



Guided Imagery, Biofeedback, and Hypnosis: A Map of the Evidence

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The review team developed the report's scope, study questions, and methodology in consultation with the Operational Partners (*ie*, topic nominators), the ESP Coordinating Center, and the technical expert panel (TEP). Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend TEP members; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for report dissemination.

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To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress.

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VA Evidence Synthesis Program overview

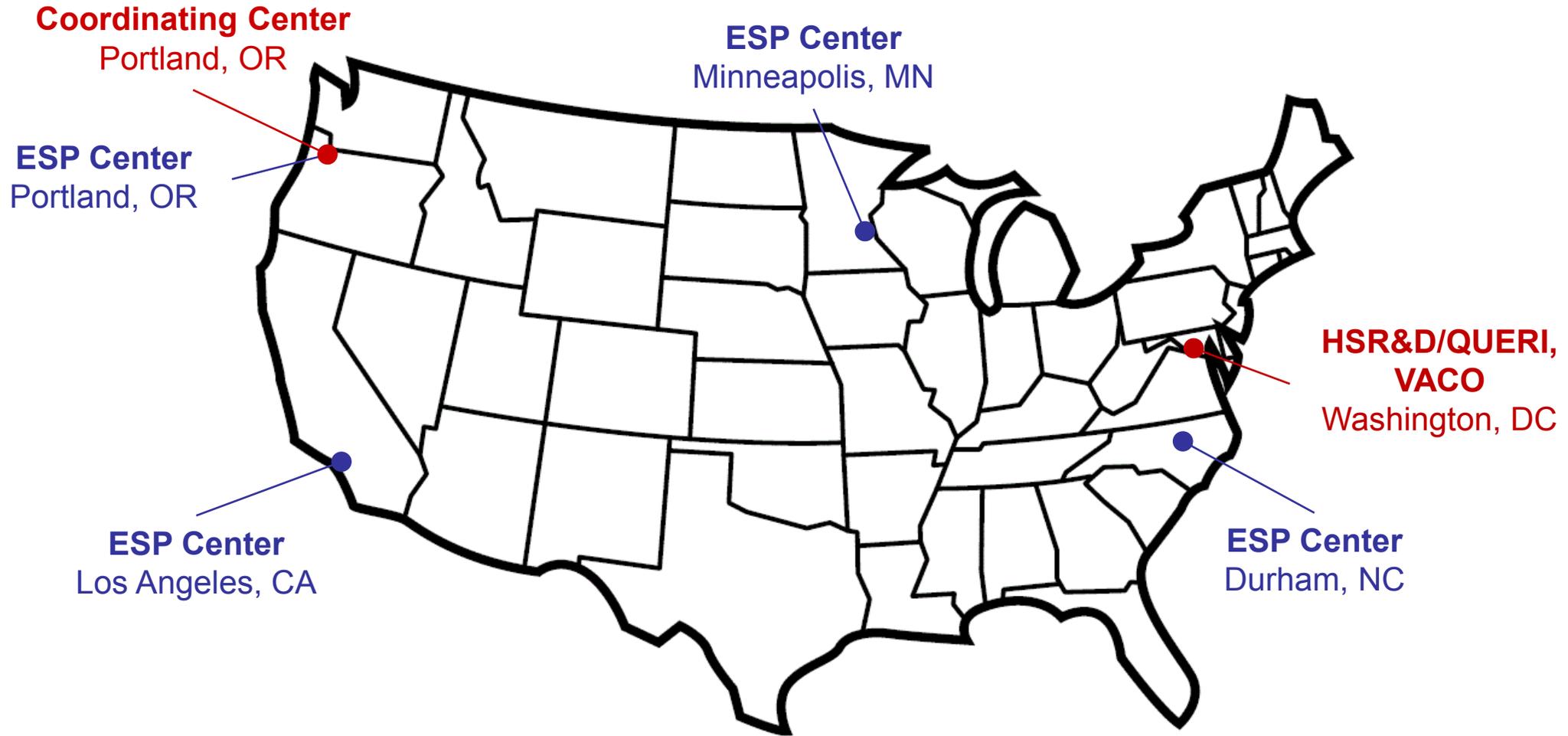


- Established in 2007
- Provides tailored, timely, and accurate evidence syntheses of VA-relevant, Veteran-focused healthcare topics. These reports help:
 - Develop clinical policies informed by evidence;
 - Implement effective services and support VA clinical practice guidelines and performance measures; and
 - Set the direction for future research to address gaps in clinical knowledge.
- Four ESP Centers across the US:
 - Directors are VA clinicians, recognized leaders in the field of evidence synthesis, and have close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration
- ESP Coordinating Center in Portland:
 - Manages national program operations and interfaces with stakeholders
 - Produces rapid products to inform more urgent policy and program decisions

To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers.

The program solicits nominations for review topics several times a year via the [program website](#).

ESP Center locations



Guided Imagery, Biofeedback, and Hypnosis: A Map of the Evidence

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Full-length report available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/reports.cfm>

Poll question

Do you recommend any of the following interventions in clinical practice? (Select all that apply)

- Guided Imagery
- Biofeedback
- Hypnosis
- Not applicable to my role/scope of work

- **Guided imagery** or guided meditation is a therapeutic technique that uses inwardly focused visualization and imaginative content to evoke sensory perceptions for improving mood and/or physical wellbeing; interventions that rely on external sensory input (eg, virtual reality or mirror therapy) were excluded.
- **Biofeedback** is a method by which a person receives data on physiological measurements (e.g., heart rate, muscle contractions, and brain wave activity) to help regulate physical and mental processes.
- **Hypnosis or hypnotherapy** is the induction of a state of consciousness in which an individual has heightened focus and suggestibility.

- Key question 1 – Guided Imagery

In which populations has guided imagery been examined, and what is the evidence of effectiveness and harms in each of these populations?

- Key question 2 - Biofeedback

In which populations has biofeedback been examined, and what is the evidence of effectiveness and harms in each of these populations?

- Key question 3 – Hypnosis

In which populations has hypnosis been examined, and what is the evidence of effectiveness and harms in each of these populations?

Pros

- Provide a broad (high-altitude) overview of the evidence on an intervention across diverse health conditions/target populations
- Can be useful for finding promising areas for treatment and prioritizing further research
- Based on methods established for systematic reviews (comprehensive literature search, assessment for risk of bias)

Cons

- Based on existing systematic reviews; evidence from recent trials not represented
- Broad brushstrokes about potential benefits; do not characterize magnitude of treatment effects
- Cannot be definitive in determining absence of evidence

PICOTS – scope parameters

Population	Included: Adults (18+) receiving an intervention of interest for any health condition. Excluded: Children and adolescents; healthy/non-elderly volunteers.
Interventions	<ul style="list-style-type: none">• Guided imagery – forms include guided meditation, yoga nidra, mental practice, mental rehearsal, Katathym-imaginative Psychotherapy, autogenic training, and integrative restoration.• Biofeedback – also neurofeedback and neurotherapy.• Hypnosis – also hypnotherapy. <p>Excluded: GI/B/H as part of a complex or multicomponent intervention</p>
Comparators	Systematic reviews and meta-analyses comparing an intervention of interest to usual care, placebo, or another intervention.
Outcomes	<ul style="list-style-type: none">• Primary effects on diagnosis-related symptoms• Secondary outcomes, including:<ul style="list-style-type: none">- Mental health outcomes (e.g., anxiety and depression) secondary to the diagnosis;- Sleep• Global outcomes including quality of life, activities of daily living, mobility, social functioning, employment• Harms
Timing	Any duration of treatment and follow-up.
Study design	Included: Systematic reviews and meta-analyses that include randomized or non-randomized controlled trials. Excluded: Non-systematic reviews, reviews of reviews, and primary studies.

Literature search and data sources

- Search strategy developed by a research librarian and peer reviewed by a 2nd research librarian
- Multiple databases searched March 2018; search of Ovid/Pubmed updated in September 2018
- Suggestions from technical experts about potentially relevant reports
- Reviewed bibliographies for additional studies
- Search yield dual-reviewed for potentially relevant publications

Study selection

- SRs/meta-analyses that included controlled trials of GIBH
- Study populations defined by medical condition or risk group (e.g., elderly or in ICU)

Criteria for potentially eligible SRs

- 1) Provided a reproducible search strategy and inclusion criteria
- 2) Conducted a comprehensive search (at least 2 electronic databases)
- 3) Assessed potential risk of bias of included trials

Selection of SRs for evidence maps

- For each GIBH intervention we selected a single SR to represent each clinical condition/risk group
- If multiple SRs for a clinical condition: selection based on recentness of search strategy, methodological quality, size of the evidence, and applicability

Data abstraction

- Characteristics of the intervention, populations studied, clinical condition, number of studies, sample size, findings for each outcome (primary, secondary, global health, harms)

Risk of bias assessment

- To qualify for inclusion in our evidence map, SRs had to have assessed the methodological quality of clinical trials using a standardized instrument.
- We took the primary adjudications conducted by SR authors at face value, and used their ratings in assessing the overall body of evidence.

We classified the evidence of effectiveness into 4 categories:

- 1) **No effect:** a preponderance of null or negative findings.
- 2) **Unclear:**
 - Mixed findings for a single outcome with no preponderance of either benefit or negative effects, or
 - The number of studies, sample sizes, and/or the methodological quality of the studies were insufficient to form a conclusion about effectiveness.
- 3) **Potential positive effect:**
 - Mixed findings for a single outcome that include some evidence of benefit, or
 - Multiple outcomes within the same category (primary diagnosis-related/secondary/global) with at least 1 clear finding of benefit.
- 4) **Positive effect:**
 - Numerous studies with a preponderance of positive findings, or
 - A large, methodologically sound trial showing a positive effect.

Methods – assessing level of confidence

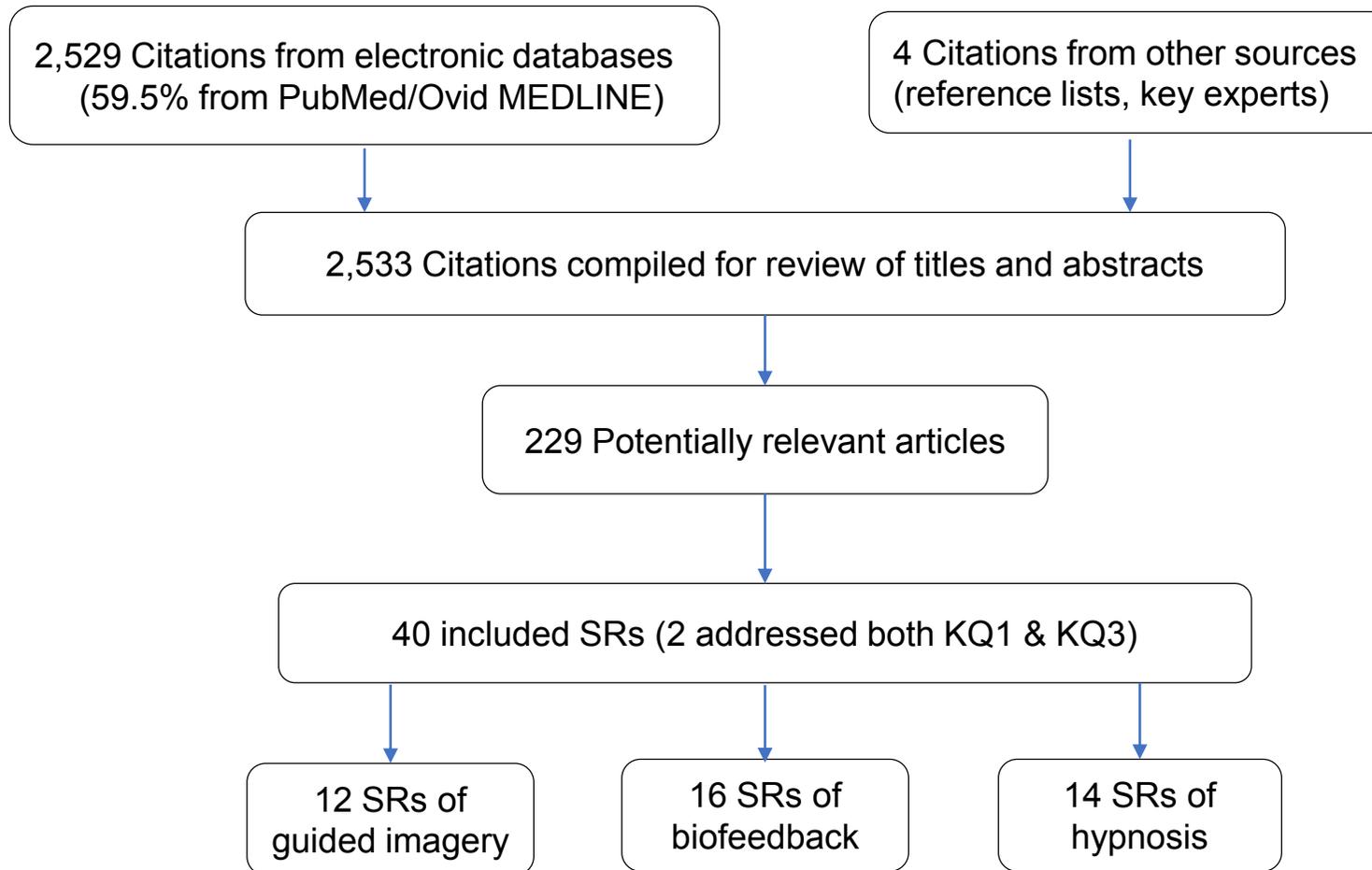
Domain: range of points	Description
Sample Size: 1 to 3	1: N ≤ 100 2: N = 100-500 3: N = 500+
Consistency: -1 or 0	0 = No major flaw, -1 = Serious inconsistency
Directness: -1 to 0	0 = No major flaw -1 = Limited applicability
Overall ROB/study quality: -1 or 0	0 = Unclear or low ROB -1 = High ROB (poor quality)

The sum of points from each domain was used to classify level of confidence into 4 categories:

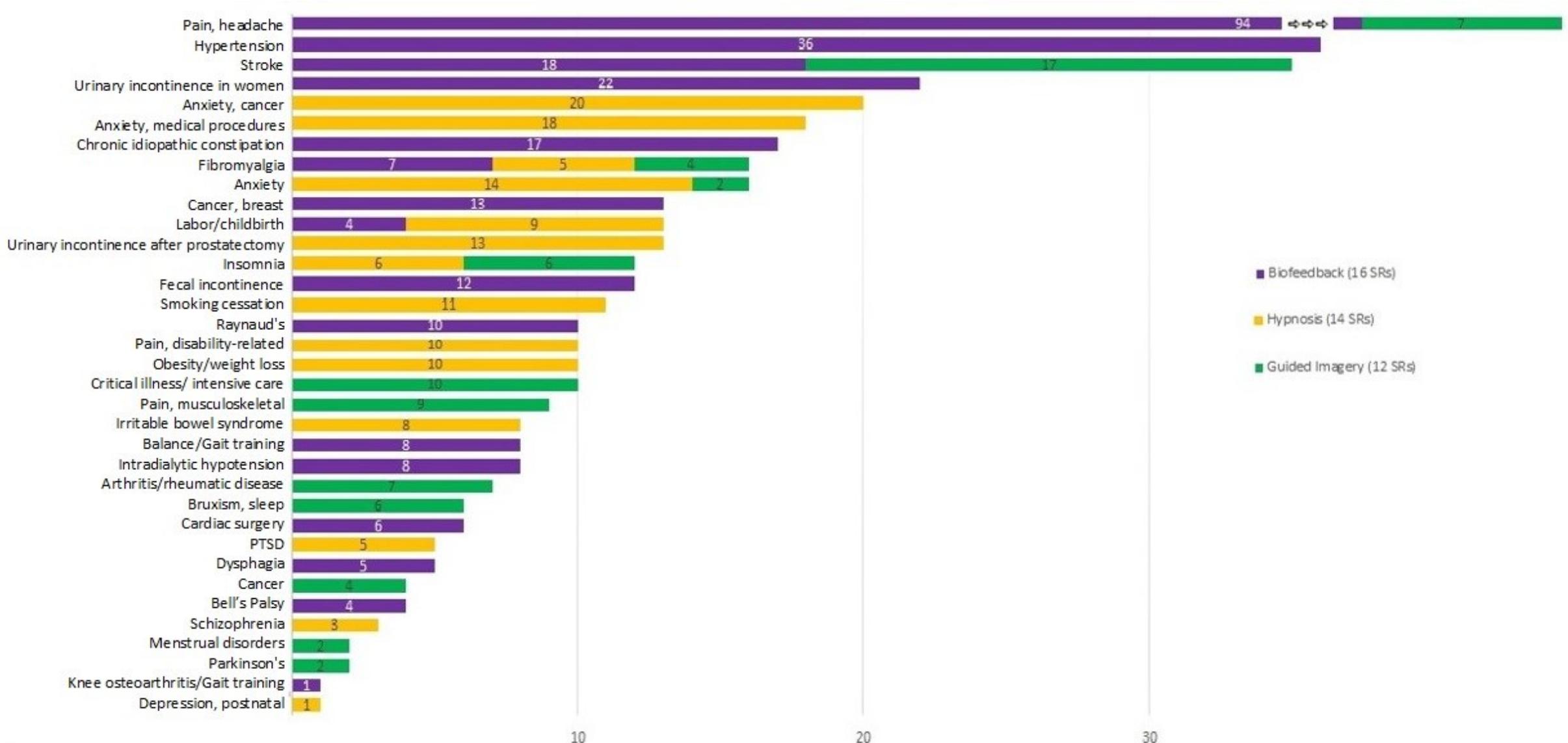
- (3) High: Consistent findings from larger studies with low risk of bias.
- (2) Moderate: Larger studies that may have limitations in study quality, applicability, or consistency of findings.
- (1) Low: Small sample size, or major deficiencies in the body of evidence.
- (≤0) Insufficient: The body of evidence has unacceptable deficiencies.

For the evidence maps, we grouped together Unclear effect with Insufficient confidence.

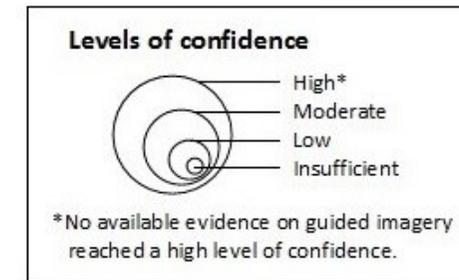
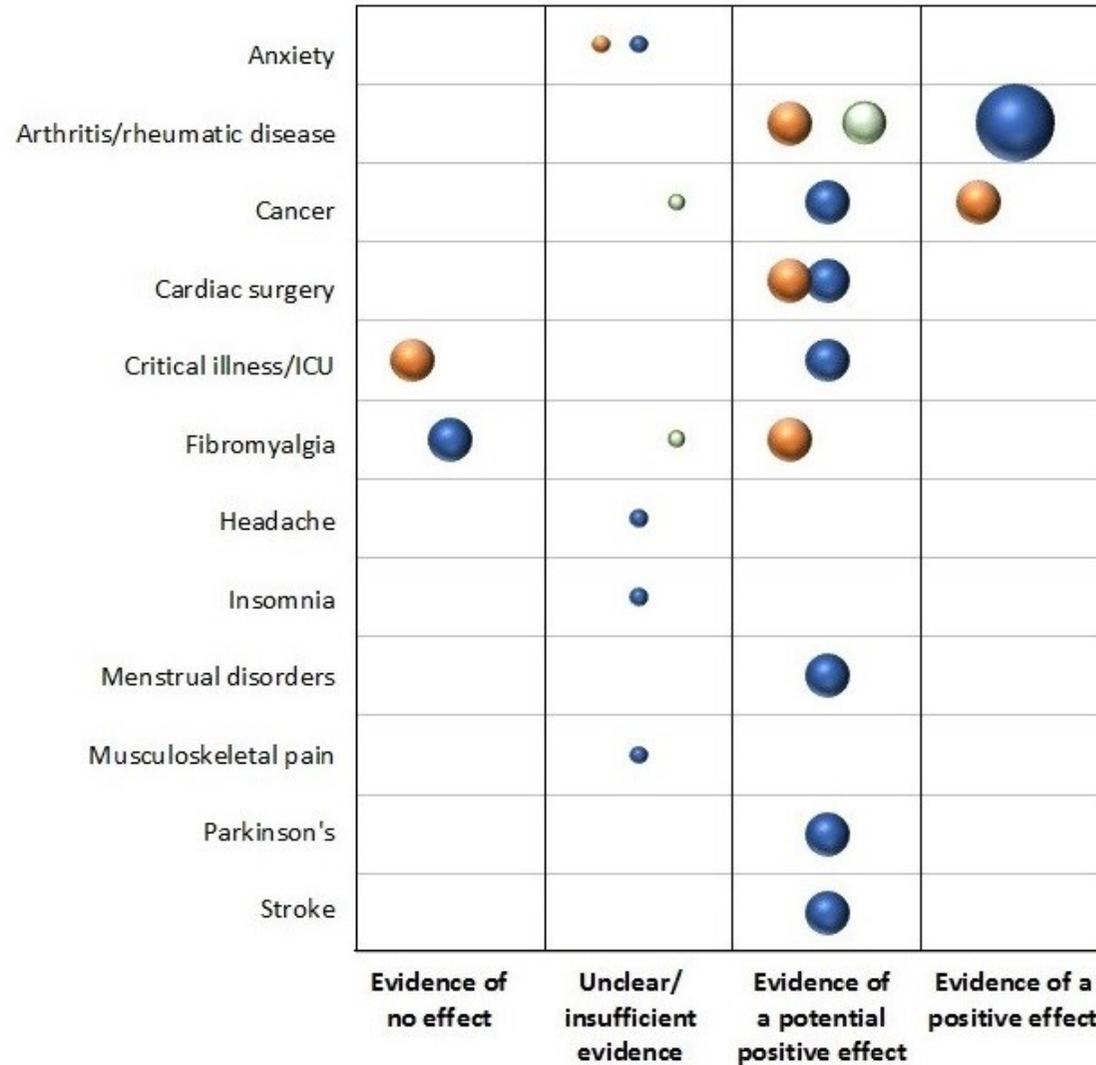
Results – literature flow



Results – N of GIBH trials in targeted health conditions



Results – KQ1: Guided Imagery



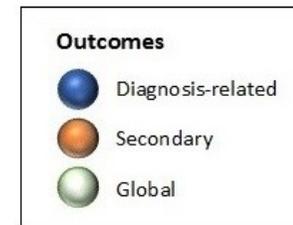
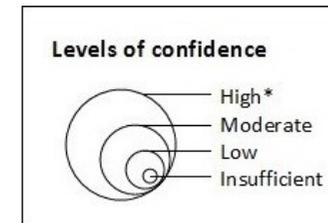
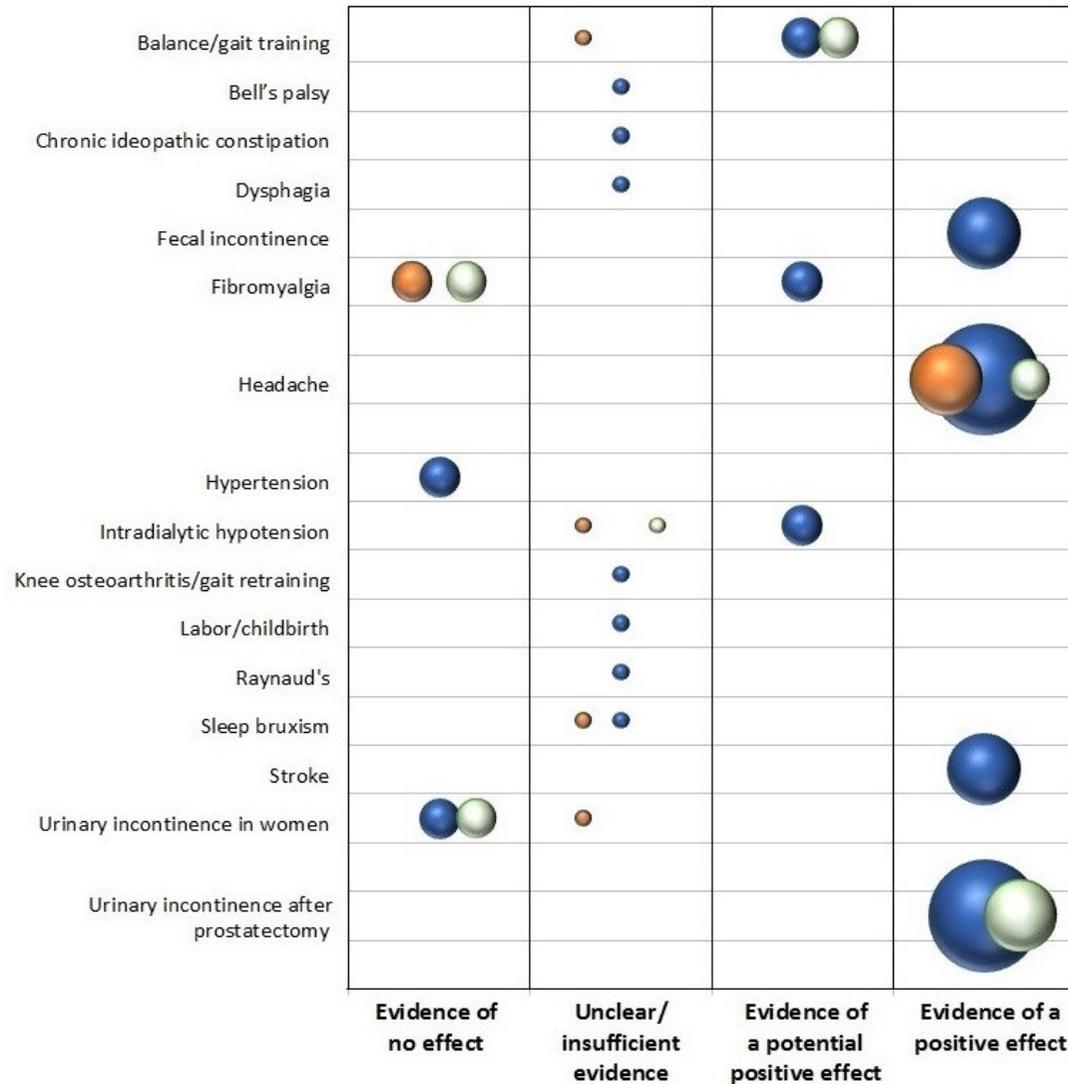
Summary of findings

- 12 SRs examined the effects of guided imagery for anxiety, arthritis, cancer, cardiac surgery, ICU patients, fibromyalgia, headache, menstrual disorders, musculoskeletal pain, Parkinson's disease, and stroke.
- Pre-recorded scripts on audio or video tapes were most commonly used; in-person sessions were also used in some studies.
- Patients with arthritis/rheumatic diseases experienced positive effects on pain symptoms; level of confidence in the evidence was moderate.
- Possible benefits found in several other populations but the findings were mixed and the level of confidence in the evidence was low overall.

Limitation: variation in what constitutes guided imagery

- Motor imagery (visualizing/imagining movement without performing the movement physically) was excluded in an SR of guided imagery for musculoskeletal pain.
- Mirror therapy and virtual reality interventions – we excluded because they are externally driven processes/externally derived images; SRs in our search yield included these as guided imagery.

Results – KQ2: Biofeedback evidence map

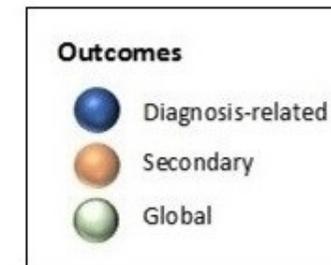
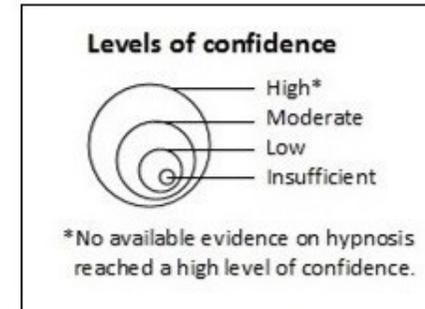
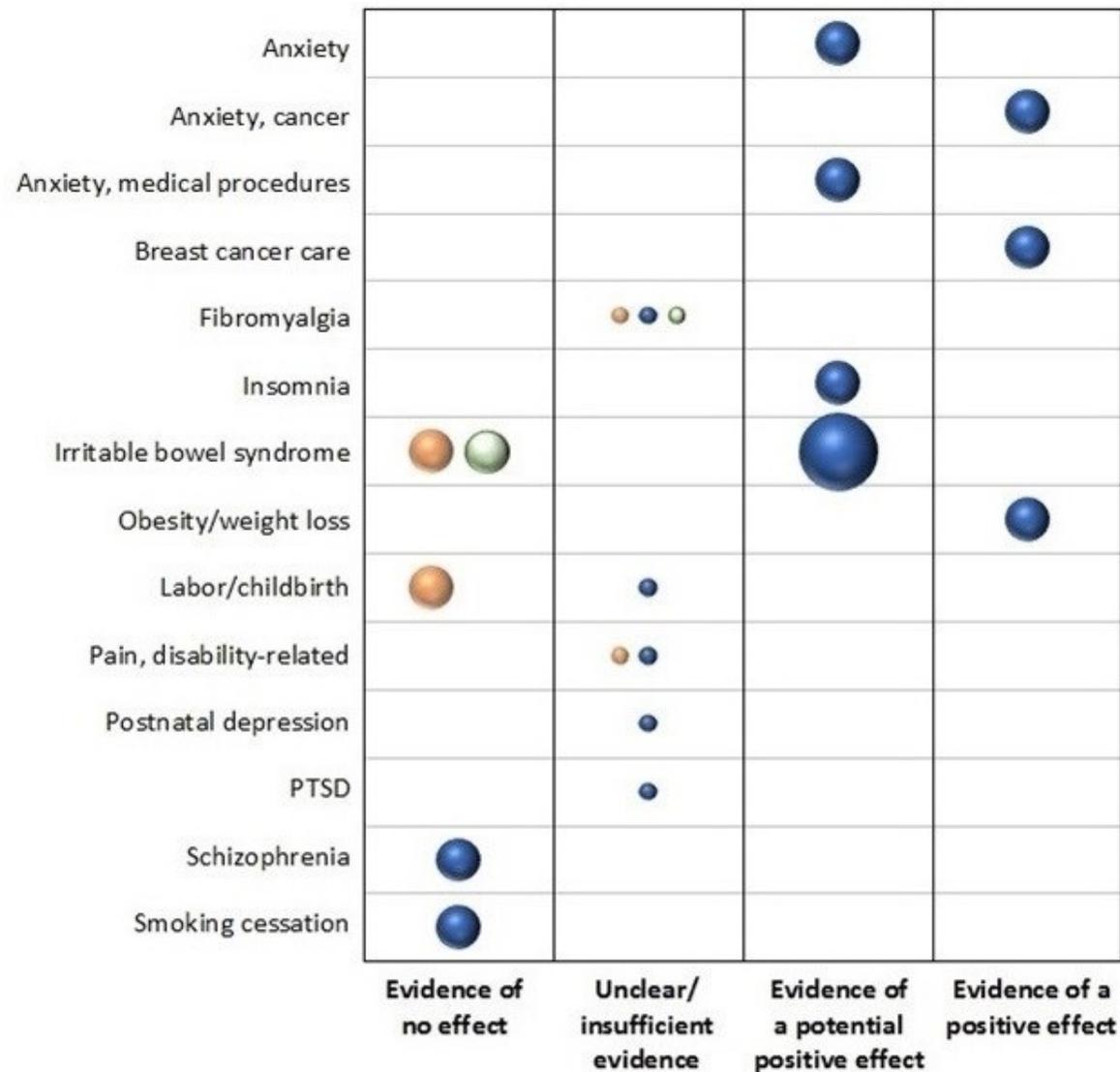


- 16 SRs of biofeedback used alone or as an adjunct to another therapy
- High-confidence evidence of **benefit** for primary outcomes:
 - Migraine and tension type headache pain
 - Urinary incontinence after prostatectomy, in adjunct with pelvic floor muscle training.
- Moderate-confidence evidence of **benefit** for primary outcomes:
 - Stroke
 - Fecal incontinence
- Low-confidence evidence of **no effect** on primary outcomes:
 - Urinary incontinence in women
 - Hypertension

Results – Biofeedback techniques used

Condition	Biofeedback techniques used	Adjunctive therapies
Balance/gait training	Wearable plantar pressure sensors, IMU	---
Bell's Palsy	EMG, biofeedback rehabilitation	With mime therapy. Other therapies varied - facial expression exercises, lip movement without eye closure.
Chronic Idiopathic Constipation	EMG biofeedback, balloon sensory biofeedback, manometry biofeedback	---
Dysphagia	sEMG, accelerometry, tongue manometry, video endoscopy, respiratory plethysmography, external laryngeal manometry	With swallow therapy
Fecal Incontinence	EMG biofeedback, balloon sensory biofeedback,	With electrical stimulation
Fibromyalgia	EMG biofeedback, EEG feedback, LENS, SMR training	Varied: PMR
Headache	TEMP biofeedback, TEMP + EMG biofeedback, EMG biofeedback, BVP biofeedback, EEG biofeedback, GSR biofeedback	Varied - relaxation
Hypertension	Blood pressure biofeedback, indirect biofeedback, direct biofeedback	Varied: relaxation, meditation, imagery, inner quality management
Intradialytic hypotension	Biofeedback hemodialysis: BVM with dialysate conductivity control, BVM with plasma conductivity-controlled	---
Knee osteoarthritis/gait retraining	Visual, haptic (not specified)	---
Labor pain	EMG, skin- conductance biofeedback	Varied - relaxation, PMR, Lamaze,
Raynaud's	Thermal biofeedback, thermal feedback + EMG	Varied - autogenic training, relaxation
Sleep bruxism	Contingent electrical stimulation	---
Stroke	Weight distribution from a force platform or sensor, muscle activity from EMG, linear gait parameters from foot sensors, joint angle from a goniometer.	With usual therapy including therapist communication
Urinary incontinence (women)	EMG, vaginal and/or anal squeeze pressure, ultrasound	With pelvic floor muscle training
Urinary incontinence after prostatectomy	Biofeedback-assisted pelvic floor muscle training	Varied - electrical stimulation

Results – KQ2: Hypnosis evidence map

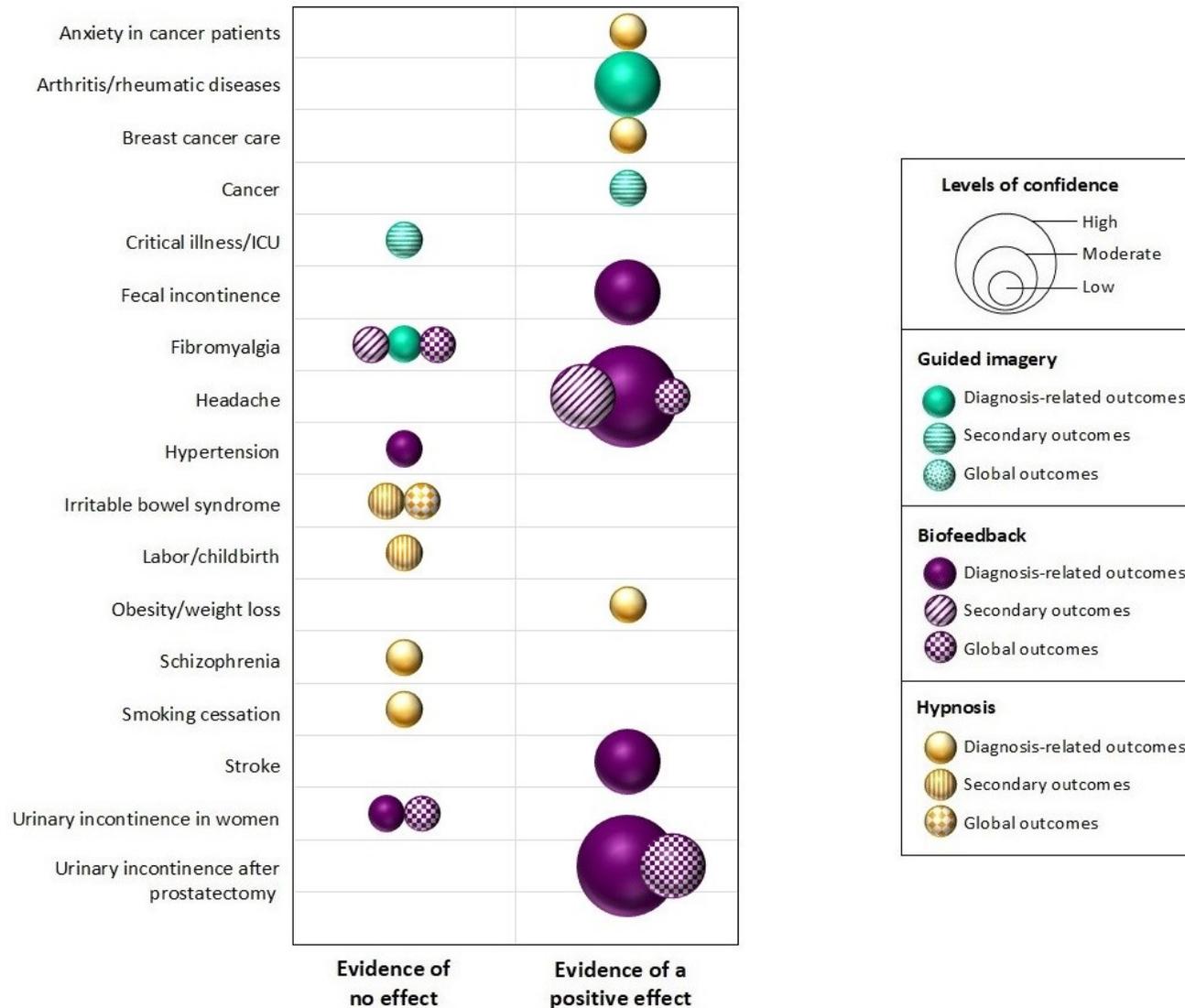


- 14 SRs of hypnosis examined a wide range of clinical conditions.
- Low-confidence evidence that hypnosis is **effective** for
 - Weight loss in obese adults
 - Anxiety in patients with cancer
 - Symptoms experienced during breast cancer treatment
- Low-confidence evidence that hypnosis provides **no benefit** for
 - Smoking cessation
 - Schizophrenia
- Factors for low confidence:
 - Small samples sizes
 - Poor study quality
 - Inconsistencies across studies within health condition/target population

- The level of confidence for the majority of outcomes and health conditions was low or insufficient. Few trials/small combined sample sizes and risk of bias in trials were the most common factors.
- There is very little information about the impact of GIBH on quality of life and functional status.
- For biofeedback, we were not able to distinguish the different types of biofeedback modalities and evaluate the utility of specific types of biofeedback.
- The role of blinding
 - The authors of the included SRs often noted lack of patient blinding in trials of GIBH.
 - Blinding is challenging given the nature of these interventions.
 - Expectancy for change may be an integral part of the intervention, in which case blinding would be counterproductive.

- Based on existing systematic reviews; did not search for more recently published trials.
- Not definitive in identifying absence of evidence. Existing evidence from GIBH trials of targeted health conditions is not represented in the evidence map if
 - no prior SR has reviewed them, or
 - a SR was conducted, but did not meet our minimum quality criteria.
- We relied on the assessments of study quality made by the authors of the systematic reviews.
- Our measure for level of confidence in the evidence is approximate; not equivalent to the more rigorous standards for determining strength of evidence.

Conclusions – GIBH evidence map: benefits and no effects



Conclusions – evidence of no effect

Primary diagnosis-related outcomes

Evidence of no effect for:

Biofeedback

- Hypertension
- Urinary incontinence (women)

Guided imagery

- Fibromyalgia

Hypnosis

- Schizophrenia
- Smoking cessation

Secondary outcomes (eg, depression/ anxiety)

Evidence of no effect for:

Biofeedback

- Fibromyalgia

Guided imagery

- ICU patients

Hypnosis

- Irritable bowel syndrome
- Labor/childbirth

Global outcomes

(eg, quality of life, functional status)

Evidence of no effect for:

Biofeedback

- Fibromyalgia
- Urinary incontinence (women)

Guided imagery

- Fibromyalgia

Hypnosis

- Irritable bowel syndrome

The level of confidence was low for these findings of no effect.

Conclusions – evidence of positive effects

- Moderate- to high-level confidence that **biofeedback** is beneficial for
 - Urinary incontinence after prostatectomy
 - Fecal incontinence,
 - Balance and gait in stroke patients
 - Headache

- Moderate level of confidence that **guided imagery** has positive effects for arthritis or other rheumatic diseases.

- Low-confidence evidence of benefit for **hypnosis** in patients with
 - Obesity
 - Anxiety in patients with cancer
 - Symptoms during breast cancer treatment

- The IHCC is charged with developing and implementing CIH strategies in clinical activities, education, and research across the system.
- Its **two major functions** are to:
 - identify and remove barriers to providing CIH across the VHA system.
 - serve as a resource for clinical practices and education for both veterans and clinicians.



- CIH Directive – **SIGNED BY USH 5/19/2017**
http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=5401
- LIST I: evidence of promising or potential benefit
 - evidence of promising or potential benefit
 - vetted by IHCC Advisory Group
 - VA must provide a mechanism to offer these approaches either within VA facility or in the community
- LIST II: generally considered safe
 - General recognition of safety requires common knowledge, throughout the expert scientific community (both internal and external to VHA) knowledgeable about the safety of CIH approaches and the impact on Veterans' physical and mental well-being, that there is a reasonable certainty that the approach is not harmful under the conditions of its intended use.
 - Optional for inclusion in VA facility, depending on capability (staff/space) at sites

CIH Therapies approved to date

- Acupuncture
- Tai chi
- Yoga
- Meditation
- Massage therapy
- Guided imagery
- Hypnosis
- Biofeedback

Chiropractic included already by specific Congressional mandate

Whole Health
is an approach
to health care that
empowers and equips
people to take charge
of their health and well-being,
and live their life to the fullest.

Whole Health System



Questions?

If you have further questions, please feel free to contact:

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Full-length report and cyberseminar available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/>