intervention levels. For comparison, we found that two participants in the waitlist-control group demonstrated significant deterioration (anxiety symptoms) at post-intervention. Second, due to the very low base rate of adverse responding, planned analyses testing predictors of adverse outcomes could not be conducted – as no harm of MBTR-R was observed regardless of degree of pre-intervention demographics or level of vulnerability.

Discussion

We are in the midst of a global mental health- and human rights- crisis [8, 19, 24]. Today, tens of millions of forcibly displaced persons may be suffering from trauma- and stress-related mental health problems [5, 91]. Relative to the scale, scope and urgency of this still growing crisis [24], our collective capacity to care for theses survivors via evidence-based mental health interventions tailored to refugees and asylum seekers is strikingly limited [8, 14]. Accordingly, in the hopes of contributing to field-wide efforts to develop a portfolio of specialized intervention programs tailored to refugees and asylum seekers, we developed MBTR-R [14, 15]. MBTR-R is a 9-session trauma-sensitive and socio-culturally adapted mindfulness- and compassion-based group intervention for refugees and asylum seekers. We tested whether MBTR-R may be an efficacious and safe intervention for stress- and trauma-related mental health outcomes among a traumatized community sample of African asylum seekers residing in an urban post-displacement setting in the Middle East (Israel).

First, relative to wait-list control, MBTR-R led to significant improvements in stress- and trauma-related mental health outcomes including PTSD, depression, anxiety, multi-morbidity as well as elevations in subjective wellbeing. Curative effects were observed for continuous symptom severity as well as categorical point-prevalence outcomes, at 1-week and again at 5-weeks post-intervention, respectively. The largest effects were observed for PTSD and posttraumatic re-experiencing and hyperarousal symptoms. These effects were observed when quantifying posttraumatic stress via western psychiatric nosological (DSM) as well when operationalizing posttraumatic stress via socio-culturally-specific idioms [105, 140]. Notably, effects for all studied outcomes were robust enough among treatment completers that they remained significant in the parallel ITT sample analyses. In light of the prevalence and severity of observed stress- and

trauma-related mental health problems in this community-based sample of asylum seekers, their severe trauma history, and the ongoing extensive post-migration living difficulties they face, as well as the prospective stability of these symptoms observed among the wait-list control condition, the observed curative effects are especially noteworthy.

Second, observed therapeutic effects were not specific to any sub-group of the studied population of asylum seekers. The intervention was similarly therapeutic among participants across key demographics of the studied population, trauma history severity, post-migration living difficulties or severity of each respective mental health outcome at pre-intervention. These findings may be important in that they indicate that the curative and salutary effects of MBTR-R are not likely limited to a small, circumscribed sub-group of refugees or asylum seekers, and critically, as effective among the most vulnerable participants. In light of the huge spectrum of populations and backgrounds who have been forcibly displaced in recent years [24] and the potential public health importance of a sufficiently universal framework for mental health care that may be locally and socio-culturally adapted [15], these are promising findings.

Third, we found that, MBTR-R appears to be safe, for even the most vulnerable asylum seekers. Indeed, MBTR-R was not associated with elevated participant-level rates of clinically significant deterioration (RCI-based classification) in any of the monitored mental health outcomes. This is critical, first, due to important questions about the capacity to safely adapt MBIs to participants with traumatic histories and trauma-related mental health problems [51, 83]. This is furthermore important due to the ethical imperative to ensure that vulnerable refugees and asylum seekers, whom have already experienced often multiple traumatic events and under significant and chronic post-migration stress, are not harmed by even the best of therapeutic intentions [94, 141].

Although only the first study of MBTR-R efficacy and safety, findings appear promising within the context of extant refuge global mental health research. First, MBTR-R was associated with clinically significant, medium to large therapeutic effects on prevalent and debilitating mental health disorders among refugees and asylum seekers [4, 91]. Second, despite the group-format of the intervention delivery – the size of the observed therapeutic effects was similar to or larger than reported effect sizes of intensive individualized psychotherapeutic interventions among refugees including exposure-based therapies (e.g., NET) [142], brief individual trans-diagnostic interventions such as PM+ [143, 144] and group-based mental health interventions for refugees such as SH+ [27]. Third, there was no demand on participants to continue mindfulness meditation or related practices, and no booster or follow-up mindfulness practice sessions were offered upon completion of MBTR-R. Yet, therapeutic effects of the intervention were largely maintained at 5-weeks follow-up. We speculate that enabling participants to continue practicing after the intervention, such as via a complementary mobile MBTR-R e-health platform could maintain or even improve therapeutic gains over time post-intervention. Finally, observed significant reductions in co- and multi-morbidity may be particularly noteworthy due to the prevalence, impairment and disability, and poor treatment outcomes associated with multi-morbidity [10, 29, 145-147].

The present findings not only support MBTR-R's efficacy and safety, but also provide initial evidence for the feasibility, acceptability implementability and scalability of MBTR-R. First, in line with its feasibility and acceptability, rates of MBTR-R session attendance were slightly lower than in other RCTs of MBIs in Western Educated Industrialized Rich Democratic (WEIRD), largely affluent populations and contexts [49, 128, 148], but similar to RCTs conducted among refugees including individual psychotherapy-based interventions [28, 29]. Furthermore,

MBTR-R feasibility and acceptability is bolstered by the potentially important finding that key demographics, trauma history severity, post-migration living difficulties, as well as mental health symptomatology at pre-intervention, did not predict number of interventions sessions attended or the likelihood to drop-out or complete the intervention. Based on similar attrition rates between conditions, we speculate that randomly-distributed factors such as instability of work and housing among asylum seekers may be more likely to determine capacity to engage with this weekly intervention format [79, 131]. Moreover, study attrition was not greater among the MBTR-R than among waitlist-controls. Accordingly, MBTR-R attendance and study attrition suggest that MBTR-R might be an acceptable and feasible intervention in a general population of asylum seekers with varying levels of vulnerability and demographic characteristics [149, 150]. In addition, the group-based intervention format and brief, flexible mode of delivery of MBTR-R may enable scaling up of its delivery. Thus, MBTR-R thus appears to be efficacious and safe, as well as feasible, readily implemented and scalable even in stressful, insecure and uncertain urban post-displacement settings. In light of the well-documented barriers to the implementation of effective mental health refugees and asylum seeker populations around the world [8, 15, 31], the observed findings are promising.

Notably, findings may also have implications for MBIs among other trauma-affected populations [43]. First, findings are in line with the growing body of research documenting reduced rates of trauma- and stress-related symptoms following participation in a MBI [51, 54, 55, 57, 58, 76, 151] as well as the well-documented stress-buffering effects of MBIs [43]. Second, similar to findings in studies of MBIs on depression and/or PTSD among WEIRD samples [128, 152, 153], MBTR-R appears to be efficacious for a wide range of asylum seekers including those with elevated depression symptoms at pre-intervention, participants with a history of trauma [128] and

co-occurring depression and PTSD. Third, despite early mixed findings with respect to effects of MBIs on anxiety outcomes [154-156], recent meta-analytic evidence indicates that MBIs outperform no-treatment control conditions and are equivalent to other active therapies for anxiety [157]. Notably, the small to moderate magnitude of the anxiolytic effects of MBTR-R are consistent with the latter meta-analytic findings.

We also observed secondary, albeit potentially important findings about the stable prospective course of symptomatology among controls across the 9-week wait-list period. Of public health importance, these data indicate that similar populations of asylum seekers may be unlikely to demonstrate spontaneous improvement in their symptoms over time [158, 159]. These prospective data thereby illustrate the urgency and importance to develop, test and deliver mental health interventions tailored for refugees and asylum seekers [14, 19].

The study is limited in a number of ways. First, there was no active intervention comparison. A waitlist-control design appeared most ethically justifiable, so as not to cause unnecessary harm by means of an unsubstantiated active control [94] or an active control intervention that is not directly comparable to MBTR-R [160, 161]. Future research may examine the effects of MBTR-R in contrast to other group-based mental health interventions with evidence of safety and efficacy for refugees. Second, we do not know with confidence that observed findings will generalize to other refugee populations (e.g. country of origin, post-displacement, socio-cultural background) or contexts (e.g., stable re-settlement communities, refugee camps). Notably, this sampling strategy was also a strength of the design. Eritrean asylum seekers constitute a large group of asylum seekers worldwide [162]. Their stressful, uncertain and insecure urban post-displacement setting represents a fast-growing context for forcibly displaced populations [24]. The socio-cultural and linguistically homogeneity of the sample protects against potential threats of

internal validity that emerge from ad-mixing of distinct refugee populations. Indeed, refugees or asylum seekers are a political status and not a socio-cultural group [163]. Though limited to this population of Eritrean refugees, findings are more likely to be reliable and replicable. Likewise, this permitted robust socio-cultural adaptation of MBTR-R to this population [15, 164, 165]. Third, although safety and efficacy were measured with well-established and socio-culturally adapted self-report measures, it remains to be tested whether we would have observed similar findings using other measurement modalities such as structured interviews or clinician ratings. We speculate that structured interviews could bias the validity of measurement [164, 166]. Due to stigma, we may have observed under-reporting of trauma history and symptomatology at pre-intervention [167, 168]; likewise, due to socio-cultural norms and experimental demand characteristics, over-reporting of desired curative effects at post-intervention [169, 170]. The interaction between measurement psychometrics and socio-cultural factors among diverse populations of refugees and asylum seekers is likely to represent an important focus for global mental health research in the coming years [113].

We hope this study will contribute to field-wide efforts to promote refugee mental health among forcibly displaced people. Reported findings of MBTR-R efficacy and safety are promising. Important next steps entail study of MBTR-R mechanisms of action [171], a second randomized experimental test of MBTR-R [172], and direct study of barriers to its implementation in urban post-displacement and refugee camp settings [8].

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Table 1:

Rates of Post-Migration-Living Difficulties and Trauma Exposure History at Pre-Intervention among whole Sample (n = 158)

	Control Group		MBTR-R Group		Total
	Men (n = 37)	Women (n = 21)	Men (n = 46)	Women (n = 49)	
Post-Migration Living Difficulties*					
Communication Difficulties	15 (40.5%)	8 (38.1%)	19 (41.3%)	23(46.9%)	65 (42.5%)
Separation from your family	31 (83.8%)	17 (85%)	37 (82.2%)	41 (83.7%)	126 (83.4%)
Not being able to find work or Bad working conditions	22 (61.1%)	14 (70%)	20 (45.5%)	29 (61.7%)	85 (57.8%)
Conflict with immigration officials	24 (64.9%)	7 (35%)	18 (40.9%)	18 (38.3%)	67 (45.3%)
Being fearful of being sent home	30 (78.9%)	19 (95%)	41(89.1%)	42 (87.5%)	132 (86.8%)
Not enough money to buy life essentials	21 (56.8%)	14 (70%)	19 (41.3%)	34 (72.3%)	88 (58.7%)
Poor access to educational services	32 (86.5%)	16 (80%)	37 (82.2%)	37 (77.1%)	122 (81.3%)
Trauma Exposure History					
Lack of food or water	18 (47.4%)	13 (61.9%)	29 (63%)	26 (52%)	86 (55.5%)
Ill health without access to medical care	20 (52.6%)	9 (42.9%)	26 (56.5%)	23 (45.1%)	78 (50%)
Imprisonment	26 (68.4%)	9 (42.9%)	31 (67.4%)	14 (28%)	80 (51.6%)
Serious injury	23 (60.5%)	5 (23.8%)	21 (45.7%)	15 (30%)	64 (41.3%)
Combat situation	16 (43.2%)	10 (47.6%)	19 (41.3%)	22 (43.1%)	67 (43.2%)
Rape or sexual abuse	6 (16.2%)	4 (19%)	2 (4.3%)	10 (19.6%)	22 (14.2%)
Being close to death	21 (55.3%)	9 (42.9%)	20 (43.5%)	19 (37.3%)	69 (44.2%)

Unnatural death of family/friend (incl. suicide)	13 (34.2%)	8 (36.4%)	15 (32.6%)	17 (33.3%)	53 (33.8%)
Lost or kidnapped	18 (48.6%)	5 (25%)	20 (42.6%)	12 (23.5%)	55 (35.5%)
Torture	22 (61.1%)	11 (52.4%)	24 (54.5%)	22 (44%)	79 (52.3%)

Note: *post-migration living difficulties posed moderate to very serious problem for participants

Table 2:

Continuous Mental Health Outcomes by Group and ANCOVAs among Treatment Completers with elevated Levels of Psychopathology (n=76)

	Waitlist-Control				MBTR-R						ANCOVA							
	Pre-Intervention		Post-Intervention		Pre-Intervention		Post-Intervention		Follow-Up		Post-Intervention				5-weeks Follow-Up			
	M (SD)	N	M (SD)	N	M (SD)	N	M (SD)	N	M (SD)	N	df	F	η^2	*p*	df	F	η^2	*p*
Total PTSD Symptoms (HTQ)	2.85 (.45)	41	2.63 (.48)	33	2.71 (.45)	29	2.10 (.59)	29	2.09 (.60)	28	1	12.44	.17	.001	1	10.44	.16	.002
PTSD Re-Experiencing Symptoms (HTQ)	2.96 (.58)	41	2.67 (.61)	33	2.69 (.70)	29	2.05 (.68)	29	1.95 (.65)	28	1	9.76	.14	.003	1	12.34	.18	.000
PTSD Arousal Symptoms (HTQ)	3.05 (.55)	41	2.95 (.66)	32	2.98 (.56)	29	2.14 (.72)	29	2.17 (.79)	28	1	23.93	.29	.000	1	19.23	.26	.001
PTSD Avoidance Symptoms (HTQ)	2.66 (.56)	41	2.41 (.51)	32	2.53 (.53)	29	2.10 (.62)	29	2.11 (.55)	28	1	3.26	.05	.076	1	2.64	.05	.110
Cultural Idioms of PTSD Symptoms (HTQ)	3.08 (.53)	41	2.88 (.69)	33	2.77 (.66)	29	2.10 (.73)	29	2.11 (.80)	28	1	10.85	.16	.002	1	7.91	.12	.007

Depression Symptoms (PHQ-9)	16.03 (4.46)	29	15.27 (5.16)	26	15.12 (4.08)	17	11.41 (5.76)	17	11.35 (7.30)	17	1	6.52	.14	.015	1	4.74	.11	.035
Anxiety Symptoms (BAI)	31.63 (13.18)	19	31.62 (14.33)	16	32.68 (9.25)	19	23.53 (14.15)	19	24.28 (14.83)	18	1	12.65	.20	.001	1	4.56	.10	.039
Comorbidity Index	2.33 (.80)	45	2.30 (1.00)	37	2.29 (.82)	31	1.50 (1.25)	30	1.74 (1.20)	27	1	8.43	.12	.005	1	4.11	.06	.047
Levels of Well-Being (BIT)	2.42 (.98)	45	2.32 (.88)	37	2.68 (1.10)	30	2.97 (1.32)	31	2.76 (1.25)	29	1	3.62	.06	.062	1	.807	.01	.373

Note: HTQ = Harvard Trauma Questionnaire [109]; PHQ-9 = Patient Health Questionnaire [116]; BAI = Beck's Anxiety Inventory [119]; BIT = Brief Inventory of Thriving [125]

Table 3:

Point-Prevalence Rates of Mental Health Outcomes at Pre-Intervention by Group and Gender and Logistic Regressions

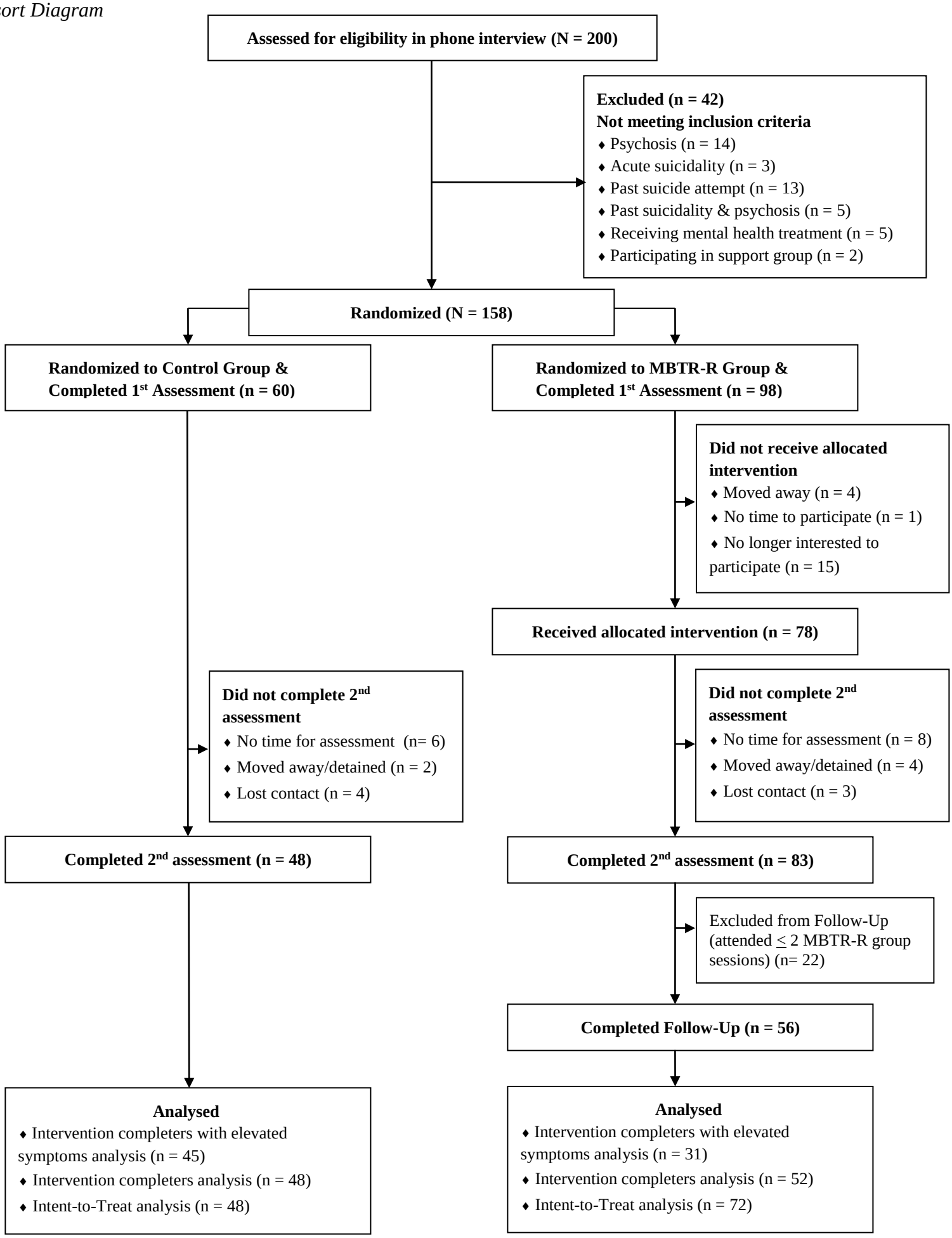
Diagnostic Symptom Status	Waitlist-Control		MBTR-R		Total	Differences in Diagnostic Status at Post-Intervention					Differences in Diagnostic Status at Follow-Up				
	Men (N = 38)	Women (N = 22)	Men (N = 47)	Women (N = 49)		$\chi2$	B (SE)	*p*	OR	95% CI [LL, UL]	$\chi2$	B (SE)	*p*	OR	95% CI [LL, UL]
PTSD (HTQ)	27 (71.1%)	14 (63.6%)	27 (57.4%)	27 (52.9%)	95 (60.1%)	14.43	2.37	.001	10.71	[2.66, 43.12]	7.47	1.83	.012	6.25	[1.50, 26.01]
Depression (PHQ-9)	19 (50%)	10 (45.5%)	14 (29.8%)	12 (24%)	55 (35%)	2.12	1.16	.153	3.19	[.65, 15.70]	5.01	1.68	.033	5.37	[1.15, 25.11]
Anxiety (BAI)	19 (50%)	16 (72.7%)	23 (48.9%)	24 (49%)	82 (52.6%)	4.54	1.50	.044	4.50	[1.04, 17.00]	1.39	.92	.247	2.50	[.53, 11.79]

Note: Note: HTQ = Harvard Trauma Questionnaire [109]; PHQ-9 = Patient Health Questionnaire [116]; BAI = Beck's Anxiety Inventory [119]; BIT = Brief Inventory of Thriving [125]. Cut-off for PTSD diagnostic symptom status: HTQ≥2, cut-off for depression diagnostic symptom status: PHQ-9≥10, cut-off for anxiety diagnostic symptom status equals: BAI≥16

1

Figure 1

Consort Diagram



Supplemental Materials for "Mindfulness-Based Trauma Recovery for Refugees (MBTR-R): Randomized Waitlist-Control Evidence of Efficacy and Safety"

Reebs, A., Yuval, K., Hadash, Y., Gebreyohans Gebremariam, S., & Bernstein, A.

Method Supplement

Participants

The selected sample of Eritrean asylum seekers are representative of a large and fast-growing population of forcibly displaced people in the current global refugee crisis [1]. First, members of this community were exposed to a large number of potentially traumatic events including serious violations of human rights, arbitrary detention, torture, sexual and gender-based violence, religious and political persecution [2, 3]. They fled from a highly repressive state and compulsory military service in Eritrea, violations of human rights, arbitrary detention, enforced disappearances, sexual and gender-based violence, religious and political persecution; and then while fleeing from their home country, a large percent of this community were survivors of human trafficking and torture in the Egyptian Sinai desert [2, 4, 5]. Furthermore, this population of African refugees residing in Israel is representative of the millions of African refugees who have been forcibly displaced throughout Europe in recent years [6, 7]. East African refugees constitute the largest refugee population from and in Africa and are one of the largest refugee populations world-wide; Sudan (including South Sudan) and Eritrea are among the top 10 major source countries of refugees world-wide [6, 8, 9]. Second, members of this community have not received refugee or formal residential status or protections such that their future remains unpredictable and uncertain due to threat of detention or deportation [10, 11]. Third, members of this community are struggling with chronic and often severe post-migratory life-stressors implicated in stress-related mental

health problems that interfere with trauma recovery yet only a tiny fraction receive any mental health care let alone evidence-based care [12-15]. Their ongoing chronic migrant status instability, future uncertainty, and post-migratory life-stressors represent a fast-growing population of forcibly displaced people worldwide [1, 16]. Finally, this sampling strategy – study of a single socio-cultural population of asylum seekers, as opposed to selection of diverse forcibly displaced people – is also a strength of the design. The socio-cultural and linguistic homogeneity of the sample protects against potential threats to internal validity that emerge from ad-mixing of distinct refugee populations [15]. Likewise, this permitted more unified socio-cultural adaptation of MBTR-R delivery for this population [17-19].

Financial Compensation. Participants in the mindfulness condition received up to a total of 840NIS (240$) for participation only in assessment sessions of the study and were not paid for participating in MBTR-R sessions. This was done to protect against coercion as well as to ensure that and participants could still participate and complete assessments while freely choosing to drop-out of the intervention. Participants that could not readily travel or afford to travel to attend any of the assessments, received an addition ~$12 in travel expenses per assessment session.

Procedure

In the event of emergency during screening, assessment session, or any MBTR-R group session, an on-call psychiatrist, specialized in mental health care for refugees was available for risk assessment and crisis care. We used this emergency response three times at screening and not again over the course of the intervention or at pre- or post-intervention assessments.

MBTR-R Intervention

Development. MBTR-R was developed and modified based on feedback from multiple researchers and clinician experts in mindfulness in traumatic stress and refugee mental health,

asylum seekers with expertise in refugee mental health, and via cognitive interviews with asylum seekers from our research team and involved in the linguistic and socio-cultural translation of the intervention. Furthermore, as noted in the main manuscript, MBTR-R format and structure parallel common MBIs including MBSR and MBCT. Yet, key cognitive elements of MBCT (e.g., reducing believability in negative thoughts) were not included in MBTR-R. Indeed, refugees' and asylum seekers' negative cognitions may often reflect real and immediate threats that they and their loved ones' experience in their chaotic environments post-displacement.

MBTR-R Mindfulness Instructors Qualification and Training. One male and one female mindfulness instructors taught the men's and women's mindfulness groups. Instructors were trained mindfulness-based teachers (trained to deliver MBSR/MBCT via Bangor University or UMass Center for Mindfulness) with 10-15 years of experience in teaching mindfulness. Both had an MA-level training in clinical or counseling psychology and previous experience in working post-traumatic stress in clinical mental health settings. Before the beginning of the study they received training to gain competency in refugee mental health and fluency in the MBTR-R intervention protocol. Throughout the intervention delivery instructors received weekly supervision by the intervention developers to ensure treatment fidelity, participant safety, and optimal delivery of weekly sessions.

MBTR-R Cultural Mediators Qualification and Training. In MBTR-R, cultural mediators have two important roles. First, in each group a cultural mediator works closely with one of the instructors to conduct real-time translation of guided practices, to facilitate communication between Eritrean group members and instructors during group discussions, and to bridge socio-cultural differences between participants and instructors. Accordingly, two male and one female cultural mediators were selected based on previous formal training and experience in

translation work with the Eritrean refugee community in Israel, as well as previous experience with cultural mediation and linguistic translation in psycho-social support groups provided to asylum seekers from this community.

Second, cultural mediators came from inside the refugee community and thus functioned as important role models for group participants. Accordingly, in MBTR-R groups it is important that cultural mediators embody mindful qualities and attitudes, and thereby facilitate direct, implicit, and experiential learning of mindfulness. Therefore, cultural mediators received training to develop a personal mindfulness practice and to learn important principles integral to MBTR-R prior to study initiation. To do so, cultural mediators participated in an 8-week mindfulness-based intervention (MBSR, MBCT, or MBTR). Afterwards, cultural mediators attended multiple meetings with their groups' instructor to support their personal mindfulness practice, to learn the intervention protocol, to understand intervention-consistent communication and language, to understand their role in the group and intervention, and to build a collaborative relationship with the mindfulness instructors. Throughout the intervention delivery they met with the instructors for weekly supervision before each MBTR-R session to discuss and clarify session procedure, practices, and principles, as well as to check-in with respect to individual participant needs.

Table 1

Mindfulness-Based Trauma Recovery for Refugees (MBTR-R) Session-by-Session Overview

Session	Main Themes	Practices
1. Mindfulness and Safe Place	• Learning what mindfulness is – conceptually and experientially • Understanding the safe place – why bringing attention to a safe place can help to self-regulate when feeling threat and arousal due to trauma	• Raising exercise • Safe place
2. Difficulties are Guests	• Relating to difficulties as guests – allowing them to come and go and letting go of internal struggle and negative judgements • Learning to recognize hyperarousal and hypoarousal and to use the safe place to self-regulate and get back to the range of tolerance	• Safe place • Short body scan
3. Mindful Movement	• Learning how to bring ease to the body using gentle movement • Noticing pleasant experiences as a remedy to negativity bias	• Mindful standing up movement • Sitting meditation – awareness of the breath • Breathing space
4. Stress Reactions	• Exploring participant's own physical and mental markers of stress • Learning about the physiological, behavioral and psychological bases of stress reactivity and chronic stress • Psychoeducation on trauma and typical stress reactions to traumatic experiences	• Walking meditation • Sitting meditation – awareness of breath and body
5. Using Mindfulness when Facing Difficulties	• Learning about maladaptive reactions to stress and their effects on chronic stress • Cultivating an attitude of acceptance, stability, and curiosity towards unpleasant emotions and sensations • Developing attention regulation skills when facing difficulties	• Sitting with the difficulty meditation
6. Self-Compassion	• Learning about the key elements of self-compassion • Learning loving-kindness and self-compassion as a new way of coping with difficulties, self-judgements, and guilt.	• Loving-kindness meditation focused on benefactor and self • Breathing space with kindness
7. Practice Session	• Cultivating curiosity, allowing, non-striving, and self-kindness during mindfulness practice	• Sitting mindfulness meditation

		• Mindful standing up movement • Short body scan • Walking meditation • Loving-kindness meditation
8. How Can I Best Take Care of Myself?	• Learning to recognize personal depleting and nurturing activities • Learning to use nurturing activities to cope with stress and lowering mood	• Mindful standing up movement • Sitting mindfulness meditation • Loving-kindness meditation
9. Living Mindfully	• Summary and personal reflection on the course • Setting intentions and a personal plan for maintaining formal and informal mindfulness practice after the intervention	• Body scan

Note: Safe place is a trauma-sensitive practice adapted for MBTR-R in which participants, first, learn to find a sensation or image in their body, environment, or mind that feels neutral, safe, or calm; and, second, practice bringing attention to their personal safe place to self-regulate when feeling overwhelmed (hyperarousal) or numb (hypoarousal). It is taught and practiced extensively in sessions 1 & 2 and integrated into each practice in all following sessions.

Table 2

Demographics, Trauma History and Post-Migration Living Difficulties predicting Intervention Completion and Session Attendance

	Intervention Completion				Session Attendance			
	B (SE)	*p*	OR	95% CI [LL, UL]	B (SE)	*ß*	*t*	*p*
Gender	-.66(.55)	.23	.52	[.18, 1.52]	1.06(.71)	.19	1.48	.14
Age	-.05(.06)	.38	.95	[.85, 1.07]	.11(.07)	.18	1.52	.13
Education	-.02(.40)	.97	.98	[.45, 2.16]	-.12(.48)	-.03	-.24	.81
Post-Migration Living Difficulties (PMLD)	.25(.34)	.46	1.29	[.66, 2.51]	.35(.41)	.12	.85	.40
Trauma History (HTQ)	.00(.08)	.98	1.00	[.86, 1.16]	.04(1.0)	.05	.38	.71

Note: PMLD = Post-Migration Living Difficulties Scale [20]; HTQ = Harvard Trauma Questionnaire [21];

Table 3:

Continuous Mental Health Outcomes by Group and ANCOVAs among Intent-to-Treat Sample (n = 120)

	Waitlist-Control				MBTR-R				ANCOVA			
	Pre-Intervention		Post-Intervention		Pre-Intervention		Post-Intervention		Post-Intervention			
	M (SD)	N	M (SD)	N	M (SD)	N	M (SD)	N	df	F	η^2	*p*
ITT sample with elevated levels of symptomatology (n = 90)												
Total PTSD Symptoms (HTQ)	2.85 (.45)	41	2.63 (.48)	33	2.65 (.43)	40	2.13 (.61)	38	1	9.14	.12	.004
PTSD Re-Experiencing Symptoms (HTQ)	2.96 (.58)	41	2.67 (.61)	33	2.65 (.68)	40	2.07 (.68)	38	1	10.12	.13	.002
PTSD Arousal Symptoms (HTQ)	3.05 (.55)	41	2.95 (.66)	32	2.91 (.58)	40	2.15 (.73)	38	1	22.55	.25	.000
PTSD Avoidance Symptoms (HTQ)	2.66 (.56)	41	2.41 (.51)	32	2.48 (.54)	40	1.87 (.63)	38	1	1.40	.02	.242
Cultural Idioms of PTSD Symptoms (HTQ)	3.08 (.53)	41	2.88 (.69)	33	2.72 (.62)	40	2.20 (.77)	38	1	6.00	.08	.017
Depression Symptoms (PHQ-9)	16.03 (4.46)	29	15.27 (5.16)	26	15.32 (4.51)	22	7.25 (5.84)	20	1	4.37	.09	.043
Anxiety Symptoms (BAI)	31.63 (13.18)	19	31.63 (14.33)	16	32.27 (9.40)	22	23.90 (14.34)	21	1	9.99	.13	.004
Comorbidity Index	2.33 (.80)	45	2.30 (1.00)	37	2.16 (.88)	45	1.48 (1.25)	42	1	10.19	.12	.002

Well-Being (BIT)	2.42 (.98)	45	2.32 (.88)	37	2.59 (1.10)	44	2.98 (1.22)	43	1	4.71	.07	.028
ITT sample with and without elevated levels of symptomatology (n = 120)												
Total PTSD Symptoms (HTQ)	2.44 (.77)	48	2.25 (.71)	48	2.06 (.73)	72	1.84 (.60)	72	1	3.99	.03	.048
PTSD Re-Experiencing Symptoms (HTQ)	2.52 (.91)	47	2.27 (.81)	48	2.05 (.74)	72	1.81 (.68)	72	1	5.13	.04	.025
PTSD Arousal Symptoms (HTQ)	2.60 (.88)	48	2.47 (.92)	48	2.26 (.85)	72	1.85 (.67)	72	1	14.28	.11	.000
PTSD Avoidance Symptoms (HTQ)	2.33 (.74)	47	2.10 (.65)	47	1.93 (.74)	72	1.87 (.63)	72	1	.01	.00	.918
Cultural Idioms of PTSD Symptoms (HTQ)	2.63 (.91)	47	2.43 (.91)	48	2.11 (.85)	72	1.85 (.74)	72	1	4.71	.04	.032
Depression Symptoms (PHQ-9)	10.13 (6.95)	48	10.83 (6.77)	48	7.11 (6.04)	72	7.31 (5.85)	72	1	2.80	.02	.097
Anxiety Symptoms (BAI)	20.32 (16.93)	31	21.67 (17.45)	31	16.94 (15.12)	48	13.86 (13.89)	49	1	7.94	.07	.006
Well-Being (BIT)	2.67 (1.14)	48	2.75 (1.16)	48	2.99 (1.17)	71	3.24 (1.19)	72	1	2.48	.02	.118

Note: HTQ = Harvard Trauma Questionnaire [21]; PHQ-9 = Patient Health Questionnaire [22]; BAI = Beck's Anxiety Inventory [23]; BIT = Brief Inventory of Thriving [24]

Table 4:

Continuous Mental Health Outcomes by Group and ANCOVAs among intervention completers (n = 101)

	Waitlist-Control				MBTR-R						ANCOVA							
	Pre-Intervention		Post-Intervention		Pre-Intervention		Post-Intervention		5-weeks Follow-Up		Post-Intervention				5-weeks Follow-Up			
	M (SD)	N	M (SD)	N	M (SD)	N	M (SD)	N	M (SD)	N	df	F	Ƞ²	*p*	df	F	Ƞ²	*p*
Total PTSD Symptoms (HTQ)	2.44 (.77)	48	2.25 (.71)	48	2.12 (.75)	53	1.86 (.57)	53	1.84 (.58)	51	1	4.65	.05	.034	1	4.23	.04	.043
PTSD Re-Experiencing Symptoms (HTQ)	2.52 (.91)	47	2.27 (.81)	48	2.09 (.89)	53	1.82 (.67)	53	1.75 (.63)	51	1	4.45	.04	.038	1	6.25	.06	.014
PTSD Arousal Symptoms (HTQ)	2.60 (.88)	48	2.47 (.92)	47	2.32 (.89)	53	1.86 (.67)	53	1.90 (.69)	51	1	13.86	.13	.000	1	9.90	.10	.002
PTSD Avoidance Symptoms (HTQ)	2.33 (.74)	47	2.10 (.65)	47	1.99 (.75)	53	1.88 (.60)	53	1.85 (.58)	51	1	.21	.00	.646	1	.35	.00	.558
Cultural Idioms of PTSD Symptoms (HTQ)	2.63 (.91)	47	2.43 (.91)	48	2.14 (.89)	53	1.85 (.69)	53	1.83 (.77)	51	1	5.61	.06	.020	1	4.40	.05	.039
Depression Symptoms (PHQ-9)	10.13 (6.95)	48	10.83 (6.77)	48	7.45 (6.22)	53	7.45 (5.74)	53	7.28 (6.15)	47	1	2.94	.03	.089	1	4.57	0.5	.035

Anxiety Symptoms (BAI)	18.20 (15.81)	41	21.68 (17.45)	31	19.05 (15.53)	38	15.76 (13.86)	38	15.42 (14.94)	36	1	8.37	.08	.005	1	2.38	.06	.033
Well-Being (BIT)	2.67 (1.14)	48	2.75 (1.58)	48	3.02 (1.17)	53	3.21 (1.23)	53	3.17 (1.28)	50	1	1.45	.02	.232	1	1.12	.01	.294

Note: HTQ = Harvard Trauma Questionnaire [21]; PHQ-9 = Patient Health Questionnaire [22]; BAI = Beck's Anxiety Inventory [23]; BIT = Brief Inventory of Thriving [24]

Table 5

Moderated Regression Analyses for Continuous Mental Health Outcomes among Intervention Completers with Elevated Levels of Symptoms (n = 92)

	Post-Intervention				Follow-Up Intervention			
	ß	SE	t	*p*	ß	SE	t	*p*
Total PTSD Symptoms								
Total PTSD Symptoms (HTQ) x Gender	-.28	.24	-1.15	.25	-.41	.26	-1.55	.13
Total PTSD Symptoms (HTQ) x Age	.03	.02	1.10	.27	.03	.02	1.28	.21
Total PTSD Symptoms (HTQ) x Education	-.20	.17	-1.16	.25	-.12	.19	-.63	.53
Total PTSD Symptoms (HTQ) x Post-Migration Living Difficulties (PMLD)	.002	.04	.05	.96	.02	.04	.48	.63
Total PTSD Symptoms (HTQ) x Trauma History (HTQ)	.02	.03	.54	.59	.02	.04	.41	.68
PTSD Re-Experiencing Symptoms								
PTSD Re-Experiencing Symptoms (HTQ) x Gender	-.22	.31	-.72	.47	-.67	.29	-2.25	.03
PTSD Re-Experiencing Symptoms (HTQ) x Age	.07	.03	.21	.83	.02	.03	.77	.44
PTSD Re-Experiencing Symptoms (HTQ) x Education	-.48	.22	-2.18	.03	-.29	.22	-1.31	.19

PTSD Re-Experiencing Symptoms (HTQ) x Post-Migration Living Difficulties (PMLD)	-.02	.06	-.36	.72	.05	.05	.91	.36
PTSD Re-Experiencing Symptoms (HTQ) x Trauma History (HTQ)	-.03	.04	-.61	.55	.02	.04	.48	.64
PTSD Arousal Symptoms								
PTSD Arousal Symptoms (HTQ) x Gender	-.29	.34	-.86	.39	-.31	.35	-.87	.38
PTSD Arousal Symptoms (HTQ) x Age	.03	.03	.86	.39	.06	.03	1.59	.12
PTSD Arousal Symptoms (HTQ) x Education	-.15	.24	-.64	.53	-.06	.25	-.25	.81
PTSD Arousal Symptoms (HTQ) x PMLD	-.04	.06	-.68	.50	.01	.06	.15	.88
PTSD Arousal Symptoms (HTQ) x Trauma History (HTQ)	.05	.05	1.20	.24	.02	.05	.36	.72
PTSD Avoidance Symptoms								
PTSD Avoidance Symptoms (HTQ) x Gender	-.14	.27	-.49	.62	-.20	.28	-.73	.47
PTSD Avoidance Symptoms (HTQ) x Age	.03	.03	1.27	.21	.02	.03	.78	.44
PTSD Avoidance Symptoms (HTQ) x Education	-.18	.19	-.92	.36	-.11	.19	-.62	.54
PTSD Avoidance Symptoms (HTQ) x Post-Migration Living Difficulties (PMLD)	.07	.05	1.38	.17	.03	.05	.57	.57
PTSD Avoidance Symptoms (HTQ) x Trauma History (HTQ)	.05	.04	1.38	.17	.05	.04	1.32	.19
Cultural Idioms of PTSD Symptoms								

Cultural Idioms of PTSD Symptoms (HTQ) x Gender	-.40	.31	-1.27	.21	-.20	.35	-.57	.57
Cultural Idioms of PTSD Symptoms (HTQ) x Age	.03	.03	.87	.39	.02	.04	.66	.51
Cultural Idioms of PTSD Symptoms (HTQ) x Education	-.15	.23	-.66	.51	-.13	.25	-.52	.60
Cultural Idioms of PTSD Symptoms (HTQ) x Post-Migration Living Difficulties (PMLD)	.03	.06	.61	.55	.12	.05	2.24	.03
Cultural Idioms of PTSD Symptoms (HTQ) x Trauma History (HTQ)	.02	.04	.56	.58	.02	.05	.31	.75
Depression Symptoms								
Depression Symptoms (PHQ-9) x Gender	-4.13	2.81	-1.47	.15	-4.27	3.37	-1.27	.21
Depression Symptoms (PHQ-9) x Age	.27	.28	.95	.35	.29	.34	.85	.40
Depression Symptoms (PHQ-9) x Education	.15	2.16	.07	.94	-1.19	2.52	-.47	.64
Depression Symptoms (PHQ-9) x Post-Migration Living Difficulties (PMLD)	.04	.51	.07	.94	.45	.60	.75	.46
Depression Symptoms (PHQ-9) x Trauma History (HTQ)	.06	.41	.14	.89	.59	.47	1.25	.22
Anxiety Symptoms								
Anxiety Symptoms (BAI) x Gender	-.22	.37	-.58	.57	-.83	.46	-1.79	.08
Anxiety Symptoms (BAI) x Age	.06	.04	1.61	.11	.06	.05	1.21	.23
Anxiety Symptoms (BAI) x Education	-.08	.26	-.28	.77	.22	.34	.64	.53

Anxiety Symptoms (BAI) x Post-Migration Living Difficulties (PMLD)	.06	.22	.27	.79	.06	.25	2.35	.02
Anxiety Symptoms (BAI) x Trauma History (HTQ)	-.05	.05	-1.09	.28	-.01	.06	-.01	.99
Levels of Well-Being								
Levels of Well-Being (BIT) x Gender	.34	.49	.71	.48	.55	.49	1.11	.27
Levels of Well-Being (BIT) x Age	.06	.05	1.07	.29	.04	.06	.76	.45
Levels of Well-Being (BIT) x Education	.03	.37	.09	.93	.21	.36	.58	.57
Levels of Well-Being (BIT) x Post-Migration Living Difficulties (PMLD)	-.01	.29	-.04	.96	-.15	.30	-.50	.62
Levels of Well-Being (BIT) x Trauma History (HTQ)	.07	.06	1.18	.24	-.01	.06	-.13	.89

Note: Because we examined multiple candidate moderators per outcome, we applied a Bonferroni correction to correct for multiple repeated statistical tests per outcome and reduce inflation of type I error [25, 26]; HTQ = Harvard Trauma Questionnaire [21]; PMLD = Post-Migration Living Difficulties Scale [20]; PHQ-9 = Patient Health Questionnaire [22]; BAI = Beck's Anxiety Inventory [23]; BIT = Brief Inventory of Thriving [24]

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