Do religion and spirituality play a role in function, pain-related beliefs and coping in patients with chronic pain? Protocol for a systematic review

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Review question
1. Are religion and spirituality associated with psychological or physical function in individuals with chronic pain?
2. Are religion and spirituality associated with pain-related beliefs and pain-coping responses?
3. Do religion and/or spirituality moderate the association between pain-related beliefs and pain-coping responses and measures of adjustment and functioning?

Searches
The search strategies to be used to identify relevant publications will be customized to suit each database. We will first search 16 databases: Web of Science Core Collection, MEDLINE, SciELO Citation Index (via Web of Science, Clarivate Analytics), EMBASE, the Cochrane Central Register of Controlled Clinical Trials (CENTRAL) (via OvidSP), PsycINFO, CINAHL (via EBSCO host), ASSIA (Applied Social Sciences Index and Abstracts), IBSS (International Bibliography for Social Sciences Index and Abstracts) (via ProQuest), Scopus, PubMed, Google Scholar, and LILACS.

The grey literature will also be searched in OpenSIGLE and in clinical trial registry platforms, namely ClinicalTrials.gov and the ISRCTN registry.

In addition, in order to identify further articles not identified during the databases searches, the references lists of the articles selected for inclusion, and of review articles identified in the searches, will also be hand searched.

Limits: adults 18 years old and over; human studies only; language of publication: Portuguese, English, Spanish, Italian.

Search strategies:
1. To identify articles related to function:
Chronic pain
AND
Religio* OR Religious belief OR Belief, Religious OR Religious ethics OR Ethic, Religious OR Prayer OR Faith OR Religious thought OR Spirituality OR Spiritual life
AND
Function* OR Adjustment OR Pain intensity OR Pain interference OR Disability OR Depress*
2. To identify articles related to pain beliefs:
Chronic pain
AND
Religio* OR Religious belief OR Belief, Religious OR Religious ethics OR Ethic, Religious OR Prayer OR Faith OR Religious thought OR Spirituality OR Spiritual life
AND
Belief* OR Attitude OR Apprais* OR Helpless* OR Self-efficacy OR Emotions OR Threat* OR Behavioral symptoms OR Kinesiophobia OR Fear Avoidance
3. To identify articles related to coping with pain:
Chronic pain
AND
Religio* OR Religious belief OR Belief, Religious OR Religious ethics OR Ethic, Religious OR Prayer OR Faith OR Religious thought OR Spirituality OR Spiritual life
AND
Adaptation, Psychological OR Emotional Adjustment OR Coping OR Cope OR Diverting attention OR Guard* OR Hoping OR Ignoring pain OR Pray* OR Relax* OR Seeking social support OR Coping self-statement* OR Task persistence OR Stretching OR Exercising OR Distract* OR Catastrophization OR catastrophiz* OR helplessness OR rumination OR Magnification

Additional search strategy information can be found in the attached PDF document (link provided below).

Types of study to be included
Inclusion criteria: observational studies and experimental studies (baseline data).
Exclusion criteria: studies with N lower than 20, narrative reviews, editorials, letters, qualitative studies, and feasibility studies.

Condition or domain being studied
Chronic pain: defined as pain lasting for three months or more.
All types of chronic pain will be included in the study irrespective of diagnosis or site of pain.

Participants/population
Adults with chronic pain, regardless of pain etiology or location of pain.

Intervention(s), exposure(s)
Different levels of religiousness or spirituality, as assessed by self-reports of religious affiliation, or by participants' self-reported scores in measures of religiousness or spirituality.

Comparator(s)/control
To address the second study aim of the review, comparisons between participants from different religious groups (e.g., the Christian Roman Catholic versus the Christian Anglican versus the Christian Orthodox versus the Christian Protestant versus the Muslim versus the Jewish versus the Buddhist versus the Hindu religions) will be made.

Context

Main outcome(s)
Quantitative patient-reported outcomes measures of physical function, psychological function, pain-related beliefs and pain coping strategies.
These will include (but will not be limited to) the following: the Visual Analogue Scale (VAS) the Numerical Rating Scale (NRS), the Verbal Rating Scale (VRS), the Brief Pain Inventory Interference Scale (BPI), the West Haven-Yale Multidimensional Pain Inventory Interference Scale (MPI), the Pain Disability Index (PDI), the Roland Morris Disability Questionnaire (RMDQ), the SF-36 Health Survey (SF-36), the Beck Depression Inventory (BDI), the Center for Epidemiological Studies Depression scale (CESD), the Profile of Mood States (POMS), the Survey of Pain Attitudes (SOPA), the Pain Beliefs Questionnaire (PBQ), the Cognitive Risk Profile for Pain (CRPP), the Tampa Scale for Kinesiophobia (TSK), the Fear-avoidance Beliefs Questionnaire (FABQ), the Pain Catastrophizing Scale (PCS), and the Pain Self-efficacy Questionnaire (PSEQ), the Coping Strategies Questionnaire (CSQ), and the Chronic Pain Coping Inventory (CPCI).

Timing and effect measures
In the case of longitudinal studies, such as RCTs, the baseline scores of these measures will be considered.

Additional outcome(s)
Timing and effect measures

In the case of longitudinal studies, such as RCTs, the baseline scores of these measures will be considered.

Data extraction (selection and coding)

The references identified in the search will be transferred to EndNote X8 (Clarivate Analytics). Cross references and duplicates will then be deleted, and the titles and abstracts of the remaining studies will be screened for eligibility by two study authors independently based on the eligibility criteria. The full texts of the articles meeting the inclusion criteria, and articles over which there is uncertainty regarding inclusion/exclusion based on the assessment of the abstracts, will be read, and eligibility confirmed by two of the study authors.

Any discrepancies will be resolved during a consensus meeting, with a third reviewer being consulted if consensus cannot be reached.

The inclusion or exclusion of a study will be recorded on a customized Microsoft Excel form. Detailed data from the studies meeting the inclusion criteria will then be extracted onto a customized Microsoft Excel extraction sheet by two independent reviewers. Discrepancies in the data collected will be settled by discussion during a consensus meeting, and a third reviewer will be available for consultation in case of difficulties reaching consensus.

The data to be extracted will include: (1) authors and year of publication; (2) country of study; (3) sample size; (4) study participant (age, percentage of female participants, education level, occupation, income, religious affiliation, chronic pain etiology; (5) pain history (duration of pain, pain location, and pain intensity); (6) statistics (mean, standard deviation, or effect sizes) of the measures of spirituality and/or religiousness, pain-related beliefs and pain-coping responses, physical function and psychological function; and (7) data on the association between measures of spirituality and/or religiousness and primary outcomes.

Risk of bias (quality) assessment

The risk of bias of the studies included in the systematic review will be evaluated based on the STROBE checklist, which was modified to fit our purposes. However, a criterion to evaluate the validity of outcome measures used including translation process of the patient-reported measures on pain-related beliefs and coping will be added, as it is difficult to interpret scales with inadequate validity and reliability. Risk of bias will be assessed by two independent authors. Discrepancies will be settled during a consensus meeting. Any disagreement will be resolved by a third author.

Strategy for data synthesis

Qualitative synthesis:
A qualitative synthesis of the body of research will be conducted, describing the methodological characteristics of the included studies, their strengths and limitations, and each study’s results. To summarize the evidence concerning these two topics, we will implement a narrative summary synthesis method based on the framework developed by the UK Economic and Social Research Council to the conduct of narrative synthesis in systematic reviews (Popay et al., 2006), modified to fit our purposes. Following the referred guidance, the synthesis process will involve three elements: (1) developing a preliminary synthesis of findings of included studies; (2) exploring relationships in the data; and (3) assessing the robustness of the synthesis.
A meta-analysis will be performed if possible, as follows:

1. For the associations between religion (affiliation and degree of engagement in religious practices) and spirituality with measures of function, pain-related beliefs, and coping responses.

Meta-analysis will be limited to studies reporting measures of bivariate association between religion/spirituality and physical/psychological function, pain beliefs and coping responses, in the event that at least two studies evaluate the same outcomes. Effect sizes of eventual significant bivariate associations will include, whenever applicable: r², r, ρ, V and odds ratios based on the dichotomization of 2 continuous variables. If an effect size estimate is not reported in any one individual study, an attempt will be made to calculate it based on the results provided in the article(s).
Multi-variable measures of association (e.g. regression coefficients and partial correlation coefficients) will be excluded as they are not comparable to bivariate association. Effect sizes will be interpreted according to the rules of thumb summarized by Kotrlik and Williams (2003) and Chen, Cohen and Chen (2010) syntheses on effect sizes. All data will be presented as effect estimates (with 95% CIs) to facilitate comparisons. For purposes of meta-analysis, all reported effect sizes will be converted to the Fisher z scale, as it normalizes and stabilizes the sampling variance of Pearson correlation coefficients and has an unbounded range. A generalized estimating equation approach and robust variance estimation will be used to estimate average effect sizes and meta-regression, allowing inferences even when the covariance structure of effect sizes drawn from common studies are unknown or misspecified. For inferences regarding single meta-regression coefficients, robust t tests involving small sample corrections will be employed. For inferences regarding multiple meta-regression coefficients, we will use robust Wald test statistics.

2. For between-religious group differences in self-reported pain-related beliefs and pain coping responses.
If at least two included articles present data on a single primary outcome (pain-related beliefs or pain coping responses), then a random-effect model will be used to pool the data from the same religious group. Effect size (d) for any differences between two or more religious groups will be computed as standardized mean difference (SMD) for each study for each belief or coping response measure separately using the values of mean and SD scores on the measures of pain beliefs and coping. Effect size less than 0.2 is considered small effect, values between 0.21-0.50 is considered medium effect, and values above 0.50 is considered large effect (Cohen, 1992). The Cochrane Collaboration Review Manager version 5.3 (RevMan, 2014) will be used to analyze the data if a meta-analysis is possible. All data will be presented as effect estimates (with 95% CIs) to facilitate comparisons.

Multi-arm studies, missing values, and study heterogeneity:
In the event that a study reports results from more than one independent sample of respondents, each unique sample will be treated as an independent study. For simplicity of presentation, we will not distinguish between independent studies and independent samples reported in the same study. Eventually existing missing data will be asked to the authors of the study(ies) via email. In the absence of a response from the authors, the study(ies) will be excluded from the analysis.
The χ2 test will be used to identify statistically significant heterogeneity, i.e., when χ2 p<.10. The I² statistic will be used to evaluate the degree of heterogeneity, we will consider I²>50% as substantial heterogeneity.

Analysis of subgroups or subsets
None planned.

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**Details of any existing review of the same topic by the same authors**

**Stage of review at time of this submission**

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14 March 2018
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