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Interventions for treating persistent pain in survivors of torture (Protocol)

Baird E, Williams ACDC, Hearn L, Amris K

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Interventions for treating persistent pain in survivors of torture.
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[Intervention Protocol]

Interventions for treating persistent pain in survivors of torture

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the efficacy of interventions for treating persistent pain in survivors of torture.

BACKGROUND

Reports of torture and other ill-treatment come from over 150 countries (AI 2010). The International Rehabilitation Council for Torture Victims (IRCT 2010) estimates that around 400,000 torture survivors live in the European Union alone, with similar estimates in the United States of America (USA) (Jaranson 1995). Many diverse injuries are inflicted during torture and ill-treatment, usually in conditions of poor nutrition and hygiene, to a highly stressed individual, and without health care. The violence, extent, and complexity of injuries often lie outside medical problems addressed in textbooks and in the scientific literature (Amris 2007), and persistent pain is a common finding in survivors (Amris 2007; Rasmussen 1990). Pain is defined by The International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (IASP 1994). Persistent or chronic pain is commonly defined as pain that is present for more than three months, assuming the initial injury to have healed in that time. In the case of injury from torture, which commonly goes untreated, this may not be the case.

Unlike many other client groups, the health concerns of torture survivors are defined not primarily by diagnosis or recognised classification systems but by their experience of torture and other ill-treatment. Torture is a deliberate assault upon the body, the psyche, the identity and the integrity of the person, aiming to dehumanise, degrade, destroy or debilitate and render the individual helpless. It is defined by the United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT), Article 1 (UN 1984) as "any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a third person information or a confession, punishing him for an act he or a third person has committed or is suspected of having committed, or intimidating or coercing him or a third person, or for any reason based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with

the consent or acquiescence of a public official or other person acting in an official capacity. It does not include pain or suffering arising only from, inherent in or incidental to lawful sanctions" (UN 1984). By extension, torture undermines communities and groups whose members are targeted, spreading distrust and fear (Patel 2007). We will use the wider definition from the World Medical Association (WMA 2006): "the deliberate, systematic or wanton infliction of physical or mental suffering by one or more persons acting alone or on the orders of any authority, to force another person to yield information, to make a confession, or for any other reason."

Physical health problems related to torture have been widely documented (Jacob 2001; Moreno 2002; Norredam 2005; for reviews see Jaranson 2011; Montgomery 2011; Quiroga 2005), as have psychological health problems (e.g. Basoglu 2001; Johnson 2008; Patel 2007). Torture-related physical health problems not only cause disability and restricted functioning but also produce psychological problems, compounding the impact on overall personal and social functioning. Additionally, torture survivors in countries of exile can experience many social, legal and practical difficulties (e.g. seeking asylum, being subject to racist attacks, inadequate housing, inability to communicate in the language of the host country, and concerns for family and friends with whom they have lost contact) which may take priority over their health problems; they may also be uncertain about their rights to health care, which may be restricted, and fearful of any perceived authority (Burnett 2001).

Torture survivors may not be recognised as such within the health service (Crosby 2006; Eisenman 2003), and the health care offered or accessible to them falls short of their needs (Amris 2007; Amris 2015; Berliner 2005; Burnett 2001; Quiroga 2005). Psychological services offered by non-governmental organisations have very variable methods and skills (Patel 2014); both they and mainstream mental health services tend to have a poor understanding of persistent pain, and may attribute it to evident psychological disturbance, in particular post-traumatic stress.

Description of the condition

Physical torture is in most instances directed towards the musculoskeletal system, aiming at producing soft tissue lesions and pain and usually at leaving either no visible, or nonspecific, findings after the acute stage. Random beatings, systematic beating of specific body parts (the head, palms, soles, and lumbar region), strapping/binding, suspension by the extremities, forced positions for extended periods, and electrical torture are frequent (Rasmussen 1990; Williams 2010). Other physical methods include asphyxiation, near-drowning, stabbing, cutting, burning, and sexual assaults including hetero- and homosexual rape (Rasmussen 2006; Olsen 2007).

Persistent pain in the musculoskeletal system is recognised as one of the most frequent physical complaints presented by torture survivors (Amris 2007; Burnett 2001; Edston 2005; Olsen 2006; Rasmussen 1990; Rasmussen 2006), but other pain has been described and is often hard to classify or describe in terms of mechanism (Amris 2007; Lund 2008; Rasmussen 1990; Williams 2010). Survivors of torture are likely to present with complex and multiple pains, and often with moderate to severe symptoms of depression, anxiety, and traumatic stress (Berliner 2005; Serraj 1996). There is no basis for the widespread belief that pain from torture is in some way produced by psychological disturbance, other than pain triggered by re-experiencing traumatic events; the origin of pain in torture does however add to the complexity of assessment and treatment (Sjölund 2009).

Description of the intervention

Any treatment intended to relieve pain or improve function despite ongoing pain is a possible intervention. Thus interventions eligible for this review include pharmacotherapy by various routes (oral, sublingual, topical), peripheral nerve blockade and other injections, physiotherapy, psychological rehabilitative treatment, peripheral stimulation such as transcutaneous electrical nerve stimulation (TENS), acupuncture, neuro-modulation (including spinal cord stimulation), and complementary and alternative therapies.

How the intervention might work

There is no suggestion that interventions would work differently in survivors of torture than in anyone who is not a survivor of torture, only that (a) pain resulting from torture can be difficult to understand in the light of current knowledge, and (b) that survivors are, because of their experience, often hypersensitive to medical procedures required for diagnosis and treatment.

Why it is important to do this review

In the era of evidence-based health care, there is considerable emphasis on services providing treatments demonstrated to be effective. However, health care of torture survivors is almost entirely addressed within the psychological literature, with serious neglect of physical sequelae and their treatment. Populations are diverse in cultural, ethnic, religious and political backgrounds and are often unable to express themselves adequately in the language of the host country. Compared to the many reviews of interventions for psychological problems (see Jaranson 2011; Patel 2014), there are few reviews of interventions for medical problems, and all of them either brief and generalised (e.g. Quiroga 2005) or specific to particular injuries or treatments (e.g. Amris 2000a: Amris 2000b). Most of the literature on physical health difficulties experienced by torture survivors (before or without treatment) consists of clinical

opinions and case studies (for review, see Mollica 2011; for example, see Mckenna 2012). There are also descriptive studies which enumerate the variety of health problems of survivors, often published with the main aim of raising awareness and concern about the issues (Jaranson 2011; Montgomery 2011; Quiroga 2005).
Of more concern here is that in developed countries, which have contributed most to the literature on health care for refugee survivors of torture, the focus of clinical and research effort has been on the psychological sequelae, often described in terms of post-traumatic stress disorder (PTSD), rather than on the physical sequelae. This, combined with the slow spread of understanding of pain mechanisms among some medical and paramedical specialties, including psychology and psychotherapy, means that reported pain is often recorded as a psychosomatic presentation of psychological disorder, reducing usefulness for the pain clinician or researcher. This is reinforced by cultural influences, particularly dualistic tendencies in medicine, and the political representation of shared trauma as individual psychopathology (Bracken 1995; Watters 2001).

OBJECTIVES

To assess the efficacy of interventions for treating persistent pain in survivors of torture.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), cluster RCTs, and quasi-RCTs (QRCTs). We wish to be as inclusive as possible, and since we expect to find a small number of RCTs, QRCTs are included; also because some methods of quasi-randomisation used in underdeveloped country settings are unlikely to introduce bias.
There will be no restrictions on publication type, status, language or date, also to maximise search yield. We will include conference abstracts and other reports if full details can be obtained from the study authors, as relevant material is often published by torture survivor centres themselves.

Types of participants

Participants must be identified as survivors of torture or ill-treatment, consistent with the UN 1984 definition above, or at least 50% of the study population identified as such.
Torture survivors may be found among refugees, asylum seekers, war survivors and survivors of organised violence, and in diverse settings, such as prison, detention centre, refugee camp, accommodation centre, healthcare facility, and community. Participants of all ages will be included.

Types of interventions

Interventions can be of any modality and provided by any practitioner or self-administered, provided that they are primarily aimed at pain relief. Comparators can be any alternative condition: no intervention, waiting list, care as usual, standard care, alternative treatment, or placebo condition.

Types of outcome measures

We will include a 'Summary of findings' table as set out in the PaPaS author guide (AUREF 2012) and recommended in the *Cochrane Handbook for Systematic Reviews of Interventions*, chapter 4.6.6 (Higgins 2011), if sufficient data are available. The 'Summary of findings' table will include outcomes of pain reduction, quality of life indicators, global improvement/satisfaction and adverse effects. These will be distinguished as immediate (end of treatment), short-term (4 to 12 week), and longer-term (over 12 week) outcomes. We will use the GRADE approach (GRADEpro GDT 2015) to assess the quality of evidence related to each of the key outcomes (chapter 12, Higgins 2011), as appropriate. See Appendix 1 for a further description of the GRADE system.

Primary outcomes

- Pain relief or reduction in pain as reported by the participant, without which the study is not eligible for inclusion in this review. Pain or pain relief may be measured by any type of scale: numerical (including percentage), verbal, pictorial. The desired outcome is 30% pain relief or pain < 5/10 or equivalent on a numerical scale, or 'none' or 'mild' on a verbal scale.
- Adverse effects, including dropout or attrition.

Secondary outcomes

- Use of analgesics, as rescue analgesia or ongoing analgesic intake.
- Disability, overall function, interference of pain with normal life, or quality of life.
- Emotional distress, including anxiety, depression, traumatic stress symptoms, overall mood.
- Global improvement, satisfaction, as rated by participant.

Search methods for identification of studies

Searches will be conducted on electronic databases and web sites and by handsearching reviews and reference lists.

Electronic searches

We will use Medical subject headings (MeSH) or equivalent and text word terms. There will be no language restrictions. Searches will be tailored to individual databases. The search strategy for MEDLINE is shown in Appendix 2.

We will search the following electronic databases:

- CENTRAL (*The Cochrane Library*);
- MEDLINE (Ovid);
- EMBASE (Ovi);
- Web of Science (ISI);
- CINAHL (Ebsco);
- LILACS (Bireme);
- PsycINFO (Ovid).

Searching other resources

- OpenGrey (online database of reports and other grey literature produced in Europe);
- Trials registers for details of ongoing trials: (www.clinicaltrials.gov); the metaRegister of controlled trials (www.controlled-trials.com/mrct); the WHO: International Clinical Trials Registry Platform (ICTRP) (http://apps.who.int/trialsearch/);
- Reference lists of reviews and retrieved full papers;
- Citation searches on key articles;
- Online Library of the Rehabilitation and Research Centre for Torture Victims (RCT, now Dignity);
- Tables of Contents from the top 10 most frequently cited sources emerging from the search (expected to be journal issues);
- We will contact authors where necessary for additional information.

Data collection and analysis

Selection of studies

Two of the authors (AW, EB) will independently undertake an initial screening of titles and abstracts using the inclusion criteria, with the aim of identifying studies which may be eligible and for which the full paper should be obtained. Where abstracts are not available electronically, or leave uncertainty about the criteria, we will seek the full paper.

The full papers will be read and selected against the inclusion criteria by two of the authors (EB, LH) independently. The final list will be achieved after comparison, and disagreements will be resolved by discussion; where there continues to be doubt or difference, a third review author (KA) will be consulted to achieve consensus.

We will include a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart in the full review which will show the status of identified studies (Moher 2009) as recommended in Part 2, Section 11.2.1 of the *Cochrane Handbook* (Higgins 2011). We will include studies in the review irrespective of whether measured outcome data are reported in a 'usable' way.

Data extraction and management

The following data will be extracted by two authors (EB, LH) independently, using a form developed in previous reviews, and checked for agreement before entry into RevMan. Where there is disagreement, a third author (AW or KA, depending on the topic) will be consulted to resolve the difference.

- Methods: study design.
- Methods - sources of bias: sequence generation, allocation sequence concealment, blinding, incomplete outcome data, study size; other concerns about bias.
- Participants: sample size at baseline and all post-treatment assessment points used for analysis; adherence to or participation in treatment; setting of intervention; baseline characteristics of the sample (age, gender, nationality, ethnicity, type of torture experienced, legal status if refugees or asylum seekers, living situation, separation from close family members).
- Interventions: number of arms; types of interventions (drugs, doses, intervention technique or school of therapy); types of placebo/control condition; protocol for intervention; training of practitioner/therapists.
- Outcomes: assessment points (collected; reported); self-report versus other-report versus objective; psychometric properties of assessment instruments; language(s) of assessment and translation or interpretation.
- N of participants in each intervention group; sample size; missing participants; completion rates.
- Funding source; key conclusions of study authors; allegiance of the trial authors.

Assessment of risk of bias in included studies

Two authors (EB, LH) will independently assess risk of bias for each study, using the criteria outlined in the *Cochrane Handbook* (Higgins 2011) and adapted from those used by the Cochrane Pregnancy and Childbirth Group, with any disagreements resolved by discussion. We will complete a 'Risk of bias' table for each included study using the 'Risk of bias' tool in RevMan (RevMan 2014).

We will assess the following for each study.

Random sequence generation (checking for possible selection bias). We will assess the method used to generate the allocation sequence as: low risk of bias (any truly random process, e.g. random

number table; computer random number generator); unclear risk of bias (method used to generate sequence not clearly stated).
Allocation concealment (checking for possible selection bias). The method used to conceal allocation to interventions prior to assignment determines whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We will assess the methods as: low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes); unclear risk of bias (method not clearly stated). Studies that do not conceal allocation (e.g. open list) will be excluded.
Blinding of outcome assessment (checking for possible detection bias). We will assess the methods used to blind study participants and outcome assessors from knowledge of which intervention a participant received. We will assess the methods as: low risk of bias (study states that it was blinded and describes the method used to achieve blinding, e.g. identical tablets; matched in appearance and smell); unclear risk of bias (study states that it was blinded but does not provide an adequate description of how it was achieved).
Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data). We will assess the methods used to deal with incomplete data as: low risk (< 10% of participants did not complete the study and/or used 'baseline observation carried forward' analysis); unclear risk of bias (used 'last observation carried forward' analysis); high risk of bias (used 'completer' analysis).
Size of study (checking for possible biases confounded by small size). We will assess studies as being at low risk of bias (≥ 200 participants per treatment arm); unclear risk of bias (50 to 199 participants per treatment arm); high risk of bias (< 50 participants per treatment arm).

Measures of treatment effect

Dichotomous outcomes (e.g. improved/not improved) will be analysed using odds ratios with 95% confidence intervals (CIs), using random effects. Categorical outcomes with more than two categories (such as improved, same, worse) will be re-categorised into two groups. We will not calculate numbers needed to treat for an additional beneficial/harmful outcome.
Continuous data will be analysed using standardised mean differences (SMDs) or effect sizes, using pooled standard deviations and weighting for sample size, and calculating the 95% CI, using random effects. SMDs will then be interpreted individually with reference to the quality and reliability of the measure where available. Where data are severely skewed, they will be normalised where possible by transformation or, if this does not produce a satisfactory distribution, will be dichotomised.

Unit of analysis issues

If there are two or more treatment or comparison groups, we will combine the two into a single treatment or comparison group for analysis.
In the case of cluster randomisation, we will adjust for the effects of clustering using an intraclass correlation coefficient (ICC).

Dealing with missing data

We will contact study authors to request missing data required for meta-analysis. Where standard deviations are missing and unobtainable from authors, we will calculate these where possible from F, t, or P values, or from standard errors. If this is not possible, we will treat the trial as having no useable data. We will identify intention-to-treat (ITT) analysis as an important marker of effort to reduce bias (see Assessment of risk of bias in included studies).

Assessment of heterogeneity

Heterogeneity, as indicated by the I^2 statistic, will be interpreted using the *Cochrane Handbook* (Higgins 2011), with reference to variation between studies.

Assessment of reporting biases

The search strategy is broad, particularly in the grey literature, in an attempt to address publication bias. If there are sufficient numbers of trials, we will use funnel plots to examine for publication bias.

Data synthesis

We will use RevMan 5.3 (RevMan 2014) software to conduct meta-analysis wherever feasible. A random-effects model will be used, given the various sources of diversity described above. Where meta-analysis is not possible, we will provide a narrative summary of evidence relating to the primary and secondary outcomes.

Subgroup analysis and investigation of heterogeneity

1. Child and adult studies will be analysed separately, since methods and outcomes usually differ, as does the type of torture experienced.
2. If there are sufficient trials, we will analyse separately by type of pain and/or by treatment modality or specific treatment.

Sensitivity analysis

Where possible, we will use sensitivity analyses to assess the effect of the different methodological decisions made throughout the review process. We will test these decisions by successively removing:

1. quasi-RCTs to leave only RCTs;
2. cluster-randomised trials to leave individually-randomised trials;

3. trials using non-ITT methods to leave only those analysed using ITT (to be considered ITT analysis, the analysis must include all participants who entered treatment, whether or not they provided data at the end of treatment: Nuesch 2009 has found that trials with ITT analyses produce smaller treatment effects in meta-analyses, and this difference is greater in meta-analyses in the presence of heterogeneity); and

4. unpublished trials. Some treatment studies in this literature are published in non-peer-reviewed sources, such as chapters and internal reports of non-government organisations. To address concerns about differences in quality between the two types of source, sensitivity analyses will be undertaken, restricted to those studies in peer-reviewed journals.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. GRADE assessment

The GRADE system uses the following criteria for assigning grades of evidence:
High = further research is very unlikely to change confidence in the estimate of effect
Moderate = further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate
Low = further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate
Very low = any estimate of effect is very uncertain
Grade of evidence if decreased further if the following are present:

- Serious (-1) or very serious (-2) limitation to study quality;
- Important inconsistency (-1);
- Some (-1) or major (-2) uncertainty about directness;
- Imprecise or sparse data (-1);
- High probability of reporting bias (-1).

Grade of evidence may be increased if:

- Strong evidence of association - significant relative risk of > 2 (< 0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1);
- Very strong evidence of association - significant relative risk of > 5 (< 0.2) based on direct evidence with no major threats to validity (+2);
- Evidence of a dose response gradient (+1);
- All plausible confounders would have reduced the effect (+1).

Appendix 2. MEDLINE search strategy

MEDLINE (OVID) strategy

1. Torture/
2. torture*.tw.
3. 1 or 2
4. victim*.tw.
5. Survivors/
6. survivor*.tw.
7. survive*.tw.
8. or/4-7
9. exp Pain/ or Stress Disorders, Post-Traumatic/
10. pain*.tw.
11. exp chronic pain/ or exp intractable pain/

12. ((chronic or persist*) adj2 pain).tw.
13. or/9-12
14. 3 and (8 or 13)

CONTRIBUTIONS OF AUTHORS

ES coordinated writing the protocol; ES, AW, KA and LH all contributed to writing the protocol.

DECLARATIONS OF INTEREST

EB: none known.

AW: none known.

LH: none known.

KA: none known.