International Journal of Conflict and Violence

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Vol. 13/2019

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Suggested Citation:	APA: Harlacher, U., Polatin, P., Taing, S., Phana, P., Sok, P., Sothera, C. (2019). Education as Treatment for Chronic Pain in Survivors of Trauma in Cambodia: Results of a Randomized Controlled Outcome Trial, 2019. *International Journal of Conflict and Violence*, *13, 1-26.* doi: 10.4119/UNIBI/ijcv.655 Harvard: Harlacher, Uwe, Polatin, Peter, Taing, Sopheap, Phana, Pich, Sok, Phaneth, Sothera, Chim. 2019. Education as Treatment for Chronic Pain in Survivors of Trauma in Cambodia: Results of a Randomized Controlled Outcome Trial, 2019. *International Journal of Conflict and Violence 13: 1-26.* doi: 10.4119/UNIBI/ijcv.655

ISSN: 1864–1385

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Abstract:
Based on the hypothesis that pain is a stand-alone problem, not just a symptom of Post-Traumatic Stress Disorder (PTSD), the effect of group psycho-education ("pain school") for survivors of the Khmer Rouge regime with pain-PTSD comorbidity was tested in Cambodia in 2015. After baseline assessment comprising pain-related measures (Brief Pain Inventory, Disability Rating Index) and measures for PTSD, anxiety, depression, and distress, 113 subjects were randomized to a waitlist control group (CG, n = 58) and a treatment group (TG, n = 55). After treatment TG improved significantly, with clinically relevant effect size. Effect size was, however, substantially lower than in two prior pilot trials, and the improvement was not maintained at six-month follow-up. The main reason for this is hypothesized to be that the intervention had been delivered in too condensed a format. It is concluded that treatment addressing pain can also ameliorate mental health problems, implying that more attention should be paid to pain treatment for subjects suffering from pain/PTSD comorbidity.

Keywords: pain school, chronic pain treatment, PTSD and persistent pain, trauma and pain, randomized controlled outcome trial in developing country

A high prevalence of chronic benign pain (persistent pain after healing of acute injury/disease not explained by progressive disease) is well-known in developed (Institute of Medicine of the National Academy of Science 2011) as well as in developing countries (Vos et al. 2012; Tsang et al. 2008). Physical trauma such as burns, or surgery, are typical starting points for the development of chronic pain (Ulrich 2007; Stone et al. 2013; Ganapathy, Brookes and Jon 2011). Accordingly, an elevated prevalence of chronic pain is to be expected among survivors of torture/organized violence who experienced physical injuries. Survivors of atrocities committed by the Khmer Rouge regime represent an example of a population with expected elevated pain prevalence. Even though a high prevalence of pain among torture survivors is known (Amris and Williams 2007; Harlacher, Polatin and Nordin 2016), treatment to date mainly addresses mental health problems like PTSD (Weiss et al. 2016), probably on the grounds that pain is perceived as an epiphenomenon of PTSD and labeled as "somatization" (Goradietsky 2012) or similar. A recent Cochrane study on treatment of persistent pain in torture survivors (Baird et al. 2017), identified worldwide three controlled trials: Wang et al. 2017; Liedl et al. 2011; and Kim and Yu 2005. In Kosovo, Wang et al. tested the effect of a "multidisciplinary intervention" consisting of ten individual sessions of "biofeedback supported" exposure therapy focusing on PTSD and ten group sessions of "physiotherapy and exercises on a weekly basis over a three-month period." Both the treatment (n = 13) and waitlist control group (n = 15) received vitamin-pills. In Germany and Switzerland, Liedl et al. compared one group receiving ten sessions

of Cognitive Behavioral Therapy (CBT) combined with Biofeedback (n = 10), and one group receiving the same treatment plus physical activity (n = 10), with a waitlist control group (n = 10). In South Korea, Kim and Yu compared the effect of complex physiotherapy (n = 15) versus self-treatment at home (n = 15). The Cochrane report judged the quality of evidence of these studies as "very low" in all categories. Additionally, ten uncontrolled studies were identified with reported pain-related outcomes. Three of these used psychoeducation as treatment, as in the present trial. One of the three is our first of two pilot studies conducted in Cambodia as preparation of the present trial (Phaneth et al. 2014). The other two studies were conducted in Sweden with traumatized refugees by Blyhammar and Larsson (2009) and Jansen et al. (2011), with n = 13 and n = 38 participants respectively. Both Swedish trials measured the effect of ten two-hour group-based pain school sessions. Besides a general positive outcome in both trials, Blyhammar and Larsson report pain reduction and Jansen et. al. an improvement in anxiety and life satisfaction. It can be concluded that persistent pain in survivors of torture/organized violence is a rarely addressed problem. The limited available literature on pain psychoeducation suggests a positive impact.

Based on the possibility that psychoeducation for chronic pain could be a cost-effective intervention in resource-scarce contexts, a cooperation between the Danish Rehabilitation and Research Center for Torture Survivors (RCT, renamed "DIGNITY" in 2012) and the Transcultural Psychosocial Organization (TPO) Cambodia was established in 2010. The purpose of this cooperation was to develop, implement and evaluate a "Khmer Pain School" and in case of positive outcomes, to disseminate it.

1 Hypotheses and Objectives

Hypotheses:

1. Pain school participants improve after treatment relative to an untreated control group to a clinically relevant extent, with the effect lasting at six-month follow-up.

2. Improvement is not limited to directly pain-related measures but is also seen in measures of PTSD, anxiety, depression, and distress. This hypothesis is based on clinical experience that amelioration of pain problems also effectuates amelioration in mental health problems (and vice versa).

A further general objective is to collect descriptive information and estimate the prevalence of pain and PTSD in the study population.

2 Method

2.1 Study design

The study-design is a parallel-group randomized trial with a treatment (TG) and waitlist control group (CG), see Figure 1. The research plan was approved by the ethical committee (established for contexts in which reliable external ethical review systems are not available) of the Danish cooperator, which also funded the study. The trial was conducted between February 2015 and January 2016. Pending funding approval, it was planned to provide post–follow-up Testimony Therapy (TT, a treatment addressing mental health problems like PTSD) to TG and to evaluate this outcome as well as to evaluate the outcome for the (delayed) pain school participation of CG.

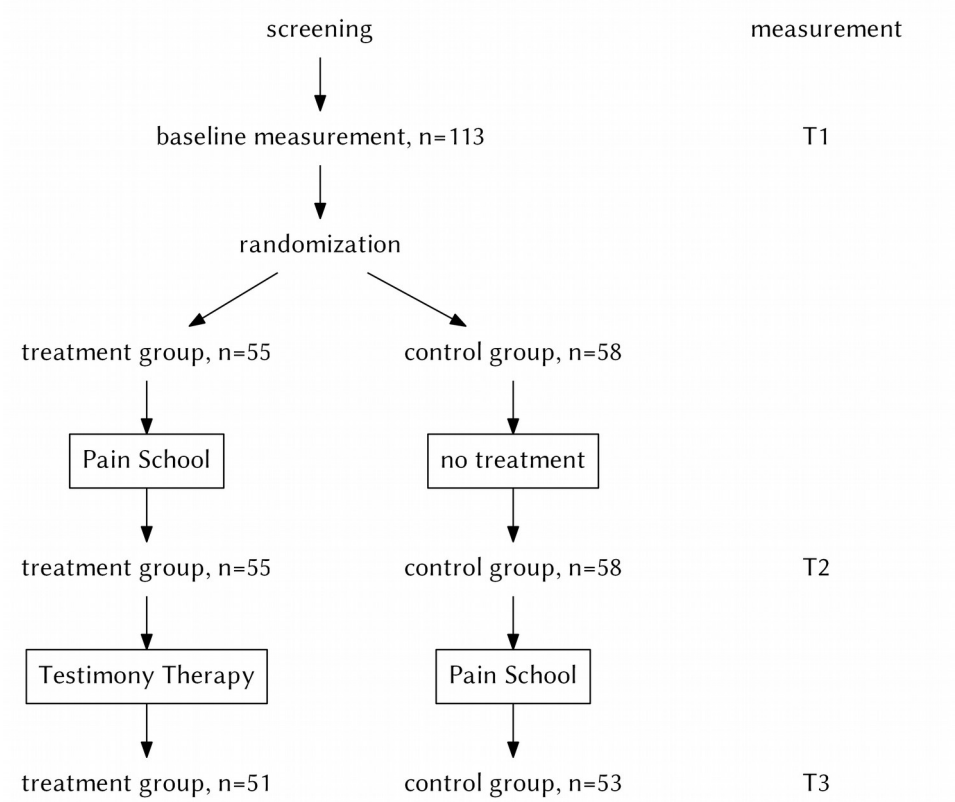
2.2 Study Population, Randomization to Study Sample and Eligibility Criteria

Participants were recruited from four thousand civil party applicants at a judicial trial against responsible members of the Khmer Rouge regime. Three hundred subjects were randomly chosen for screening (using Random.org). Eligible subjects participated in baseline assessment and those finally included were randomized to CG or TG. A Brief Pain Inventory sum score ≥ 25 and a PTSD Checklist sum score ≥ 30, access to a phone and being Buddhist were inclusion criteria. Pain due to an ongoing disease, severe psychiatric illness (including substance dependency) and suicidality were exclusion criteria (see supplement topic 2 for more information).

2.3 Education of Therapists and Intervention

During initial missions to Cambodia, RCT staff observed TPO patients obviously suffering from pain typically related to previous trauma-associated physical injury, which TPO staff were neither aware of nor able to treat. In subsequent missions, RCT staff provided education about chronic pain and introduced

Figure 1: Study Design



the group-based "Pain School" (which had been successfully used with RCT-patients in Copenhagen) to 15 TPO therapists. The RCT "Pain School" comprises education about chronic pain and appropriate ways to deal with it. It is interdisciplinary, covering biological/medical aspects (such as appropriate medication) as well as psychological aspects (such as correction of catastrophizing thinking about pain). The pain school "teachers" are usually two therapists, one with a somatic background (physiotherapist or physician) and one with a psychosocial background (social worker or psychologist).

The education delivered to TPO was interactive, with the content communicated stepwise, and each step discussed with TPO staff to reflect on whether the content needed modification to fit into the Cambodian context. TPO staff contributed for example by modifying illustrative case examples. One major modification involved reliance on psychosocial therapists, since somatic therapists such as physiotherapists were not readily available in Cambodia. Somatic/physiological aspects of the intervention therefore had to be covered by therapists not originally educated for this task.

The education resulted in a first version of a "Khmer Pain School" manual, which was used in two pilot trials (Phaneth et al. 2014; Harlacher et al. 2016; see supplement topic 1 for further references). Twelve therapists, working in pairs, delivered six Khmer pain schools, comprising ten weekly two-hour sessions for fifty-two clients, who showed large improvement from pre- to post treatment. While preparing the main trial, the question of whether the treatment format could/should be condensed to eight Pain School sessions given during one week was intensely discussed. The main argument for applying this format was based on the disadvantages associated with the delivery of an extended weekly treatment format in a resource-scarce context in which patients possess limited ability to cover costs of transportation and accommodation associated with longer journeys to the location of treatment. Based on the consideration that the pain

school comprises primarily education and to a much lesser extent treatment elements explicitly requiring training, it was finally decided to accept the risk of less successful treatment outcomes, and to apply the condensed format. In January 2015, the first author provided a final training session and an updated second Khmer Pain School manual was finalized (available on request to the first author).

The intervention was delivered by eight TPO therapists (working in pairs), who had received training and gained practical experience through their involvement in the pilot trials. Six pain-schools were conducted for TG and six for CG, all at TPO headquarters in Phnom Penh. Therapists had access to supervision by the principal therapist and (via e-mail or Skype) by the first author.

2.4 Measures

See in Table 1 for collected descriptive information. Except for "previous pain treatment" and "pain duration," the items are the same as in the trial by Esala and Taing 2017 on Testimony Therapy; the PCL, HSCL-25 and TPO BI described below were previously used in that trial.

The following instruments were used as outcome measures. The internal consistency (Cronbach's Alpha) is given for each measure, computed on the baseline data (T1, n = 113); for all measures, higher scores are indicative of more pronounced symptomatology.

Brief Pain Inventory (BPI), short form (Cleeland 1991): used to measure pain severity and the degree to which pain interferes with wellbeing and function; consisting of eleven items answered on category scales ranging from 0 to 10. The mean of the first four BPI items constitutes the "pain intensity" subscale (Cronbach's Alpha = .81) and items 5 to 11 the "pain interference subscale (Cronbach's Alpha = .82).

Disability Rating Index (DRI) (Salén et al. 1994), Cronbach's Alpha = .83: measures disability caused by impairment of common motor functions and is widely used for pain-related assessment. It comprises twelve items addressing reduced functioning in everyday life situations, which are usually answered on a visual analogue scale (VAS). For the present study a numeric scale ranging from 1 ("no difficulty") to 5 ("complete difficulty") was used, as this was easier for Cambodian subjects to understand. The mean of all items constitutes the DRI score.

BPI and DRI had already been used with translated items in pilot study 1, and with retranslated items in pilot study 2, and can be considered as "primary outcome measures"; the instruments described below are "secondary outcome measures." As described in section 1.2., however, we expected a correlation of "primary" and "secondary" outcome.

PTSD checklist (PCL) (Blanchard et al. 1996), Cronbach's Alpha = .86: a widely used seventeen-item self-report rating scale of PTSD symptoms. Respondents rate the severity of their symptoms on a five-point scale (ranging from 1 = "not at all", to 5 = "extremely"), and the instrument provides a cut-off score (≥ 30) as the criterium for a PTSD diagnosis.

Hopkins Symptoms Checklist (HSCL-25) (Derogatis et al. 1974): a twenty-five item self-report measure with two subscales: anxiety (ten items) and depression (fifteen items). Items are answered on a four-point scale ranging from 0 ("not at all") to 3 ("extremely"). The HSCL-25 is internationally the most widely used measure for anxiety and depression in survivors of torture/organized violence. Cronbach's Alpha for anxiety is .87 and for depression .83.

TPO-Baksbat Inventory (TPO BI) (Sothera 2012), Cronbach's Alpha = .92: is an "indigenous" Cambodian twenty-four-item checklist measuring three subdimensions of trauma-based psychological distress. In the present study we use the Inventory's total score ("psychological distress") over all items that are answered on a scale from 0 ("not at all") to 4 ("very frequent").

2.5 Determination of Sample Size

Available resources limited the maximum sample to n = 120, with an expectation of 40 completers in each group. Based on the pre-post overall mean effect size of 1.84 in the two pilot trials, we expected that a clinically relevant effect size of .50 should be achievable. A power analysis (Faul, Erdfelder, and Buchner 2007) with an alpha of .05 and a power of .95 found a treatment effect size of ≥.44 in a repeated measurement analysis of variance in order to detect a treatment

effect; it was therefore assumed that the achievable sample size would be sufficient.

2.6 Data Analysis

SPSS version 23 was used for most statistical computations. Calculators available on the internet were used for effect size (Psychometrica), Chi-square (MedCalc's comparison of proportions calculator) and for Fisher exact test (Socscistatistics.com) calculations. Two-sided testing and an alpha level of ≤ .05 is applied for all comparisons.

For group comparability at baseline, t-tests (Man-Whitney U-test for pain duration) were computed for continuous variables and Fisher exact tests for categorical variables (after dichotomizing descriptives with more than two categories: farmer/non-farmer, married/other, none and primary school versus longer education).

Outcome-measure group means were compared by analyses of variance (ANOVA) for repeated measures from T1 (baseline) to T2 (after treatment), T2 to T3 (follow-up) and T1 to T3; additionally, change-score differences were computed and t-tests for T3-outcome.

Effect size analysis comprises both within-group and relative effect from T1 to T2, T2 to T3 and T1 to T3. The baseline (n = 113) standard deviation is used as denominator and the respective group mean difference as nominator. To explore the hypothesis that treatment gain is not limited to the primary BPI and DRI outcome, the mean effect size for the associated three directly pain-related scales (labelled "Pain Score") was computed as well as the mean effect size for the four not directly pain-related scales (labelled "Non-Pain Score") associated with the secondary outcome in PCL, HSCL-25 and Psychological distress.

In line with the desired outcome of 30 percent symptom relief in the Cochrane report (Baird et al. 2017), reliable change was computed using a criterion of ≥ 30 percent change from baseline. To achieve a "net outcome" comparison, simultaneously considering both improvement and deterioration, the proportion of improved CG subjects was compared (using chi-square statistic for proportions, MedCalc) with the proportion of improved TG subjects, the latter adjusted by subtracting the difference between percentage deteriorated TG and percentage deteriorated CG (see supplement topic 5 for additional information). Since a percentage change criterion could be perceived as arbitrary, an alternative analysis based on critical change scores sensu Jacobson and Truax (1991) was also computed (see supplement topic 5).

The Relative Risk for improvement ("RR+" = % improved TG divided by % improved CG subjects) and for deterioration ("RR-" = % deteriorated TG divided by % deteriorated CG subjects) were also computed. A proportion of 1 indicates no group difference, a proportion > 1 an increased risk and a proportion between 1 and 0 a reduced risk. Following the suggestions of Monson (1990), an increased risk of ≥ 1.5 and a decreased risk of ≤ .70 is interpreted as a "moderate to strong" association and as clinically relevant.

Analysis of potential outcome moderators was conducted for TG. The descriptives as described above were assumed as moderators and correlated (Pearson, Spearman for pain duration) with the outcome measure change scores from T1 to T2 and T1 to T3. In case of a significant correlation, a closer analysis was conducted using t-tests, for continuous predictors comparing median-split subgroups (for example for age: below median = "younger", above median = "older").

Drop-out analysis was conducted by comparing all drop-outs (n = 9) versus all completers (n = 104), CG drop-outs (n = 5) versus CG completers (n = 53) and TG drop-outs (n = 4) versus TG completers (n = 51). The comparison again included the descriptives as above, as well as the outcome measures at T1 and T2 and the change scores from T1 to T2. ANOVA, Man-Whitney U-test and Fisher exact test were used depending on the kind of variables.

2.7 Dealing with Missing and Equivocal Data

The proportion of single missing data points in the outcome measures is 0.29 percent roughly equally distributed over the three measurements and variables. These missing data were estimated using the mean of the affected item, at measurement 1 the mean of the whole study sample and at measurements 2 and 3 the mean of CG or TG respectively. No imputation was applied for descriptive/demographic data, except for obviously available information, for example when "other trauma" was described but in a preceding item it was not noted that such other trauma had occurred.

One subject with a BPI score below the inclusion criterion was in error randomized to the treatment group and post hoc not excluded (negligible influence).

Figure 2: Participant flow chart

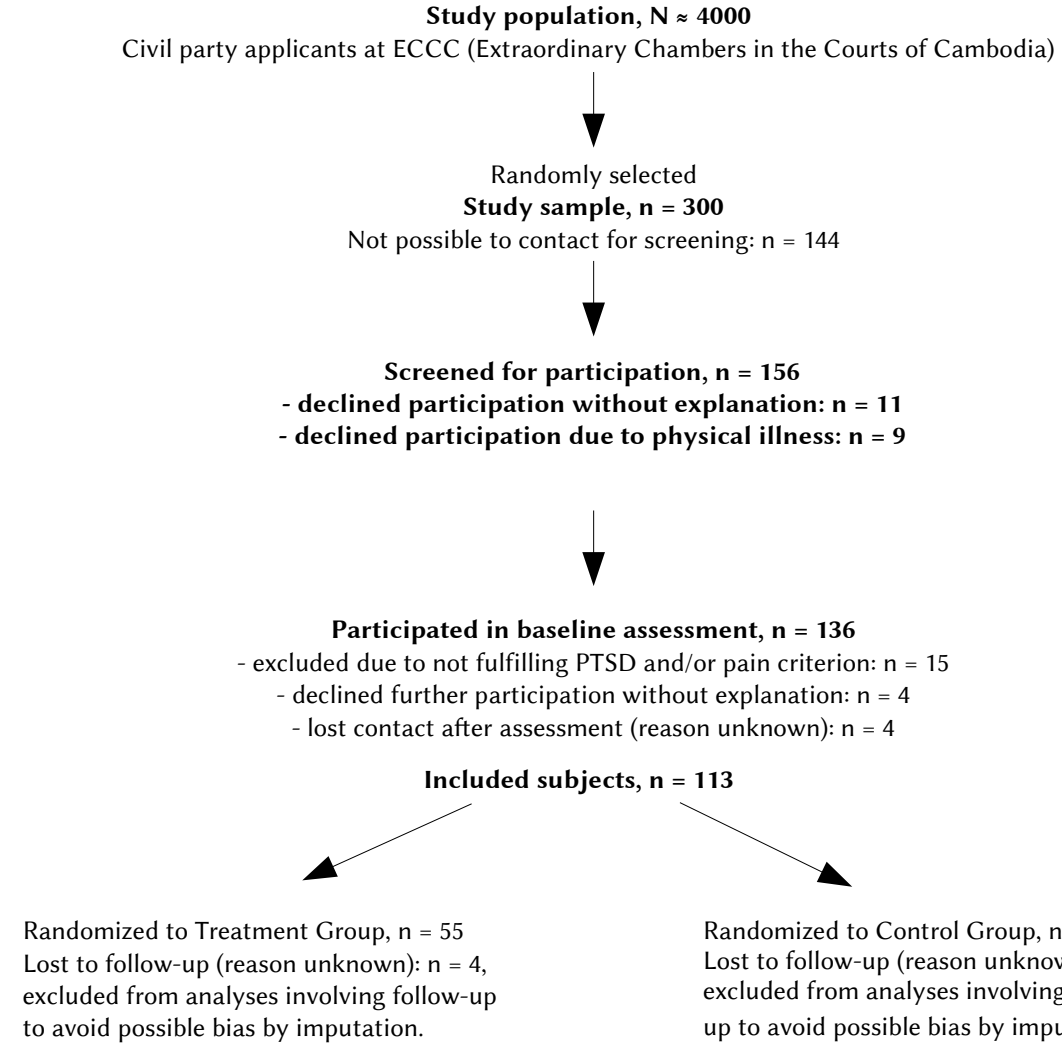


Table 1: Summarizing description of the control (CG) and treatment group (TG)

		CG n = 58	TG n = 55
Age	mean	60.43	60.05
	SD	9.11	7.53
Sex	female	34 (59%)	41 (74%)
	male	24 (41%)	14 (26%)
Occupation	farmer	37	35
	other	21	20
Civil status	married	36	35
	widowed	19	18
	other	3	2
Education	none	9	12
	primary school	32	25
	secondary school	5	8
	other	12	10
Number of children	mean	4.53	4.22
	SD	2.42	2.18
Family size	mean	5.22	5.11
	SD	2.40	2.35
Economic situation	poor	25 (43%)	20 (36%)
	average	33 (57%)	35 (64%)
Previous pain treatment	yes	56	53
	no/no answer	2	2
Number of trauma experiences	mean	12.43	12.09
	SD	2.70	2.85
	min-max	(6-17)	(5-18)
Pain duration	mean	46,79	45.74
< 120 months	SD	35.22	31.10
	n	38	38
Pain duration	mean	371.50	325.41
> 144 months	SD	64.16	86.52
	n	20	17

Table 2: Group means and standard deviations at baseline and after treatment

	T1 Mean/*SD*		T2 Mean/*SD*		Change score difference (dif CG – dif TG) /*CI 95%*	ANOVA time / *time by group*
Measure	CG	TG	CG	TG		F/p
1. Pain intensity	4.88	4.70	5.05	3.91	-.96	1.99/.161
Scale 0–10	*1.67*	*1.66*	*1.65*	*2.21*	*-1.83/-.08*	*4.82/.030*
2. Pain interference	5.88	5.58	5.18	4.36	-.53	27.14/.000
Scale 0–10	*1.60*	*1.61*	*1.59*	*1.96*	*-1.26/.12*	*2.07/.153*
3. Disability Rating Index	3.12	3.09	2.95	2.66	-.26	16.63/.000
Scale 1–5	*.66*	*.56*	*.60*	*.63*	*-.55/.03*	*3.22/.075*
4. PCL (PTSD measure)	2.86	2.91	2.69	2.46	-.27	20.64/.000
Scale 1–5	*.63*	*.57*	*.67*	*.61*	*-.54/-.00*	*3.94/.050*
5. HSCL-25 Anxiety	2.45	2.46	2.44	2.10	-.35	6.19/.014
Scale 0–3	*.71*	*.62*	*.67*	*.74*	*-.66/-.05*	*5.31/.023*
6. HSCL-25 Depression	2.45	2.40	2.42	2.03	-.34	8.98/.003
Scale 0–3	*.55*	*.49*	*.57*	*.70*	*-.60/-.07*	*6.25/.014*
7. Psychological distress	1.52	1.61	1.43	1.16	-.34	19.46/.000
Scale 0–4	*.77*	*.57*	*.59*	*.65*	*-.59/-.10*	*7.55/.007*

Control (CG, n = 58) and treatment (TG, n = 55) group means and standard deviations (SD) at baseline (T1) and after treatment (T2) and differences (CG minus TG) in change scores from T1 to T2 with 95% confidence intervals (CI). Repeated measurement Analysis of Variance (ANOVA) contrasts (F and p-values) for time (T1-T2) and interaction time by group.

Between measurement 2 (post-treatment) and 3 (follow-up), five CG (8.62 percent) and 4 TG-subjects (7.27 percent) dropped out. These cases are excluded from analyses involving T3 outcome; analyses with imputation of T2 outcome and imputation of group means at T3 were computed as well, not leading to major differences in results.

3 Results

3.1 Deviations from Research Plan

Due to insufficient funding only ten TG subjects could be offered Testimony Therapy (TT) and no resources were available for outcome evaluation after follow-up; therefore, no data are available on the outcome of TT nor on that of pain school for CG. DIGNITY dismissed all Danish staff involved in the project at the end of 2015, four months prior to the planned conclusion. The de facto premature project-discontinuation prohibited retrieval of otherwise accessible information, it is for example not possible to access information of TG-subjects who resided in a hotel during the week of pain school intervention. Data on participants' treatment expectation and whether "blinding" of assessors succeeded cannot be retrieved. TPO was provided with a video camera and a sample of pain-school sessions were filmed, but this material cannot be utilized for evaluation of treatment integrity. Further data analysis and publication of outcomes were delayed, and it has not been possible to include client-handout material in the English version of the Pain School manual, nor to realize the plan to publish the manual in a Khmer version.

3.2 Attrition of Subjects from Randomization to Follow-up Measurement

An overview of the participant flow is provided in Figure 2.

Table 3: Group means and standard deviations after treatment and at follow-up

	T2 Mean/*SD*		T3 Mean/*SD*		Change score difference (dif CG – dif TG) /*CI 95%*	ANOVA time/ *time by group*
Measure	CG	TG	CG	TG		F/p
1. Pain intensity	5.04	3.77	5.24	4.94	.97	11.72/.001
Scale 0–10	*1.67*	*2.15*	*1.59*	*1.76*	*.19/1.76*	*6.00/.016*
2. Pain interference	5.16	4.32	5.41	4.83	.27	.4.02/.048
Scale 0–10	*1.59*	*1.99*	*1.68*	*1.76*	*-.47/1.01*	*.52/.474*
3. Disability Rating Index	2.92	2.66	2.81	2.74	.02	.64/.80
Scale 1–5	*.59*	*.65*	*.59*	*.58*	*-.06/.42*	*2.28/.134*
4. PCL (PTSD measure)	2.68	2.48	2.60	2.61	.26	.18/.676
Scale 1–5	*.68*	*.61*	*.66*	*.68*	*-.04/.47*	*2.88/.093*
5. HSCL-25 Anxiety	2.42	2.09	2.28	2.43	.48	2.33/.130
Scale 0–3	*.68*	*.75*	*.67*	*.69*	*.22/.74*	*13.24/.000*
6. HSCL-25 Depression	2.43	2.01	2.34	2.41	.49	7.36/.008
Scale 0–3	*.58*	*.72*	*.61*	*.54*	*.26/-.73*	*17.84/.000*
7. Psychological distress	1.40	1.16	1.32	1.39	.31	2.13/.148
Scale 0–4	*.60*	*.66*	*.62*	*.70*	*.11/.51*	*9.39/.003*

Control (CG, n = 53) and treatment (TG, n = 51) group means and standard deviations (SD) after treatment (T2) and at follow-up (T3) and differences (CG minus TG) in change scores from T2 to T3 with 95% confidence intervals (CI). Analysis of Variance (ANOVA) contrasts (F and p-values) for time (T2-T3) and interaction time by group.

The data gained from the baseline assessment allow for an estimation of prevalence of pain and PTSD (as operationalized in this trial) in the study population. A conservative prevalence-estimation (see supplement topic 2 for detailed information) for pain is 80.8 percent, for PTSD 77.6 percent and for pain/PTSD comorbidity 75.6 percent.

All baseline-assessed subjects with incomplete information and all contacted subjects who declined participation were assumed not to be suffering from pain nor PTSD.

3.3 Descriptive Information

Descriptive information is given in Table 1 (see supplement topic 3 for less aggregated information including for CG/TG dropout and comprehensive results for previous pain treatment and trauma experiences). "Pain duration" is not normally distributed and therefore presented in two categories.

3.4 Comparability of Control and Treatment Group

No significant between-group differences were found in descriptives or outcome measures at T1, see supplement topic 4 for more information.

3.5 Comparison of Group Means

3.5.1 Comparison of Group Means from Baseline to after Treatment

The results for the group mean comparison from baseline to after treatment are given in Table 2.

Except for "pain intensity", both groups improved from T1 to T2 (significant ANOVA time effect). The improvement in TG is larger in all measures (negative change-score differences). The larger improvement in TG is significant (ANOVA interaction) except for Pain interference and Disability Rating Index. We interpret the overall outcome as compatible with a treatment effect for TG.

Table 4: Group means and standard deviations at baseline and follow-up

Measure	T1 Mean/*SD*		T3 Mean/*SD*		Change score difference /*CI*	ANOVA time/ *time by group*	Independent group T-test for T3
	CG	TG	CG	TG		F/p	T/*p*
1. Pain intensity	4.84	4.87	5.24	4.94	-.13	2.56/.112	.911
Scale 0–10	*1.67*	*1.70*	*1.59*	*1.76*	*-.95/.70*	*.09/.764*	*.365*
2. Pain interference	5.86	5.52	5.41	4.83	-.23	8.84/.004	1.700
Scale 0–10	*1.61*	*1.64*	*1.61*	*1.76*	*-.99/.54*	*.35/.554*	*.092*
3. Disability Rating Index	3.11	3.06	2.82	2.74	-.02	27.47/.000	.705
Scale 1–5	*.66*	*.56*	*.55*	*.58*	*-.26/.21*	*.04/.842*	*.483*
4. PCL (PTSD measure)	2.85	2.88	2.60	2.61	-.03	11.94/.001	-.051
Scale 1–5	*.60*	*.58*	*.66*	*.68*	*-.33/.28*	*.27/.870*	*.959*
5. HSCL-25 Anxiety	2.45	2.47	2.28	2.43	.14	2.22/.139	-1.147
Scale 0–3	*.71*	*.63*	*.67*	*.69*	*-.15/.45*	*.88/.350*	*.254*
6. HSCL-25 Depression	2.45	2.40	2.34	2.41	.13	.724/.397	-.653
Scale 0–3	*.56*	*.49*	*.61*	*.54*	*-.09/.34*	*1.35/.248*	*.515*
7. Psychological distress	1.53	1.59	1.32	1.39	.00	10.43/.002	-.498
Scale 0–4	*.77*	*.58*	*.62*	*.70*	*-.24/.25*	*1.35/.248*	*.619*

Control (CG, n = 53) and treatment (TG, n = 51) group means and standard deviations (SD) at baseline (T1) and follow-up (T3) and differences (CG minus TG) in change scores from T1 to T3 with 95% confidence intervals (CI). Analysis of Variance (ANOVA) contrasts (F and p-values) for time (T1-T3) and interaction time by group. T- and p-values for independent group T-test at T3.

3.5.2 Comparison of Group Means from after Treatment to Follow-up

The results for the group mean comparison from after treatment to follow-up are given in Table 3.

From T2 to T3, TG deteriorated (change-score differences positive) relative to CG in all measures, the difference being statistically significant (ANOVA interaction) in Pain intensity, Anxiety, Depression, and Psychological distress. We interpret the result as meaning that TG overall deteriorates upon follow-up.

3.5.3 Comparison of Group Means from Baseline to Follow-up

The results for the group-mean comparison from baseline to follow-up are given in Table 4.

From T1 to T3 there were only minor differences in the change scores, none being significant. No group difference in T3 outcome is observed in the t-test. There is a significant (ANOVA time effect) reduction in Pain interference, Disability Rating Index, PCL, and Psychological distress, independent of treatment condition. We interpret the outcome as meaning that there is no substantial difference between the groups at follow-up, implying that TG lost the gains found immediately after treatment.

Table 5: Within-group and relative effect sizes

	T1-T2			T2-T3			T1-T3		
	CG n=58	TG n=55	Relative d	CG n=53	TG n=51	Relative d	CG n=53	TG n=51	Relative d
Measure	**d**/*CI*	**d**/*CI*	**d**/*CI*	**d**/*CI*	**d**/*CI*	**d**/*CI*	**d**/*CI*	**d**/*CI*	**d**/*CI*
1. Pain intensity	**-.10**	**.47**	**.91**	**-.12**	**-.70**	**-.59**	**-.24**	**-.16**	**.08**
	-.41	*-.06*	*.53*	*-.66*	*-1.27*	*-.98*	*-.78*	*-.71*	*.46*
	.62	*1.01*	*1.29*	*.42*	*-.14*	*-.20*	*.30*	*.39*	*-.39*
2. Pain interference	**.43**	**.77**	**.33**	**-.15**	**-.32**	**-.17**	**.29**	**.43**	**.14**
	-.09	*.22*	*-.04*	*-.69*	*-.87*	*-.55*	*-.26*	*-.13*	*-.24*
	.95	*1.31*	*.70*	*.39*	*.23*	*.22*	*.83*	*.98*	*.53*
3. Disability Rating Index	**.27**	**.70**	**.43**	**.18**	**-.12**	**-.30**	**.49**	**.53**	**.04**
	-.25	*.15*	*.05*	*-.37*	*-.67*	*-.69*	*-.06*	*-.03*	*-.35*
	.79	*1.24*	*.80*	*.71*	*-.43*	*.09*	*1.04*	*1.09*	*.42*
4. PCL	**.29**	**.74**	**.45**	**.13**	**-.22**	**-.36**	**.42**	**.45**	**.04**
(PTSD measure)	*-.23*	*.20*	*.08*	*-.41*	*-.77*	*-.74*	*-.13*	*-.10*	*-.35*
	.81	*1.29*	*.82*	*.67*	*.33*	*.03*	*.96*	*1.01*	*.42*
5. HSCL-25 Anxiety	**.02**	**.55**	**.53**	**.21**	**-.51**	**-.72**	**.27**	**.06**	**-.21**
	-.49	*.01*	*.16*	*-.33*	*-1.08*	*-1.17*	*-.27*	*-.49*	*-.59*
	.54	*1.09*	*.91*	*.75*	*.05*	*-.32*	*.81*	*.61*	*.18*
6. HSCL-25 Depression	**.06**	**.71**	**.65**	**.17**	**-.78**	**-.95**	**.21**	**-.03**	**-.25**
	-.45	*.17*	*.27*	*-.37*	*-.1.35*	*-1.36*	*-.33*	*-.57*	*-.63*
	.58	*1.26*	*1.03*	*.71*	*-.21*	*-.55*	*.75*	*.52*	*.14*
7. Psychological distress	**.15**	**.65**	**.50**	**.12**	**-.34**	**-.45**	**.30**	**.30**	**-.004**
	-.38	*.11*	*.13*	*-.42*	*-.89*	*-.84*	*-.24*	*-.25*	*-.39*
	.68	*1.20*	*.88*	*.66*	*.22*	*-.07*	*.84*	*.84*	*.38*
Overall mean	.25	.66	.54	.08	-.43	-.51	.25	.23	-.02
Pain Score mean	.27	.65	.55	-.14	-.38	-.35	.18	.27	.09
Non–Pain Score mean	.13	.67	.53	-.16	-.46	-.62	.30	.20	-.10

Within-group (d) and relative effect sizes (relative d) with 95% confidence intervals (*CI*) for the three observation periods T1–T2 (baseline to after treatment), T2–T3 (follow-up) and T1–T3; a negative d indicates deterioration. Overall mean and mean for the directly pain-related measures (1.–3.: "Pain-Score") and the not directly pain-related measures (4.–7.: "Non-Pain Score").

Table 6: Reliable change analysis

	T1 -T2					T1 – T3				
	CG n = 58		TG n = 55			CG n = 53		TG n = 51		
	+	-	+	-	p	+	-	+	-	p
Pain intensity	10	15	23	14		7	5	11	12	
Group difference / CI	24.99% / (8.16 - 40.17)				.004	(-) 1.07% / (-12.39 - 4.34)				.870
RR+ / RR-	2.43/.98					1.63 / (-) 2.50				
Pain interference	12	8	19	6		11	8	12	12	
Group difference / CI	16.74% / (.02 - 32.42)				.051	(-) 5.66% / (-9.38 - 20.33)				.455
RR+ / RR-	1.67 / .79					1.13 / (-) 1.56				
Disability Rating Index	7	6	17	3		7	4	7	3	
Group difference / CI	23.73% / (8.05 - 38.28)				.003	2.19% / (-11.61 - 16.16)				.751
RR+ / RR-	2.56 / .53					1.04 / .78				
PCL (PTSD)	9	6	16	4		10	5	9	3	
Group difference / CI	16.64% / (.91 – 31.61)				.038	2.33% / (-13.05 - 17.76)				.768
RR+ / RR-	1.88 / .70					(-).94 / .62				
HSCL-25 Anxiety	9	12	20	8		10	7	7	11	
Group difference / CI	26.98% / (10.31 – 41.92)				.002	(-) 13.50%/ (.62 - 26.50)				.037
RR+ / RR-	2.34 / .70					(-).73 / (-) .1.63				
HSCL-25 dep.	5	10	19	7		5	5	5	6	
Group dif. / CI	30.44% / (14.98 – 44.51)				.000	(-) 1.96%/ (-9.86 - 13.71)				.721
RR+ / RR-	4.01 / .74					1.04 / (-) 1.25				
Psychological Distress	14	12	31	6		17	10	19	9	
Group difference / CI	42.00% / (23.90 - 56.39)				.000	6.39% / (-11.67 - 23.96)				.497
RR+ / RR-	2.33 / .53					1.16 / .94				
Overall mean	9.43	9.86	20.71	6.86		9.6	6.3	10.0	8.0	
Group difference / CI	25.92% / (9.19 - 40.97)				.003	(-) 2.30% / (-12.46 - 16.82)				.756
RR+ / RR-	2.28 / .72					1.08 / (-) 1.32				

Number of CG and TG subjects improving (+) and deteriorating (-) with ≥ 30% from baseline (T1) to after treatment (T2) and from T1 to follow-up (T3). P-values (p) and 95% confidence intervals (CI) for chi-square for proportions (MedCalc) comparisons of "net-improvement" in CG and TG (% improved CG versus % improved TG minus (% deteriorated TG minus % deteriorated CG)).

Relative Risk for improvement (RR+: % improved TG divided by % improved CG), and deterioration (RR-: % deteriorated TG divided by % deteriorated CG); a proportion of ≥ 1.5 (increased risk) and ≤ .70 (decreased risk) is assumed as clinically relevant (Monson 1990). Proportions indicating TG disadvantage are marked with "(-)".

3.6 Effect Size Analysis

Effect sizes are provided in Table 5.

The relative effect sizes from T1 to T2 are all in favor of TG, ranging from small to large with medium size overall. From T2 to T3 all relative effect sizes are disadvantageous to TG, overall with medium size. From T1 to T3, the relative effect sizes are all small, inconsistent in direction and the overall size is close to zero. We conclude that TG improved from T1 to T2, lost the improvement between T2 and T3 and from T1 to T3 does not substantially differ from CG. The relative effect size for "Pain Score" and "Non–Pain Score" is almost identical at T2 and broadly corresponding in the other effect sizes. We conclude that there is no substantial effect size difference between the directly pain-related and the not directly pain-related outcome measures.

3.7 Reliable Change Analysis

The outcome of the reliable change analysis is given in Table 6.

The relative risks for several outcome measures are based on small subject-numbers and dubious to interpret; interpretation is therefore limited to the overall mean of the outcome measures.

The "net difference" in proportion of improved subjects after treatment is in favor of TG in all outcome measures, and significant except for Pain interference. The "risk to improve" (RR+) is clinically relevant, overall 2.28 times higher for TG than for CG, while the risk to deteriorate (RR-) is reduced by 28 percent, (thus missing the criterion for clinical relevance by 2 percent). From T1 to T3 all "net differences" are smaller and both RR+ and RR- are close to 1 and overall clinically not relevant, indicating equivalence between the groups. A significant "net difference" in disadvantage of TG in Anxiety from baseline to follow-up could be suspected as a delayed negative effect of pain-school participation; this interpretation is, however, not supported by the result of the alternative reliable change analysis (supplement topic 5). It is concluded that the proportion of improved TG subjects after treatment is clinically relevant, that there is no clinically relevant difference in the risk to deteriorate and that the advantage of TG after treatment is lost upon follow-up.

3.8 Analysis of Moderators for Treatment Outcome

Significant but small (r between .29 and .33) associations with treatment outcome are found. Higher age is associated with poorer outcome in pain intensity. A larger family is associated with better outcome in anxiety and depression. More educated subjects improve more in pain interference and DRI. Of the t-test comparisons, only the difference between low versus more education in DRI change from T1 to T2 is significant. It is concluded that age, family size and education are associated with outcome in individual measures and, with exception of the association between education and DRI change, to an only moderate degree. See supplement, topic 6 for more detailed information.

3.9 Drop-out Analysis

No association with dropout is found; closest to significance ($p = .085$) is higher pain intensity after treatment in TG dropout (all female), see supplement topic 7 for more information.

4 Discussion

One major limitation of the study is that funding was insufficient to cover all participants residing in a hotel and thus providing CG a "placebo" treatment, resulting in the potential bias that a proportion of the TG subjects resided in a hotel during the intervention while CG did not (apart from a proportion on the night before assessments). Since information about participants residing in hotel is not retrievable, a potential impact of this factor on outcome cannot be analyzed.

Lack of information on treatment expectancy and on the success of blinding assessors to treatment condition are further sources of potential bias, due to loss of access to data. Not being able to evaluate treatment integrity is another limitation. Although the therapists were well-trained and there were no indications for this during supervision, it cannot be excluded that therapists deviated from the treatment manual. Data on participants' literacy levels and assistance provided by assessors are lacking, so the possible impact of this factor on assessment outcome cannot be analyzed; it can, however, be expected that random-

ization will balance potential influence between the groups.

Considering the limitations, we believe that the achieved study quality is sufficient to conclude as a main finding that a positive effect of pain school participation is probable but dissipates upon follow-up.

Since we are not aware of other studies in the development cooperation context on pain education for survivors of organized violence, we are unable to discuss the outcome in the context of broader empirical findings, other than from the two pilot trials conducted as preparation for the present study. The overall effect size in the pilot trials is 1.84 versus .65 for the corresponding effect in the present trial. Given the same study pool and essentially the same intervention, it is not likely that the large discrepancy is entirely explainable by differences in design such as lack of therapist-independent outcome assessment in the pilot trials. We hypothesize that poorer treatment outcome in the present study and the loss of treatment gains upon follow-up is mainly explained by the mistake of underestimating the negative impact of condensing the treatment format to one week instead of the ten-week format used in the pilot trials. We hope that future studies, using a less condensed pain school format, will be conducted to specifically test the alternative hypothesis that a sustainable improvement for patients with chronic pain is not attainable with a single time-limited intervention but, as in other chronic diseases, demands the provision of continuous care for a more extended period of time.

The positive impact of pain school intervention on PTSD and other mental health problems suggests that there is an interaction between pain and mental health problems. The hypothesis that improvement or worsening of one type of problem correlates with a congruent effect on the other type of problem needs to be tested in future studies, using both types of outcome measures. We also hope that future studies will be conducted to investigate whether combined treatment of pain and mental health problems will improve treatment outcome.

The pain school manual addresses only pain-related problems. Age, education, and family size influence outcome only partly and moderately. The present manual is constructed for use in a Buddhist context but can be adapted to any other context. It can therefore be assumed that the pain school intervention is applicable for broad target groups of chronic non-malignant pain patients with or without mental health comorbidity.

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Supplement for article: Education as Treatment for Chronic Pain in Survivors of Trauma in Cambodia: Results of a Randomized Controlled Outcome Trial

Topic 1	Pilot study 2 – summary
Topic 2	Study population, randomization to study sample and eligibility criteria – more detailed
Topic 3	Descriptive and demographic information – more detailed
Topic 4	Comparability of control and treatment group – more detailed description of used methods and results
Topic 5	Reliable change – more detailed information and alternative analysis
Topic 6	Analysis of outcome moderation – more detailed information
Topic 7	Dropout analysis – more detailed information

Topic 1: Pilot study 2 – summary

In pilot study 1 (n = 34), a positive outcome was observed after participation in four group-based "pain schools" (Phaneth et al. 2014). Subsequently, a second pilot trial, comprising eighteen participants on two pain schools delivered by two pairs of therapists, was conducted between August 2013 and March 2014. The treatment format comprised a ten-week period comprising one pain school session per week. The results have not been published other than as part of a presentation at a conference in December 2016 (Harlacher et al. 2016). The results are summarized in the following. The participants stemmed from the same study population as in the present trial: applicants at the ECCC (Extraordinary Chambers in the Courts of Cambodia). Deviating from the present study, the two pain schools were not implemented at TPO's main center in the capital Phnom Phen but at two of TPO's field centers, and clients came from different Cambodian provinces, most numerously Pursat (n = 8), Kampot and KG Speu (n = 3 respectively). The same outcome measures were used as in the first pilot trial (BPI and DRI), but with retranslated items resulting in a slightly modified wording.

Descriptive and demographic characteristics of the participants are presented in Table 1. including comparisons between included and excluded cases.

All clients who entered treatment (n = 18) completed it. Twenty-seven clients (preselected by attorneys) were screened for participation and all were judged as suitable for participation. Due to communication problems (changed phone numbers, no tele-communication coverage at subject's residence) and deteriorated health condition in a few cases, nine subjects, all male, could not be included in the trial. Since the reasons for non-inclusion are not gender-specific, it remains unexplained why exclusively men had to be excluded.

No significant differences were observed between included and excluded clients. "Farmer" was by far the most prevalent occupation category, Buddhist the predominant religion and economic problems (impaired ability to work and/or expenses for medicine) the most frequent pain consequence. Self-medication was, the most frequent among a variety of previously treatments and most clients experienced a positive, but temporary, effect of previous treatments. Regarding the experience of trauma, exposure to violence related to the Khmer Rouge regime is predominant. The mean duration of pain is obviously underestimated since five clients who described a pain onset clearly related to Khmer Rouge–inflicted violence reported suffering pain between "near twenty" and "thirty years" ago while the Khmer Rouge regime ended in 1979, which was already thirty-six years ago at the time of the research in 2015. The underestimation is probably due to participants failing to exactly determine the onset of very longstanding pain. An exact determination is, however, also complicated by the fact that the Khmer Rouge regime continued to control certain areas of Cambodia for many years even after 1979.

Table 1: Descriptive/demographic data for included and excluded clients.

	Included (max. n = 18)	Excluded/n (max. n = 9)	Test
Male/female	13/5	9/0	Fisher exact test $p \geq .14$
Married/widowed	11/3	6/3	
Buddhist/Muslim	11/3	6/3	
	Mean/SD/n	Mean/SD/n	T/p
Age	56.7 (5.2)/18	58.9 (3.8)/7	.98/.34
Duration of pain	22.7 (12.89)/16	25.5 (14.70)/9	.38/.71
Family size	6.69 (1.99)/16	8.29 (3.99)/7	1.30/.21
Number of children	4.53 (2.00)/15	5.57 (2.88)/7	.99/.34
Occupation			
Farmer	7	3	
Laborer	1	2	
Housewife	2		
Salesperson		1	
Civil servant		2	
Major adverse pain consequence			
Economic problems	10	5	
Other impairment	5	2	
Not analyzable		1	
Previous treatment			
Hospital/Health center	3	3	
Private clinic	3	4	
Self-medication	7	1	
Traditional healer	1		
Surgery	1		
Effect of previous treatment			
Improved	10	4	
Not improved	4	2	
Unanalyzable	2	2	
Type of violence experienced			
Khmer Rouge–related	9	7	
Domestic violence–related	2	2	
Other/not definable	5	0	

T/p-values for T-tests and p-values for Fisher exact tests (Socscistatistics.com) for the comparison between included and excluded cases (only for proportions that are not obviously equivalent by visual inspection)

Table 2: Means/SDs for outcome variables.

Measures	Pre Mean/SD	Post Mean/SD	T/p	d	Alpha	Dcrit	+	-
1. BPI-Pain intensity Scale 0–10	8.60 (.99)	4.67 (1.24)	10.43 /.000	3.50	.86	1.03	17	0
2. BPI-Pain interference Scale 0–10	8.61 (1.33)	4.07 (1.02)	12.81 /.000	3.83	.92	1.05	18	0
3. DRI index Scale 1–5	3.17 (.63)	2.12 (.55)	7.07 /.000	1.78	.87	.63	15	0
4. Total score (mean of above three measures, scale standardized to 0–10)	7.55 (1.03)	3.85 (1.00)	12.65 /.000	3.65	.68	1.62	16	0

T/p-values for paired sample t-tests and effect sizes ("d") sensu Cohen (Psychometrica.de. 2017). Internal consistency of each measure (Cronbach's Alpha) and critical value (Dcrit) for reliable change (prob. 95%) sensu Jacobson and Truax 1991. "+/-" = with at least the critical value improved/deteriorated.

Mean differences, effect sizes and reliable change

The results for the outcome variables are given in Table 2. All comparisons between before and after treatment indicate a statistically significant improvement with some very large effect sizes. The internal consistency of all outcome variables is high and almost all clients improved while no client deteriorated.

Outcome moderation

No significant correlation with gender, age, and duration of pain was found for the difference scores of the four outcome variables. The DRI change score was positively correlated with family size (r =. 74, p = .001) and number of children (r = .54, p = .039), i.e. the larger the family and as more the children, the better the DRI outcome.

Negative outcome

On the basis of the quantitative findings, there are no indications for cases with a negative outcome. Only in one single case, in the DRI-index, was a small negative change observed (- 0.18). The therapists did not receive (or at least not perceive) any client feedback indicating negative experience related to pain school participation.

Conclusions

1. The outcome indicates that there might be a positive effect of the applied pain school intervention.

2. The positive outcome seems to be largely independent of gender, age, number of children and pain duration. A large family and the number of children seem to increase positive DRI outcome.

3. There are no indications for subgroups with negative response.

Though statistically not significant, there might be difficulties recruiting male subjects for the treatment.

After the second pilot study, it was concluded that there was enough preparation to conduct a controlled experimental trial. The very large effect sizes (even though these must be interpreted with caution due to small sample size) encouraged the assumption that it would be possible to detect a true Pain school effect with a realistically achievable sample size providing acceptable statistical power.

Topic 2: Study population, randomization to study sample and eligibility criteria – more detailed

The study population comprises about four thousand survivors of the Khmer Rouge regime who were civil party applicants at the ECCC (Extraordinary Chambers in the Courts of Cambodia), a court established to try the most senior responsible members of the Khmer Rouge regime. TPO had a role in the ECCC as a consulting institution and provided psychosocial support to survivors. Via cooperation with the survivors' attorneys, TPO had access to the list of ECCC applicants. The study population included subjects living in the capital Phnom Penh as well as subjects from urban and rural areas in the provinces. It is known that almost all clients in the study population suffer from at least some PTSD symptoms, that about one-third are partly or entirely illiterate. From the pilot studies is known that there is a sizable prevalence of pain.

From the list of ECCC applicants, three hundred were randomly chosen, using Integer Generator (Random.org). Six times during 2015, fifty subjects were chosen (the first five times randomly, again using Integer Generator) and individually screened either by phone or home visits. Eligible subjects were invited to one of six baseline assessments conducted during 2015 at TPO's main office in Phnom Penh. After assessment eligible subjects were randomly assigned to either CG or TG (using RANDOM ORG "Coin Flipper") and informed about their allocation. TG subjects were invited to the next pain school. The recruitment procedure upon screening was implemented by TPO staff experienced in this task (including from a previous study with similar design). Randomization was performed by the research coordinator (fourth author) who was not involved in treatment delivery. The baseline as well as all subsequent assessments were conducted by experienced external professional assessors, independent of TPO and hired for the task. The assessors were not informed which group participants belonging to. Seven assessors conducted the assessments at T1 and T2 and four assessors at T3. The assessment was individual, at the same time and place (TPO main office) but on separate floors for CG and TG. The second assessment was conducted immediately after the intervention (last day of pain school) and the third approximately six months later. Participants partly or entirely unable to read and write received help from the assessors to answer the questions (in case of complete illiteracy the questions were read by the assessors and the answers written down on behalf of the participant). Participants coming from the provinces (CG for the night before assessment) were accommodated in a hotel of simple standard, free of cost. The treatment and the transfer to/from the hotel was free and the participants received a small per diem for food (US$7/day). Participants from the Phnom Penh region, living near the treatment location, were provided the same per diem but stayed at home overnight. Informed consent secured verbally at screening and in writing at baseline-assessment.

Inclusion criteria were: persistent pain (> 6 months) and PTSD comorbidity, operationalized by a BPI (all items) sum score ≥ 25 (at least moderate pain, derived from pilot studies) and a PCL-sum score ≥ 30 (at least moderate PTSD), subject being reachable by phone (own or within family or close neighbors), being Buddhist (due to the plan to offer TG Testimony Therapy which includes a Buddhist ceremony).

Exclusion criteria were pain explained by an ongoing disease, severe psychiatric/psychotic disorder and/or severe substance dependency, suicidality.

To contact potential participants for screening via phone became a demanding task due to out of date phone numbers, poor telecommunication coverage, and other technical/logistical problems. Of the three hundred subjects in the study sample, 48 percent could not be contacted. For subjects who could be contacted by phone either directly or indirectly, screening by phone could be conducted for only seventy-six subjects. For eighty subjects the screening necessitated home visits/personal meetings causing a significant burden for TPO in terms of time and resources.

Based on the information collected during the screening and first assessment, it is possible to estimate the prevalence of pain and PTSD in the study population, applying the operationalization in the present study – a BPI sum score of ≥ 25 and a PTSD-checklist score of ≥ 30. Assuming that all twenty sub-

jects excluded after screening did not meet the criteria for pain and PTSD and three subjects with missing data regarding pain in the first assessment did not suffer from a pain problem, a conservative estimation of 80.8 percent with pain is found (126 out of 156 screened subjects). The prevalence of PTSD can be estimated at 77.6 percent (121 out of 156 screened subjects) and the prevalence of pain/PTSD comorbidity at 75.6 percent (118 out of 156 screened subjects).

Topic 3: Descriptive and demographic information – more detailed

Table 3 expands the information provided by Table 1 in the article, including descriptives for CG and TG-dropout. "Pain duration" is statistically not normally distributed (having two "peaks") and the overall mean and SD is therefore supplemented by two subcategories.

Given that the subjects were victims of the Khmer Rouge regime that was in power between 1975 and 1979, the study population has a high mean age of slightly above sixty years.

A few participants were born during or shortly after this period but were nevertheless defined as victims of the Khmer Rouge regime on the basis of the circumstance that the regime continued to control certain areas of Cambodia for many years after 1979. The studied group comprises 66 percent women, 64 percent working in agriculture, almost 96 percent either married or widowed, and 68 percent have no or limited (primary) school education. The average size of household is little more than five persons and the number of children is around 4.5. The participants describe their economic situation as either "poor" (40 percent) or "average"; the category "wealthy" was not chosen.

Only four subjects described the duration of pain as thirty-six years or longer even though the Khmer rouge regime (counting from 2015) had ended thirty-six years earlier (1979). One possible explanation is that reporting over such a long time-span is not expressed in a mathematically correct manner but rather as a rough subjective estimate. As already identified in the two pilot trials, it is a problem to clearly determine whether a current pain problem is due to incidents related to the Khmer Rouge regime, even though a large proportion of the participants report such an association (even though mathematically incorrect). For the subgroup of participants reporting a pain onset much more recent than the end of Khmer Rouge influence, other reasons for pain onset or at least other reasons for aggravating preexisting Khmer-Rouge–related pain have to be assumed. The data do not allow an exact determination of the proportion of pain onset caused by physical injury coincidental with trauma inflicted by the Khmer Rouge regime or other and later reasons.

For the hypothesis that pain is interacting with trauma-related mental health problems, it is not assumed to be relevant whether pain onset and trauma (Khmer-Rouge or otherwise induced) are coincidental; it would however be of interest to study this question in future research.

Previous pain treatment

Almost all participants had previously received pain treatment. If answered with "yes" a first subsequent question was on care provider/place of treatment with predefined answer-categories; the answers are presented in table 4A. The answers given to a second subsequent question on eventual other provider/place of treatment with open answering format, is presented in table 4B (the answers slightly aggregated/categorized). The answers given on a third subsequent question about pain treatment procedure, with open answering format, is given in table 4C (answers slightly aggregated/categorized).

The answers given in table 4A can be interpreted as indicating that the degree of the pain problem is not trivial, especially when considering the subject's limited economic resources and the costs of pain treatment.

The same applies to the answers given in tables 4B and 4C even though the interpretability is limited due to a high proportion of non-responses (around 50 percent). Self-medication is named as the most common pain treatment, followed by traditional medicine. The relatively frequent use of surgery, a drastic intervention (which is usually without effect for chronic benign pain but rather associated with adverse outcomes) supports the interpretation that the participants suffer from non-trivial significant pain problems.

Table 3: Descriptive and demographic information, more detailed

		CG	TG	CG-dropout	TG-dropout
		n = 58	n = 55	n = 5	n = 4
Age	Mean	60.43	60.05	55.4	59.5
	SD	9.11	7.53	8.30	6.56
	Min-max	38-77	44-74	44-66	54-69
Sex	Female	34 (59%)	41 (74%)	4	4
	Male	24 (41%)	14 (26%)	1	0
Occupation	Farmer	37	35	4	3
	Skilled laborer	2	0	0	0
	Unskilled laborer	1	1	0	0
	Civil servant	5	3	0	0
	Salesperson	2	1	0	0
	Housewife/retired	8	13	1	0
	Blacksmith	1	0	0	0
	Garment worker	1	0	0	0
	Work for NGO	1	1	0	1
	Boatman	0	1	0	0
Civil status	Single	1	1	0	0
	Married	36	35	3	1
	Divorced	2	1	1	0
	Widowed	19	18	1	3
Education	None	9	12	0	1
	Primary school	32	25	3	1
	Secondary school	5	8	0	0
	High school	5	5	0	1
	Higher education	3	0	0	0
	Religious school	3	2	2	0
	Other	1	3	0	1
No. of children	Mean	4.53	4.22	4	4
	SD	2.42	2.18	3.10	2.45
	min-max	0–10	0–11	1–8	1–6
Family size	Mean	5.22	5.11	6.20	4.50
	SD	2.40	2.35	3.50	1.92
	min-max	0–11	1–11	3–12	3–7
Economic situation	Poor	25 (43%)	20 (36%)	3	0
	Average	33 (57%)	35 (64%)	2	4
	Wealthy	0	0	0	0
Suffer from pain?	Yes	58	55	5	4
	No	0	0	0	0
Previous pain treatment	Yes	56	53	5	4
	No/no answer	2	2	0	0
Pain duration (months)	Mean	157.42	133.00	56.40	69.00
	SD	163.14	140.42	40.61	82.19
	min-max	(5-456)	(12-480)	(24-120)	(24-192)
Pain duration ≤ 120 months	Mean	46,79	45.74	56.40	28.00
	SD	35.22	31.10	40.61	6.93
	n =	38	38	5	3
Pain duration ≥ 144 months	Mean	371.50	325.41	-	192.00
	SD	64.16	86.52	-	-
	n =	20	17	0	1
Number of trauma experiences	Mean	12.43	12.09	11.20	12.25
	SD	2.70	2.85	.84	1.71
	min.-max	(6-17)	(5-18)	(10-12)	(10-14)

Description of the control (CG) and treatment group (TG) and the CG (CG-drop) and TG (TG-drop) subjects who dropped out between measurements 2 (post treatment) and 3 (follow up).

Table 4A: Previous treatment for pain, predefined answer categories

Previous treatment for pain, Categorized	CG n = 58	TG n = 55	CG dropout (n=5)	TG dropout (n=4)
Private clinic	35	34	3	4
Hospital	7	4	1	
Traditional healer	3	5		
Health center	11	8	1	
Other		2		
No treatment	1	1		
No answer	1	1		

Table 4B: Previous treatment for pain, open answering format

Previous treatment for pain, Categorized (multiple answers possible)	CG n = 58	TG n = 55	CG dropout (n=5)	TG dropout (n=4)
Health center	6	7		1
Hospital and health center	6	1		
Hospital and traditional healer	2	4		
Traditional healer	2	4		
Traditional healer and health center	3	3	1	
Hospital	1	3		
Hospital, traditional healer and health center	3	1		1
Care by NGO	2	1		
Other	1	3	1	
No answer	32	28	3	2

Table 4C: Previous treatment for pain, kind of treatment procedure, open answering format.

Previous treatment for pain, categorized (multiple answers possible)	CG n = 58	TG n = 55	CG dropout (n=5)	TG dropout (n=4)
Self-medication	7	10	2	1
Self-medication and massage	5	1		
Self-medication and other treatment	2	1		
Traditional medicine (including magic and medication)	4	6		1
Traditional medicine and other treatment	2	2	1	
Surgery and other treatment	4	2		
Surgery	3	1		
Massage	1	2		
Injection	1	1		
Other		3		
No answer	29	26	2	2

Traumatic events

The responses to the items in the list on traumatic experiences are shown in Table 5.

The maximum number of traumatic experiences being twenty, the participants report between five and maximally eighteen experiences, characterizing the study population as having been exposed to multiple severe events.

The answers to item 20 of the trauma list ("Other trauma…?", see Table 5) are presented in Table 6, categorized into thematic themes.

Table 5: Trauma list and answers

	CG n = 58	TG n = 55	CG dropout n = 5	TG dropout n = 4
Please indicate whether you have experienced any of the following events (check YES or NO)	Yes/no/ missing	Yes/no/ missing	Yes/no/ missing	Yes/no missing
1. Lack of food and water	51/0/2	51/0/0	5/0/0	4/0/0
2. Ill health without access to medical care	49/2/0	50/1/0	0/5/0	0/4/0
3. Lack of shelter	46/5/0	43/8/2	4/1/0	4/0/0
4. Imprisonment	14/37/2	14/37/0	0/5/0	1/3/0
5. Serious physical injury from combat situation or landmine	26/25/0	19/32/0	4/1/0	0/4/0
6. Combat situation (e.g. shelling or grenade attacks)	9/42/2	6/45/0	0/5/0	0/4/0
7. Have you been sexually abused or raped	8/40/5	5/46/0	0/5/0	0/4/0
8. Forced isolation	43/8/2	47/4/0	4/1/0	4/0/0
9. Have you been close to death	45/6/2	45/6/0	5/0/0	4/0/0
10. Forced separation from family	46/5/2	45/6/0	4/1/0	4/0/0
11. Witnessed death of family member or friend	42/9/2	39/12/51	4/1/0	2/2/0
12. Witnessed murder of family member or friend	40/11/2	37/14/0	1/4/0	4/0/0
13. Torture	17/34/2	17/33/0	1/4/0	0/4/0
14. Witnessed torture	35/16/2	31/20/0	4/1/0	3/1/0
15. Witnessed murder of stranger	31/19/3	32/18/1	4/1/0	2/2/0
16. Forced to betray or harm someone	5/46/2	3/47/0	0/5/0	1/3/0
17. Forced marriage	17/34/2	13/35/3	1/4/0	1/3/0
18. Did you witness Khmer Rouge forced someone sexually	28/23/2	29/21/1	1/4/0	4/0/0
19. Witnessed one of the events in this list happened to someone else	51/0/2	51/0/0	5/0/0	4/0/0
20. Other trauma than those listed? - describe	25/6/22	30/2/19	4/1/0	2/1/1
Sum of trauma experiences				
Mean	12.43	12.09	11.20	12.25
SD	2.70	2.85	0.84	1.71
min-max	(6–17)	(5–18)	(10–12)	(10–14)

Table 6: Categorized answers to item 20 in Table 5 whether there has been trauma other than defined by items 1–19

	CG n = 58	TG n = 55	CG dropout (n=5)	TG dropout (n=4)
Enforced heavy work	8	10	0	2
Frequent moving from place to place	0	3	0	0
Enforced witnessing horrible things	1	0	0	0
Insulting, humiliation	4	2	1	0
Interrogation/accusation	4	2	0	0
Killing family members	9	13	0	1
Killing other than family members	3	3	0	0
Threat to kill	2	0	0	0
Torturing/severe physical hurting	3	3	1	0
Starvation (own and others, including to death)	2	2	1	0
Other	1	3	0	0
Missing cases (no answer given)	37	39	2	1

Topic 4: Comparability CG/TG

There are no significant differences between the groups in descriptives and outcome measures at baseline (T1) and the uneven distribution of gender is not significant (Fisher exact test value = .111). Since gender turned out not to be a moderator for treatment outcome (see topic 6), no corrective measures for gender (such as use as covariate) were applied.

Topic 5: Reliable change – more detailed information and alternative analysis

Regarding the comparison of proportion of subjects improved in CG versus in TG corrected by subtracting the difference between proportion of subjects deteriorated in TG and CG, there are three cases. In case of the same proportion of deteriorated in both groups, the difference is zero and the comparison between groups is directly based on the proportion of improved subjects. In case of a larger proportion of deteriorated subjects in TG, the difference is positive, and the amount subtracted from the proportion of improved TG-subjects. In case of a lower proportion of deteriorated subjects in TG, the difference is negative, and the amount added to the proportion of improved TG-subjects.

The results of the alternative reliable change analysis based on change scores sensu Jacobson and Truax 1991 are given in Table 7. The standard deviation and internal consistency (Cronbach's Alpha) derived from the baseline assessment (n = 113) were used for computation of critical change scores.

The relative risks for several outcome measures are based on small numbers of subjects and are dubious to interpret; interpretation is therefore limited to the overall mean of the outcome measures. The difference in proportion of "net improved" subjects after treatment is in favor of TG in all outcome measures and significant (except for borderline significant in "Pain interference" and "Disability Rating Index"). The "risk to improve" (RR+) is clinically relevant, overall 1.75 times higher for TG than for CG and the risk to deteriorate (RR-) is with 30 percent reduced at a clinically relevant level. From T1 to T3 all differences for "net improved" subjects are much smaller than between T1 and T2 and are not significant. Both RR+ and RR- are overall clinically not relevant and close to 1, indicating equivalence between the groups.

Table 7: Reliable change analysis

	T1 – T2					T1 – T3				
	CG n = 58		TG n = 55			CG n = 53		TG n = 51		
	+	-	+	-	p	+	-	+	-	p
Pain intensity	8	10	21	11		14	5	10	8	
Group difference, CI	21.63% / (5.76 - 36.41)				.008	(-) 13.07% / (-2.48 - 27.89)				.097
RR+ / RR-	2.77 / 1.16					(-) .74 / (-) 1.66				
Pain interference	13	4	20	3		3	9	5	12	
Group difference, CI	15.4 % / (- 1.48 - 31.28)				.075	(-) . 2.41% / (-7.32 - 12.42)				.554
RR+ / RR-	1.62 / .80					1.73 / (-) 1.39				
Disability Rating Index	13	7	17	3		3	17	2	10	
Group difference, CI	15.12% / (-1.74 - 31.01)				.080	9.66% / (-2.55 - 22.48)				.108
RR+ / RR-	1.38 / .45					(-) .69 / .61				
PCL (PTSD)	16	9	23	5		4	17	4	14	
Group difference, CI	20.74% / (2.87 - 36.94)				.024	4.92 / (-7.27 - 17.54)				.405
RR+ / RR-	1.52 / .59					1.04 / .86				
HSCL-25 Anxiety	12	11	20	7		7	11	8	11	
Group difference, CI	21.91% / (4.77 - 37.52)				.013	1.66% / (-12.06 - 15.55)				.808
RR+ / RR-	1.76 / .67					1.19 / -1.04				
HSCL-25 Depression	16	13	21	7		5	9	8	10	
Group difference, CI	20.27% / (2.42 - 36.49)				.027	3.63 / (-9.09 - 16.65)				.559
RR+ / RR-	1.38 / .57					1.66 / (-) 1.15				
Psychological Distress	11	7	26	5		3	15	6	17	
Group difference, CI	31.36% / (13.89 - 46.43)				.001	1.07% / (-.9.53 - 12.04)				.822
RR+ / RR-	2.49 / .75					2.08 / (-) 1.18				
Overall mean	12.71	8.71	21.14	5.86		5.57	11.86	6.14	11.71	
Group difference, CI	20.90 (3.66 - 36.65)				.018	.95% / (-.11.72 - 13.85)				.878
RR+ / RR-	1.75 / .70					1.15 / (-) 1.03				

Reliable change analysis sensu Jacobson and Truax 1991: number of control (CG) and treatment group (TG) subjects reliably improved (+)/deteriorated (-) from baseline (T1) to after treatment (T2) and from T1 to follow-up (T3) with ≥ a critical value computed on the measures' SDs and internal consistency (derived from baseline assessment, n = 113). P-values (p) and 95% confidence intervals (CI) for chi-square for proportions (MedCalc) comparisons of "net-improvement" in CG and TG (% improved CG versus % improved TG minus (% deteriorated TG minus % deteriorated CG)). Relative Risk for improvement (RR+: % improved TG divided by % improved CG), and deterioration (RR-: % deteriorated TG divided by % deteriorated CG); a proportion of ≥ 1.5 (increased risk) and ≤ .70 (decreased risk) is assumed to be clinically relevant (Monson 1990). Proportions indicating TG disadvantage are marked with "(-)".

It is concluded that the proportion of "net improved" TG subjects after treatment is higher at a clinically relevant level, that the risk to deteriorate is reduced at a clinically relevant level, and that these advantages are lost upon follow-up.
Since no substantial group difference is seen in the proportion of deteriorated subjects, the analysis gives no indication for a negative impact of pain school participation.

Topic 6: Analysis of outcome moderation – more detailed information

Age correlates with the change scores in pain intensity from T1 to T2 ($r = .33$, $p = .01$) and from T1 to T3 ($r = .29$, $p = .03$), with younger (< 60 years, $n = 25$) subjects improving more than older subjects (> 60 years, $n = 25$). Family size correlates from T1 to T2 with the change scores for both anxiety ($r = .30$, $p = .03$) and depression ($r = .32$, $p = .03$), those with a smaller family (< 5, $n = 23$) improving less than those with a larger family (> 5, $n = 22$) in both change scores.

Education correlates ($r = .31$, $p = .021$) with the DRI-change score from T1 to T2, with those with no/primary education ($n = 37$) showing smaller improvement (mean change = .26) than those with more education ($n = 18$, mean change = .76). Education also correlates ($r = .32$, $p = .02$) with the pain interference change score from T1 to T3, with subjects with less education improving less than those with more education. Of the observed differences, only education on DRI change from T1 to T2 is significant ($t = 2.37$, $p = .021$).

Topic 7: Dropout analysis – more detailed information

For the comparisons at baseline (T1) all TG dropouts are female. For the comparisons after treatment (T2), there is a borderline significant ($F = 3.09$, $p = .085$) difference between TG dropouts ($n = 4$) showing higher scores (mean 5.75, SD = 2.47) in "Pain intensity" than TG completers ($n = 51$, mean 3.77, SD 2.15). The absence of any other (borderline) significant differences leads to the conclusion that TG dropout is associated with some probability with a pain intensity above the mean after pain school participation.