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A randomized controlled trial of mental health interventions for survivors of systematic violence in Kurdistan, Northern Iraq

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Introduction

- Survivors of systematic violence, including torture, are at risk of:
  - ✓ PTSD
  - ✓ Depression
  - ✓ Generalized Anxiety
  - ✓ Other mental distress
  - ✓ Physical Health Problems

Literature Review

- A total of 40 treatment studies for survivors of torture and other systematic violence:
  - ✓ 11 RCTs
  - ✓ 5 RCTs in LMIC
  - ✓ Only 1 (quasi-experimental study) in MENA

- Most of the services were delivered outside clients' country of origin, focused on PTSD, consisted of CBT, NRT, multidisciplinary rehabilitation or outpatient Psychiatry.

Kurdistan Region of Iraq

- Saddam Hussein's government conducted:
  - ✓ Genocide Campaign ('the Anafal') Killing 50,000-100,000 persons and 4,000 villages destroyed
  - ✓ Bombing
  - ✓ Chemical attack on Halabja city killed 5,000 civilians
  - ✓ Forced dislocations
  - ✓ Arbitrary imprisonment,
  - ✓ Torture,
  - ✓ Mass killings

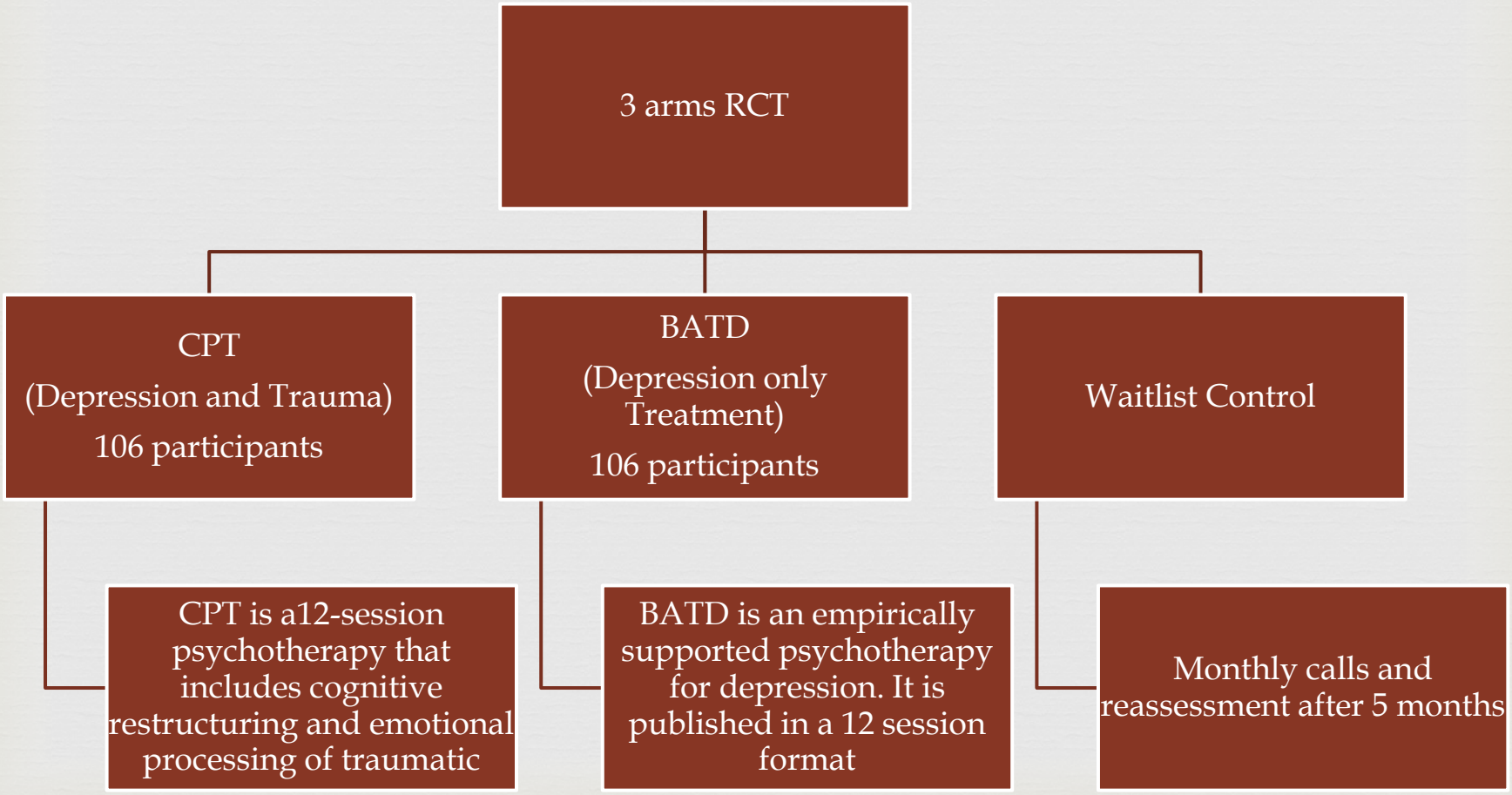
Study Setting

Objectives

- To assess the:
  - ✓ Acceptability,
  - ✓ Feasibility, and
  - ✓ Effectiveness of

  ….scalable mental health treatments for survivors of systematic violence

Methods


3 arms RCT
CPT
(Depression and Trauma)
106 participants
BATD
(Depression only Treatment)
106 participants
Waitlist Control
CPT is a12-session psychotherapy that includes cognitive restructuring and emotional processing of traumatic
BATD is an empirically supported psychotherapy for depression. It is published in a 12 session format
Monthly calls and reassessment after 5 months

Intervention Training and Supervision

- Apprenticeship Model:
  - ✓ US-Based Trainers (2 weeks training in BATD or CPT) to CMHWs (7 women, 13 men) and Supervisors
  - ✓ Supervisors provided ongoing supervision and training to CMHWs at 14 health clinics.
  - ✓ Supervisors received weekly oversight from US-based trainers by Skype, e mail and phone.

Instrument Development and Testing

- Qualitative study data were used to adapt:
  - ✓ Hopkins Symptom Checklist for Depression and Anxiety (HSCL-25)
  - ✓ Harvard Trauma Questionnaire (HTQ)
  - ✓ The Inventory of Traumatic Grief
- 13 locally relevant questions were added
- Instrument measured in the prior 2 weeks symptoms of:
  - ✓ Depression
  - ✓ Anxiety
  - ✓ Post-traumatic stress
  - ✓ Traumatic Grief

  (0 Never, 3 Always)
  - ✓ Locally developed function scales for men and women (0 No difficulty, 4 unable to do activity)
- Instrument reliability and validity were tested for all outcomes among local survivors of systematic violence (N=128).

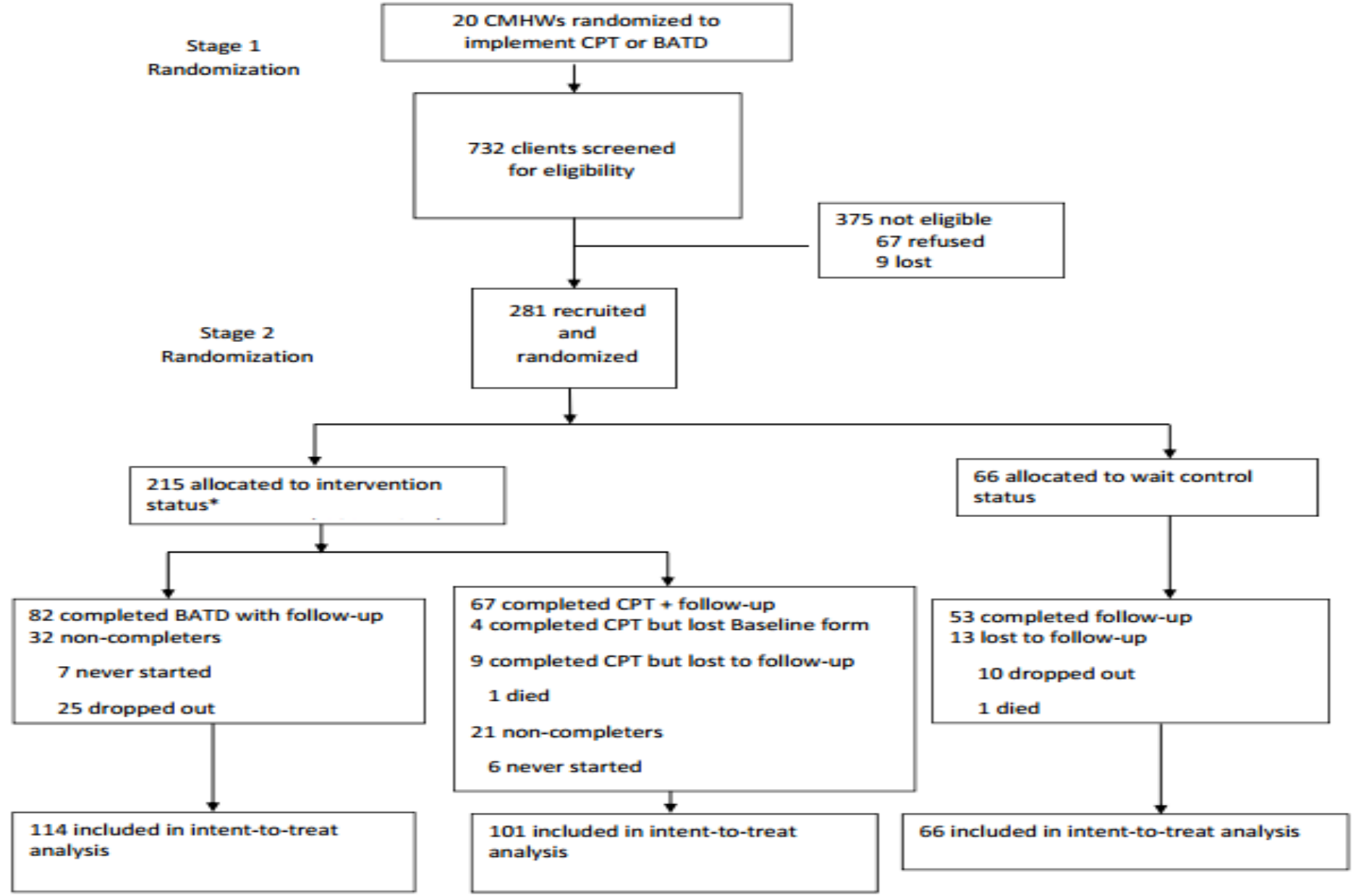
Study Eligibility

- Recruitment occurred from May 2009 to June 2010
- Eligible persons were
  - ✓ survivors of systematic violence living in the governorates of Erbil or Sulaimaniyah,
  - ✓ aged 18 or over
  - ✓ fluent in Sorani Kurdish
  - ✓ reported significant depression symptoms
  - ✓ had no current psychotic symptoms or active suicidality
  - ✓ appeared mentally competent to consent
  - ✓ had a total symptoms score of at least 20 for depression
- 'Survivor of systematic violence' was defined as experiencing and/or witnessing physical torture, imprisonment, and/or military attacks.

Consent and Randomization

- If eligible,
  - ✓ the CMHW obtained informed verbal consent
  - ✓ explained that participants would be randomized to immediate treatment (BATD or CPT) or waitlist.
  - ✓ If a person consented the CMHW opened a sealed envelope attached to the consent form containing the participant's assignment
- Two Tier Randomization:
  - ✓ CMWHs to therapy
  - ✓ Participants to therapy

Figure 1: Flow Chart of study participants



*which intervention depended on the intervention provided by the CMHW who recruited them

Analysis

- All analyses were conducted using Stata 12.0 and R
- The study was approved by Johns Hopkins University's Internal Review Board and University of Sulaimaniyah College of Medicine's Ethical Committee
- All analyses were conducted on the full intent to treat sample and based on change in mean scale scores between baseline and post-assessment.
- Outcomes:
  - Primary:
    - ✓ mean depression
    - ✓ mean dysfunction
  - Secondary
    - ✓ mean post-traumatic stress
    - ✓ mean anxiety
    - ✓ mean traumatic Grief

Analysis

- BATD and CPT was first compared to all controls, per the original study design.
- This relied on the homogeneity assumption that each patient's outcome is a random draw from a common distribution independent of site.
- However, a post-hoc analysis of participant characteristics suggested site-specific differences between treatment arms at baseline, challenging the homogeneity assumption.

Analysis

- Therefore a second analysis was done comparing BATD only to controls generated by the BATD CMHWs (BATD-controls) and CPT only to controls at generated by CPT CMHWs (CPT-controls).
- This is less precise due to a smaller sample size but more robust by not making the homogeneity assumption.

Analysis

- maximum likelihood mixed-effect regression models was used with a robust variance estimator.
- All analyses controlled for participant sex, age, marital status, and disability.
- Additional variables that differed between treatment and control at baseline or that predicted change in outcome were included as covariates ($p<0.10$).
- Clustering at the levels of CMHW and governorate were reviewed
- Effect sizes reflecting regression adjustments were calculated using Cohen's d

Analysis

- A third analysis was done to independently test the null hypothesis of no effect of treatment by applying Rosenbaum et al.'s permutation-based method which has been applied to cluster randomized trials of mental health interventions
- This general method has the advantage of not needing to rely on regression model assumptions nor the aforementioned homogeneity assumption. data from all the participants randomized to BATD or CPT and their respective controls was used.

Baseline Characteristics

	BATD (N=114)	BATD Control (N=33)	CPT (N=101)	CPT Control (N=33)	All Control (N=66)
Demographics					
Mean age in years	36.9 (12.4)	42.4 (11.1)	41.5 (13.7)	42.3 (14.0)	42.3 (12.5)
Female	65 (57%)	16 (49%)	59 (58%)	23 (70%)	39 (59%)
Location:					
Erbil	50 (44%)	14 (42%)	32 (32%)	11 (33%)	25 (38%)
Sulaimaniyah	64 (56%)	19 (58%)	69 (68%)	22 (67%)	41 (62%)
Marital Status:					
Married	76 (67%)	20 (61%)	60 (59%)	21 (64%)	41 (62%)
Single/Divorced[1]	30 (26%)	7 (21%)	24 (24%)	3 (9%)	10 (15%)
Widowed	8 (7%)	6 (18%)	17 (17%)	9 (27%)	15 (23%)
Employment:					
Not working	57 (50%)	17 (52%)	47 (48%)	20 (61%)	37 (56%)
Regular work	25 (22%)	10 (30%)	32 (33%)	10 (30%)	20 (30%)
Self-employed or Irregular work[2]	32 (28%)	6 (18%)	18 (19%)	3 (9%)	9 (14%)
Education:					
None	59 (52%)	18 (55%)	44 (44%)	20 (61%)	38 (58%)
Primary	26 (23%)	11 (33%)	30 (30%)	7 (21%)	18 (27%)
Secondary	24 (21%)	4 (12%)	13 (13%)	4 (12%)	8 (12%)
Bachelors/Institutional degree or certificate	5 (4%)	0 (0%)	14 (14%)	2 (6%)	2 (3%)
Traumatic Experiences					
Physical torture:					
Experienced personally	43 (38%)	16 (48%)	41 (42%)	16 (48%)	32 (48%)
Witnessed it happen to others	64 (56%)	15 (45%)	45 (46%)	15 (45%)	30 (45%)
Imprisonment:					
Experienced personally	58 (51%)	20 (61%)	62 (64%)	15 (45%)	35 (53%)
Witnessed it happen to others	75 (66%)	20 (61%)	50 (52%)	17 (52%)	37 (56%)
Gas attacks:					
Experienced personally	13 (11%)	4 (12%)	19 (20%)	3 (9%)	7 (11%)
Witnessed it happen to others	16 (14%)	5 (15%)	16 (16%)	4 (12%)	9 (14%)
Other military attacks:					
Experienced personally	71 (62%)	19 (58%)	74 (76%)	23 (70%)	45 (68%)
Witnessed it happen to others	74 (65%)	22 (67%)	61 (63%)	21 (64%)	40 (61%)

Baseline mean scale scores by treatment condition

	BATD (N=114)	BATD Control (N=33)	CPT (N=101)	CPT Control (N=33)	All Control (N=66)
Primary Outcomes					
Depression					
Total	1.6 (0.5)	1.5 (0.3)	1.7 (0.4)	1.5 (0.4)	1.5 (0.3)
Male	1.4 (0.3)	1.5 (0.3)	1.5 (0.4)	1.3 (0.4)	1.4 (0.3)
Female	1.8 (0.5)	1.7 (0.3)	1.8 (0.4)	1.6 (0.3)	1.6 (0.3)
Dysfunction					
Total	1.7 (0.7)	1.5 (0.5)	2.1 (0.8)	1.9 (0.8)	1.7 (0.7)
Male	1.6 (0.6)	1.4 (0.5)	1.9 (0.8)	1.2 (0.4)	1.3 (0.5)
Female	1.8 (0.7)	1.6 (0.6)	2.2 (0.8)	2.2 (0.8)	2.0 (0.7)
Secondary Outcomes					
Post-Traumatic Stress					
Total	1.3 (0.5)	1.2 (0.4)	1.4 (0.4)	1.2 (0.3)	1.2 (0.4)
Male	1.1 (0.4)	1.1 (0.4)	1.2 (0.3)	1.0 (0.3)	1.1 (0.4)
Female	1.4 (0.5)	1.3 (0.4)	1.5 (0.4)	1.3 (0.3)	1.3 (0.3)
Anxiety					
Total	1.3 (0.6)	1.2 (0.5)	1.4 (0.5)	1.0 (0.5)	1. (0.5)
Male	0.9 (0.4)	1.0 (0.4)	1.2 (0.5)	1.0 (0.5)	1. (0.4)
Female	1.5 (0.5)	1.3 (0.6)	1.5 (0.5)	1.1 (0.5)	1.2 (0.6)
Traumatic Grief					
Total	0.6 (0.4)	0.5 (0.4)	0.9 (0.4)	0.8 (0.4)	0.6 (0.4)
Male	0.4 (0.3)	0.5 (0.5)	0.8 (0.4)	0.7 (0.5)	0.6 (0.5)
Female	0.8 (0.4)	0.6 (0.4)	1.0 (0.5)	0.8 (0.3)	0.7 (0.4)

Changes in All Study Outcomes for CPT and BATD compared with all Wait Controls

	CPT		BATD	
	Treatment (n=101)	All Controls (n=66)	Treatment (n=114)	All Controls (n=66)
Primary Outcomes				
Depression				
Baseline, mean (se)	1.65 (0.07)	1.60 (0.04)	1.58 (0.07)	1.60 (0.04)
Follow up, mean (se)	0.89 (0.07)	1.16 (0.09)	0.88 (0.10)	1.15 (0.09)
Pre-post change	-0.76 (0.12)	-0.45 (0.10)	-0.71 (0.16)	-0.46 (0.10)
Net effect (95% CI)	-0.31 (-0.54, -0.09)		-0.25 (-0.53, 0.03)	
Effect Estimate[2]	0.70**		0.60	
Dysfunction				
Baseline, mean (se)	2.02 (0.11)	1.78 (0.14)	1.74 (0.06)	1.71 (0.12)
Follow up, mean (se)	1.14 (0.12)	1.65 (0.12)	1.24 (0.14)	1.59 (0.12)
Pre-post change	-0.88 (0.22)	-0.13 (0.17)	-0.50 (0.17)	-0.12 (0.17)
Net effect (95% CI)	-0.75 (-1.20, -0.30)		-0.38 (-0.71, -0.05)	
Effect Estimate[2]	0.90**		0.55*	

Changes in All Study Outcomes for CPT and BATD compared with all Wait Controls

	CPT		BATD	
Secondary Outcomes	Treatment (n=101)	CPT-site Controls (n=33)	Treatment (n=114)	BATD-site Controls (n=33)
Posttraumatic Stress				
Baseline, mean (se)	1.32 (0.05)	1.28 (0.05)	1.28 (0.05)	1.28 (0.05)
Follow up, mean (se)	0.72 (0.07)	1.00 (0.07)	0.79 (0.08)	0.99 (0.07)
Pre-post change	-0.60 (0.11)	-0.29 (0.08)	-0.49 (0.13)	-0.29 (0.09)
Net effect (95% CI)	-0.32 (-0.51, -0.12)		-0.21 (-0.43, 0.02)	
Effect Estimate[2]	0.71**		0.47	
Traumatic Grief				
Baseline, mean (se)	0.85 (0.03)	0.71 (0.05)	0.67 (0.04)	0.69 (0.06)
Follow up, mean (se)	0.30 (0.07)	0.55 (0.06)	0.41 (0.07)	0.53 (0.06)
Pre-post change	-0.55 (0.08)	-0.16 (0.07)	-0.26 (0.08)	-0.16 (0.07)
Net effect (95% CI)	-0.38 (-0.58, -0.19)		-0.10 (-0.31, 0.10)	
Effect Estimate[2]	0.82***		0.24	
Anxiety				
Baseline, mean (se)	1.34 (0.06)	1.18 (0.06)	1.25 (0.07)	1.15 (0.05)
Follow up, mean (se)	0.75 (0.10)	0.97 (0.08)	0.75 (0.11)	0.94 (0.08)
Pre-post change	-0.58 (0.11)	-0.21 (0.08)	-0.49 (0.16)	-0.21 (0.09)
Net effect (95% CI)	-0.38 (-0.60, -0.15)		-0.29 (-0.56, -0.01)	
Effect Estimate[2]	0.66**		0.53*	

Changes in All Study Outcomes for CPT compared with own controls and BATD compared with own controls

	CPT		BATD	
	Treatment (n=101)	CPT-site Controls (n=33)	Treatment (n=114)	BATD-site Controls (n=33)
Primary Outcomes				
Depression				
Baseline, mean (se)	1.64 (0.07)	1.62 (0.06)	1.60 (0.09)	1.60 (0.06)
Follow up, mean (se)	0.92 (0.08)	1.12 (0.15)	0.89 (0.09)	1.25 (0.09)
Pre-post change	-0.72 (0.12)	-0.50 (0.15)	-0.71 (0.16)	-0.35 (0.12)
Net effect (95% CI)	-0.21 (-0.47, 0.04)		-0.35 (-0.50, -0.21)	
Effect Estimate[2]	0.44		0.84***	
Dysfunction				
Baseline, mean (se)	2.04 (0.10)	1.98 (0.21)	1.69 (0.07)	1.54 (0.13)
Follow up, mean (se)	1.20 (0.13)	1.70 (0.20)	1.21 (0.13)	1.57 (0.15)
Pre-post change	-0.84 (0.22)	-0.29 (0.25)	-0.48 (0.17)	0.03 (0.22)
Net effect (95% CI)	-0.55 (-1.07, -0.02)		-0.51 (-0.69, -0.33)	
Effect Estimate[2]	0.63*		0.79***	

Changes in All Study Outcomes for CPT compared with own controls and BATD compared with own controls

	CPT		BATD		CPT	
Secondary Outcomes	Treatment (n=101)	All Controls (n=66)	Treatment (n=114)	All Controls (n=66)	Treatment (n=101)	All Controls (n=66)
Posttraumatic Stress						
Baseline, mean (se)	1.35 (0.05)		1.33 (0.06)	1.25 (0.09)	1.20 (0.08)	
Follow up, mean (se)	0.79 (0.07)		1.05 (0.12)	0.77 (0.07)	0.98 (0.08)	
Pre-post change	-0.56 (0.12)		-0.29 (0.13)	-0.48 (0.13)	-0.22 (0.10)	
Net effect (95% CI)	-0.27 (-0.48, -0.07)			-0.26 (-0.40, -0.12)		
Effect Estimate[2]	0.61**			0.56***		
Traumatic Grief						
Baseline, mean (se)	0.88 (0.03)		0.87 (0.05)	0.62 (0.04)	0.54 (0.08)	
Follow up, mean (se)	0.36 (0.06)		0.67 (0.10)	0.35 (0.06)	0.45 (0.06)	
Pre-post change	-0.52 (0.08)		-0.21 (0.12)	-0.27 (0.08)	-0.09 (0.05)	
Net effect (95% CI)	-0.32 (-0.56, -0.07)			-0.18 (-0.34, -0.02)		
Effect Estimate[2]	0.69*			0.42*		
Anxiety						
Baseline, mean (se)	1.33 (0.06)		1.15 (0.05)	1.24 (0.10)		1.23 (0.09)
Follow up, mean (se)	0.77 (0.11)		0.94 (0.12)	0.74 (0.09)		0.99 (0.08)
Pre-post change	-0.56 (0.11)		-0.21 (0.09)	-0.50 (0.17)		-0.24 (0.13)
Net effect (95% CI)	-0.35 (-0.57, -0.12)			-0.26 (-0.48, -0.04)		
Effect Estimate[2]	0.59**			0.48*		

Limitations

- Follow-up occurred within a month following the intervention, preventing evaluation of long-term treatment effects
- The study design called for post-assessment 3-5 months after recruitment, following treatment completion but many clients took much longer than expected to finish treatment (mean follow up time was 5.5 months).
- Participants were not blinded to their own treatment/control status
- How much of the difference between intervention and control groups is due to regularly meeting with CMHWs regardless of intervention content
- 35 out of 232 follow-up interviews were not blinded and therefore subject to possible bias although sensitivity analysis suggests that this was not significant.

Conclusions

- This study supports the effectiveness of two psychotherapies for survivors of systematic violence in rural Kurdistan by workers with limited prior experience.
- Trainers adapted both treatments for illiterate participants.
- Stigma associated with mental problems was a major issue; families and individuals frequently resisted treatment fearing family reputation and marriageability would be affected.
- The similarity in drop-out rates between this sample and those in high-resource countries combined with the robust treatment effects suggests that locally adapted CPT and BATD are useful mental health treatments in this setting.

Thanks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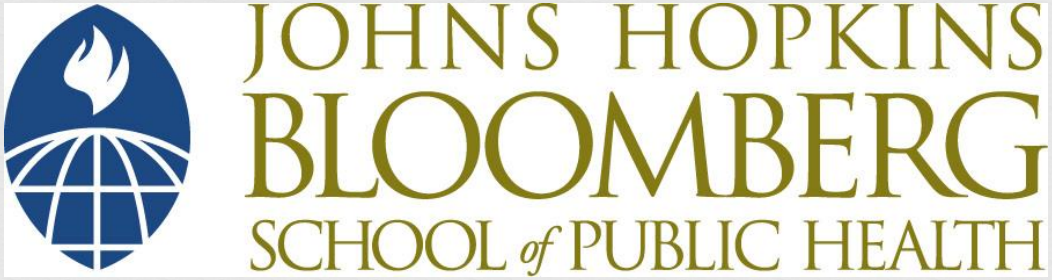
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