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

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program is comprised of four ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, and interface with stakeholders. 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](#).

Comments on this evidence report are welcome and can be sent to Nicole Floyd, Deputy Director, ESP Coordinating Center at Nicole.Floyd@va.gov.

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ACKNOWLEDGMENTS

This topic was developed in response to a nomination the Office of Patient Centered Care and Cultural Transformation (OPCC&CT) to guide the use of guided imagery, biofeedback, and hypnosis in the VHA. The scope was further developed with input from the topic nominators (*ie*, Operational Partners), the ESP Coordinating Center, the review team, and the technical expert panel (TEP).

In designing the study questions and methodology at the outset of this report, the ESP consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

The authors gratefully acknowledge Robin Paynter, MLIS, Jessica Montgomery, MPH, and the following individuals for their contributions to this project:

Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend Technical Expert Panel (TEP) participants; 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 dissemination of the report to field and relevant groups.

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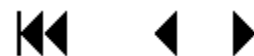
To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members are listed below:

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The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center and the ESP Center work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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ABBREVIATIONS TABLE

Abbreviation	Term
BF	Biofeedback
BVM	blood volume monitoring
BVP	blood volume pulse
CBT	Cognitive behavioral therapy
CCT	Controlled clinical trial
CDSR	Cochrane Database of Systematic Reviews
CI	Confidence interval
CIH	Complementary and integrative health
D	Cohen's d
df	Degrees of freedom
EBM	Evidence-based Medicine
EEG	Electroencephalograph
EMG	Electromyograph
ESP	Evidence Synthesis Program
g	Hedge's g
GI	Guided imagery
GSR	Galvanic skin response
HTA	Health Technology Assessment
IBS	Irritable bowel syndrome
ICU	Intensive care unit
IDH	Intradialytic hypotension
IHCC	Integrative Health Coordinating Center
IMU	Inertial measurement units
ITT	Intention-to-treat
KQ	Key Question
LENS	Low-intensity neurofeedback system
LOS	Length of stay
MA	Meta-analysis
MD	Mean difference
MI	Motor imagery
MWES	Mean weighted effect size
NICU	Neonatal intensive care unit
NR	Not reported
OPCC&CT	Office of Patient Centered Care and Cultural Transformation
P	P-value
PFMT	Pelvic floor muscle training
PICOTS	Population, interventions, comparators, outcomes, timing, setting, and study design
PMR	Progressive muscle relaxation
PND	Postnatal depression
pts	Participants
PTSD	Posttraumatic stress disorder

Abbreviation	Term
Q	Q-value
QOL	Quality of Life
QUERI	Quality Enhancement Research Initiative
RCT	Randomized controlled trial
RD	Risk difference
ROB	Risk of bias
RR	Risk ratio
SB	Sleep bruxism
SE	Standard error
SMD	Standard mean difference
SMR	Sensorimotor rhythm
SR	Systematic review
TEMP	Peripheral temperature feedback
TEP	Technical expert panel
TTH	Tension-type headache
TUG	Timed Up and Go
UPDRS	Unified Parkinson's disease rating scale
US	United States
VHA	Veterans Health Administration
Z	Z-value

EVIDENCE REPORT

INTRODUCTION

The Veterans Health Administration (VHA) is currently transforming its healthcare model, with a shift from problem-based disease care to a personalized, proactive, patient-driven (whole health) care model that prioritizes active patient engagement in a patient-centered health care system. Part of this mission is to identify, develop, and implement new practices and approaches that are found to be effective in helping to promote the transformation to a patient-centered model that focuses on the Veterans' goals and priorities for their health. The VHA established the Integrative Health Coordinating Center (IHCC) with the Office of Patient Centered Care and Cultural Transformation (OPCC&CT) to aid in development and implementation of complementary and integrative health (CIH) strategies across the VHA. Guided imagery, biofeedback, and hypnosis are low-risk complementary treatment modalities that may have the potential to benefit patients experiencing a wide range of conditions, including pain,¹⁻³ stroke recovery,^{1,4} hypertension,⁵ and gastrointestinal conditions,⁶ as well as mental health conditions¹ such as anxiety⁷ and stress.⁸

The purpose of this report is to provide a broad overview of the effectiveness of guided imagery, biofeedback, and hypnosis, and the health conditions for which these interventions have been examined, and to display the overall findings in the form of evidence maps. Evidence maps are a relatively new form of evidence synthesis, and their purpose is to identify research gaps and future research needs, rather than to conduct comprehensive, in-depth analyses and form conclusions about a focused research question. Although standardized definitions and methodology are still being established, they generally include a systematic search of a broad field of research and a visual representation of the body of literature.⁹ The evidence maps will be used to guide and support decision-making about these treatment modalities in the VHA.

METHODS

TOPIC DEVELOPMENT

This topic was nominated by Dr. Ben Kligler, National Director of the Coordinating Center for Integrative Health (IHCC) and Laura Krejci, Associate Director of the Office of Patient Centered Care and Cultural Transformation (OPCC&CT). We further developed the scope of the project in collaboration with our operational partners and Technical Expert Panel (TEP). The key questions (KQs) for the evidence map were as follows:

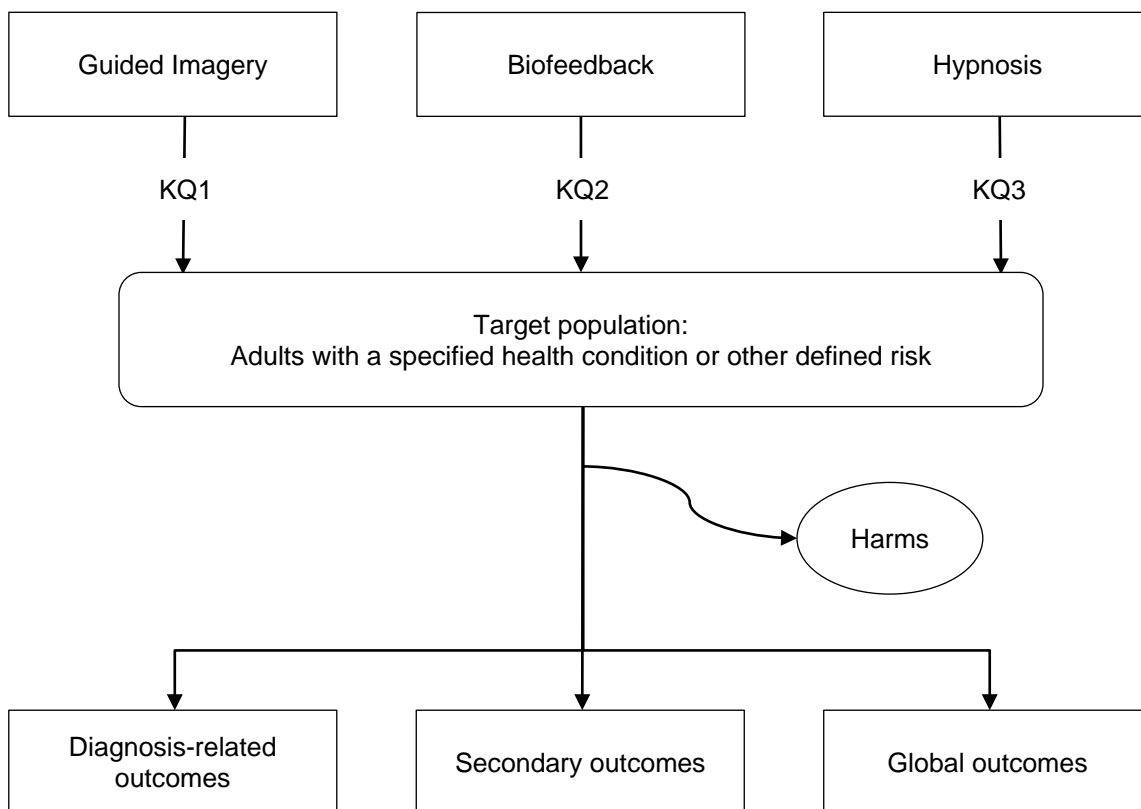
KQ1: In which populations has guided imagery been examined, and what is the evidence of effectiveness and harms in each of these populations?

KQ2: In which populations has biofeedback been examined, and what is the evidence of effectiveness and harms in each of these populations?

KQ3: In which populations has hypnosis been examined, and what is the evidence of effectiveness and harms in each of these populations?

The analytic framework for our approach to the research questions is shown in Figure 1.

Figure 1. Analytic framework



SEARCH STRATEGY

The search strategies were developed in consultation with a research librarian, and were peer-reviewed by a second research librarian using the instrument for Peer Review of Search Strategies.¹⁰ We conducted a review of the literature by systematically searching, reviewing, and analyzing the scientific evidence as it pertained to the research questions. To identify relevant systematic reviews/meta-analyses, we searched Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE, Ovid PsycINFO, CINAHL, Epistomonikos, and Ovid EBM Reviews Cochrane Database of Systematic Reviews (CDSR, DARE, HTA, Cochrane CENTRAL, *etc*). We searched all available years of publication from database inception (1946 for Ovid MEDLINE®) through March 2018, and performed an update search of Ovid MEDLINE in September 2018. To identify additional reviews, we reviewed the bibliographies of relevant reviews of reviews, searched the review registry PROSPERO for completed reviews, and queried subject matter experts.

STUDY SELECTION

We assessed the titles and abstracts yielded by the literature search based on pre-specified criteria (Appendix B) using Abstrackr,¹¹ an online tool for screening citations, and retrieved potentially relevant articles for review at the full-text level. Two investigators independently assessed all abstracts and full-text articles for inclusion, and resolved disagreements through discussion and consensus.

We identified systematic reviews and meta-analyses that included controlled trials of guided imagery, biofeedback, or hypnosis in subjects defined by specific medical conditions or risk groups, such as elderly populations or patients in intensive care. The criteria for population, interventions, comparators, outcomes, timing, and setting (PICOTS) that apply to each key question are specified in Table 1.

Potentially eligible systematic reviews met all of the following quality criteria: 1) clearly reported their search strategy and inclusion criteria; 2) performed a comprehensive search of at least 2 electronic databases; and 3) assessed the methods and potential risk of bias in the included trials using validated criteria.¹²

We included systematic reviews that focused explicitly on the interventions of interest, and excluded systematic reviews that examined guided imagery, biofeedback, or hypnosis as one of multiple interventions for a condition or population. To mitigate potential loss of information by excluding well-conducted reviews with comprehensive scopes that included interventions of interest along with other interventions for distinct health conditions, we compared the findings and included trials from these more broadly scoped reviews with those of systematic reviews that were more narrowly focused on our target interventions.

In the evidence map, each data point – or bubble – represents the evidence for guided imagery, biofeedback, or hypnosis for a distinct health condition. In order to define the health conditions for the evidence map in which target interventions have been studied, we comprehensively listed the health conditions studied across all potentially eligible systematic reviews. Through iterative discussions among the authors and the technical expert panel, we collapsed similar health conditions into a single broadly defined category when clinically appropriate, particularly if a single systematic review included the breadth of the conditions. For example, we combined headache and migraines into a single category and selected a systematic review that covered the

wider scope.¹³ However, we did include systematic reviews examining biofeedback for both stroke¹⁴ and the more broadly defined (including stroke) balance/gait training¹⁵ because the modalities and findings differed between the reviews. When there were several qualified reviews of an intervention for the same health condition, we selected a single review based on how recent it was and its methods, scope, and applicability.

Table 1. PICOTS by key question

Key Questions	KQ1. In which populations has guided imagery been examined, and what is the evidence of effectiveness and harms in each of these populations?	KQ2. In which populations has biofeedback been examined, and what is the evidence of effectiveness and harms in each of these populations?	KQ3. In which populations has hypnosis been examined, and what is the evidence of effectiveness and harms in each of these populations?
Population	Adults (18+) receiving an intervention of interest for any health condition. Children and adolescents are excluded. Exclude studies of healthy/non-elderly volunteers.		
Interventions	Guided imagery (also “guided meditation,” “yoga nidra,” “mental practice,” “mental rehearsal,” “Katathym-imaginative Psychotherapy,” “autogenic training,” and “integrative restoration”). Studies of guided imagery as part of a complex or multicomponent intervention are excluded.	Biofeedback (also “neurofeedback,” and “neurotherapy”). Studies of biofeedback as part of a complex or multicomponent intervention are excluded.	Hypnosis (also “hypnotherapy”). Studies of hypnosis as part of a complex or multicomponent intervention are excluded.
Comparators	Systematic reviews and meta-analyses comparing an intervention of interest to usual care, placebo, or another intervention.		
Outcomes	Effect on diagnosis-related symptoms; secondary outcomes (eg, anxiety, depression, or other mental health outcomes that are not primary to the diagnosis; sleep); global health outcomes (eg, quality of life, activities of daily living, mobility, social functioning, employment); and harms.		
Timing	Any duration and follow-up.		
Study design	Systematic reviews and meta-analyses that include randomized or non-randomized controlled trials. Non-systematic reviews, reviews of reviews, and primary studies are excluded.		
Setting	All health care settings.		

DATA ABSTRACTION

Data from studies meeting inclusion criteria were abstracted by 1 investigator and confirmed by at least 1 additional reviewer. From each review, we abstracted the following where available: focus of the systematic review (*ie*, intervention of interest, multiple interventions, condition-specific), number of studies included from the systematic review and total number of subjects included in the review, whether duration was provided, condition treated, and summaries of relevant findings (*ie*, condition-related symptoms, harms, cost).

We abstracted outcomes data in 4 categories: diagnosis-related outcomes, secondary outcomes, global health outcomes, and harms (Figure 2). We defined diagnosis-related outcomes as

symptom outcomes that were directly related to the target health condition; for example, pain in headache. Global health outcomes were those that extended beyond a single symptom, and included outcomes such as quality of life and functional status. Secondary outcomes included sleep, anxiety, depression, or other outcomes that are not primary to the diagnosis. We also examined harms outcomes, but these were almost always poorly reported and thus are not represented in the evidence maps.

QUALITY ASSESSMENT

To qualify for inclusion in our evidence map, systematic reviews had to have assessed the methodological quality of clinical trials using a standardized instrument. These primary adjudications were taken at face value and used to rate the overall body of evidence.

DATA SYNTHESIS

We used the vector graphics in Microsoft Excel (2016) to generate scatter plots based on categorical values representing levels of effect and confidence in the evidence. Each bubble in the scatter plots represents the summary of findings for 1 of 3 outcome categories (diagnosis-related, secondary, and global), based on data from trials reported in the systematic reviews. We also provide a brief narrative synthesis of the findings.

We classified the effect of the intervention for each targeted health condition and outcome as follows:

- 1) No effect: a preponderance of null or negative findings.
- 2) Unclear: the systematic review reported 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 that include some evidence of benefit; or multiple outcomes within the same category (diagnosis-related/secondary/global) with at least 1 clear finding of benefit; or mixed findings for a single outcome with a preponderance of evidence of a positive effect.
- 4) Positive effect: numerous studies or a large sample showing a positive effect.

For a modality to be classified as having a positive effect required consistent, statistically significant effects from well-conducted trials. When there were mixed findings for a single outcome that included both positive and null findings, we classified the overall effect as either unclear or potentially positive, depending on the preponderance of findings and the quality of the evidence. If the findings across a group of studies were truly mixed to the extent that there was no preponderance of evidence in 1 direction or another, or if there were methodological limitations in the included trials, we classified it as unclear/insufficient. However, if there were a clear signal for benefit on at least 1 outcome, we classified the overall body of evidence as having a potential positive effect.

RATING THE BODY OF EVIDENCE

For each conclusion on the effect of an intervention (*ie*, no effect, unclear, potential positive, or positive effect) we characterized the level of confidence in the body of evidence specific to that outcome and health condition. We calculated a rough estimate of confidence based on the number of participants in the included trials; the quality of the included trials, and the overall risk of bias; whether there were serious inconsistencies in the findings; and any limitations in the applicability of the evidence (Appendix C). Table 2 outlines the criteria we used for scoring.

Table 2. Domains for 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 (good quality) -1: High ROB (poor quality)

ROB = Risk of bias

We used the sum of points from each domain to classify the level of confidence into 4 categories as follows:

- (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: No evidence is available, or the body of evidence has unacceptable deficiencies.

For the evidence maps, we grouped together studies with either unclear effect or insufficient level of confidence into a combined category of Unclear/Insufficient evidence.

PEER REVIEW

A draft version of this report was reviewed by technical experts and key stakeholders. Reviewer comments and our responses are provided in Appendix E.

RESULTS

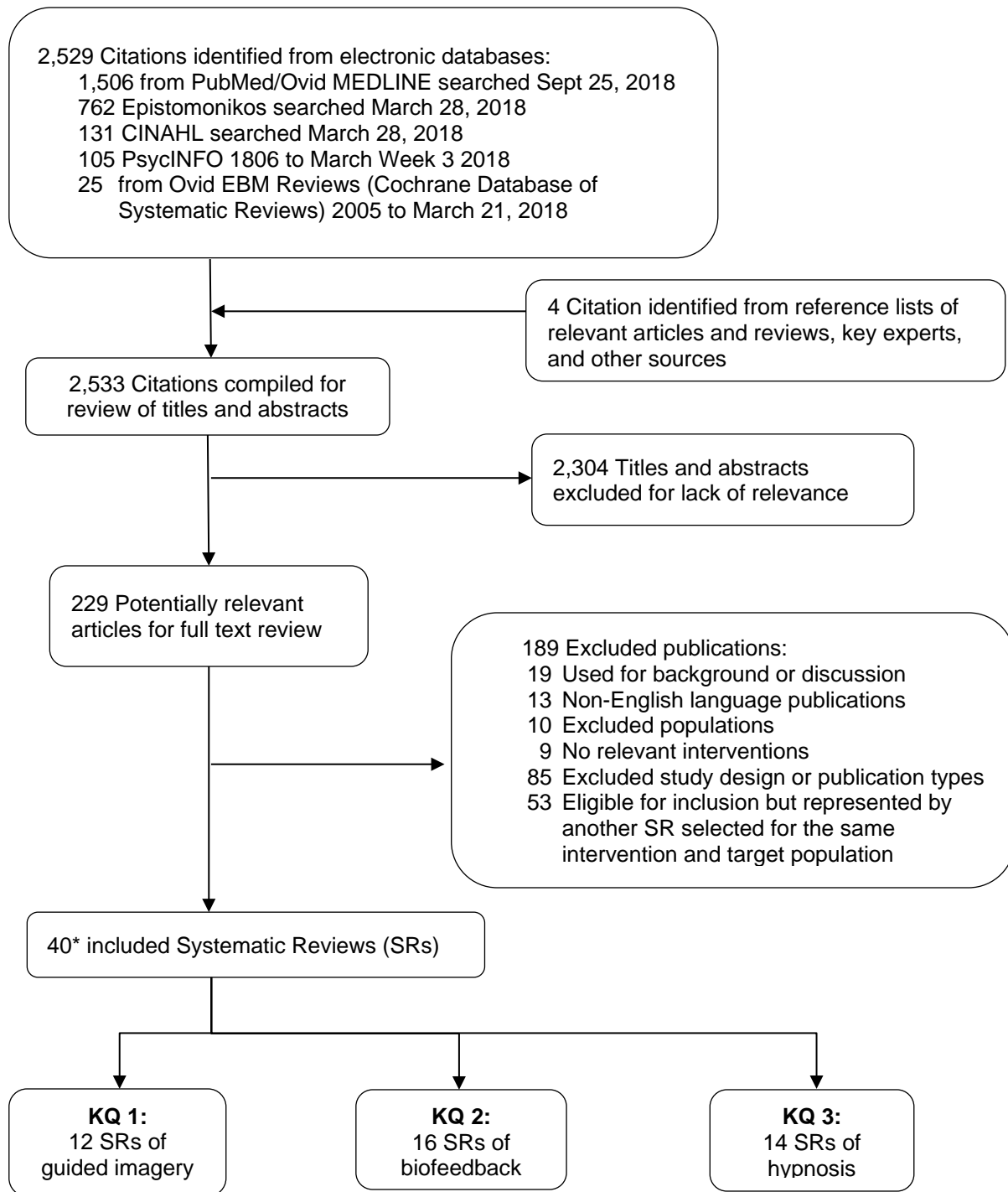
LITERATURE FLOW

Our search of electronic databases, bibliographies, and other sources resulted in a total of 2,533 citations. After reviewing titles and abstracts, we included 229 for further screening at the full-text level. Of these, 93 systematic reviews met our inclusion criteria. From those 93 systematic reviews we selected 40 representing the most recent and comprehensive evidence available on each intervention, as applied to distinct medical conditions and target populations (Figure 2).

Table 3 lists the target populations examined in the systematic reviews that met our inclusion criteria, according to treatment modality. Biofeedback interventions were studied in the largest number of health conditions and target populations (N=16), followed by hypnosis (N=14), and guided imagery (N=12). Pain conditions and various forms of anxiety were among the most widely represented. All 3 interventions were studied in patients with fibromyalgia. The findings of each systematic review are provided in Appendix D.

The health conditions for which guided imagery, biofeedback, and hypnosis interventions have been researched are not listed comprehensively in Table 3. Evidence from clinical trials may be available for health conditions not listed, or for additional treatment modalities within the health conditions listed. For example, a systematic review of heart rate variability (HRV) biofeedback for anxiety occurred in our literature search but did not meet our inclusion criteria, and is therefore not represented in Table 3 or in the evidence maps that follow. Although there is research using HRV biofeedback and EEG biofeedback for ADHD, the studies on ADHD and biofeedback that were captured in our literature search did not meet our inclusion criteria.

Figure 2: Literature Flow Chart



*2 SRs addressed both KQ1 and KQ3.

Abbreviations: EBM = evidence-based medicine; KQ = key question; SR = systematic review

Table 3. Medical conditions and target populations studied in systematic reviews of guided imagery, biofeedback, and hypnosis

Condition/population	Number of controlled trials (N=participants combined)			Total trials	Total pts
	Guided Imagery (12 SRs)	Biofeedback (16 SRs)	Hypnosis (14 SRs)		
Anxiety	2 (N=44) ¹⁶		14 (N=653) ¹⁷	16	697
Anxiety, cancer			20 (N=878) ¹⁸	20	878
Anxiety, medical procedures			18 (N=968) ¹⁹	18	968
Arthritis/rheumatic disease	7 (N=207) ²⁰			7	207
Balance/Gait training		8 (N=243) ¹⁵		8	243
Bell's Palsy		4 (N=118) ²¹		4	118
Bruxism, sleep		6 (N=126) ²²		6	126
Cancer	4 (N=199) ²³			4	199
Cancer, breast			13 (N=1357) ²⁴	13	1357
Cardiac surgery	6 (N=433) ²⁵			6	433
Chronic idiopathic constipation		17 (N=931) ²⁶		17	931
Critical illness/ intensive care	10 (N=1363) ²⁷			10	1363
Depression, postnatal			1 (N=63) ²⁸	1	63
Dysphagia		5 (N=141) ²⁹		5	141
Fecal incontinence		12 (N=350) ³⁰		12	350
Fibromyalgia	4 (N=240) ³	7 (N=321) ³¹	5 (N=388) ³	16	949
Hypertension		36 (N=1660) ³²		36	1660
Intradialytic hypotension		8 (N=716) ³³		8	716
Insomnia	6 (N=284) ³⁴		6 (N=218) ³⁴	12	502
Irritable bowel syndrome			8 (N=464) ³⁵	8	464
Knee osteoarthritis/ Gait training		1 (N=56) ³⁶		1	56
Labor/childbirth		4 (N=186) ³⁷	9 (N=2954) ³⁸	13	3140
Menstrual disorders	2 (N=250) ³⁹			2	250
Obesity/weight loss			10 (N=882) ⁴⁰	10	882
Pain, disability-related			10 (N=380) ⁴¹	10	380
Pain, headache	7 (N=400) ⁴²	94 (N=3500) ¹³		101	3900
Pain, musculoskeletal	9 (N=325) ⁴³			9	325
Parkinson's	2 (N=60) ⁴⁴			2	60
PTSD			5 (N=383) ⁴⁵	5	383
Raynaud's		10 (N=531) ⁴⁶		10	531
Schizophrenia			3 (N=149) ⁴⁷	3	149
Smoking cessation			11 (N=1120) ⁴⁸	11	1120
Stroke	17 (N=735) ⁴⁹	18 (N=429) ¹⁴		35	1164
Urinary incontinence after prostatectomy		13 (N=1108) ⁵⁰		13	1108
Urinary incontinence in women		22 (N=1361) ⁵¹		22	1361

Abbreviations: pts = participants; PTSD = posttraumatic stress disorder; SR = systematic review



KEY QUESTION 1: In which populations has guided imagery been examined, and what is the evidence of effectiveness and harms in each of these populations?

Summary of Findings

We identified 12 systematic reviews examining the effectiveness of guided imagery interventions for anxiety, arthritis, cancer, cardiac surgery, ICU patients, fibromyalgia, headache, menstrual disorders, musculoskeletal pain, Parkinson's disease, and stroke. The systematic reviews varied in the scope of interventions they defined as guided imagery. Patients with arthritis/rheumatic diseases experienced positive effects on pain symptoms and the confidence in the evidence was moderate. Possible benefits were reported in several of the other populations studied, but the findings were mixed and the level of confidence in the evidence was low overall.

Detailed Findings

We included 12 systematic reviews of guided imagery interventions. Guided imagery interventions were most commonly delivered using pre-recorded scripts on audio or video tapes, though some studies also used in-person sessions. We found 1 systematic review of yoga nidra as a form of guided imagery.³⁹

The systematic reviews varied in the scope of interventions they defined as guided imagery. Our search strategy included motor imagery, while a systematic review of guided imagery for musculoskeletal pain excluded motor imagery.⁴³ Although some trials combined guided imagery with relaxation techniques, we excluded a systematic review of progressive muscle relaxation (PMR) combined with guided imagery in cancer patients because PMR was the predominant intervention in some the included trials.⁵² In our initial literature yield, there were 2 systematic reviews that included mirror therapy and virtual reality interventions as forms of guided imagery. Because we defined guided imagery as excluding externally driven processes or externally derived images, we excluded virtual reality and mirror therapy.

Figure 3 shows the effects of guided imagery in the 12 populations studied. Evidence of a positive effect was found for outcomes on 2 of the studied conditions: pain in patients with arthritis/rheumatic disease, and secondary outcomes (anxiety and depression) in cancer patients.

Patients with arthritis or rheumatic diseases²⁰ experienced positive effects on pain (moderate confidence) with guided imagery, as well as potential positive effects on the secondary and global outcomes of anxiety, mobility, and quality of life (low level of confidence). Table 8 in Appendix D provides greater detail on the findings from systematic reviews of guided imagery.

Potential positive effect on diagnosis-related outcomes was found for 7 of the 12 targeted health conditions with a generally low level of confidence. (Table 5 in Appendix C). Cancer patients experienced reductions in anxiety and depression with guided imagery, and there was evidence of a potential positive effect on patient comfort during radiation/chemotherapy.²³ The level of confidence in these findings was low.

Potentially positive effects on diagnosis-related outcomes, as well as anxiety and tension, for patients undergoing cardiac surgery were identified with a low level of confidence. For critically ill ICU patients there was also evidence of potentially positive effect on diagnosis-related

outcomes, but evidence of no effect on a range of secondary outcomes (see Table 8 for more detail). The level of confidence in these findings was low.

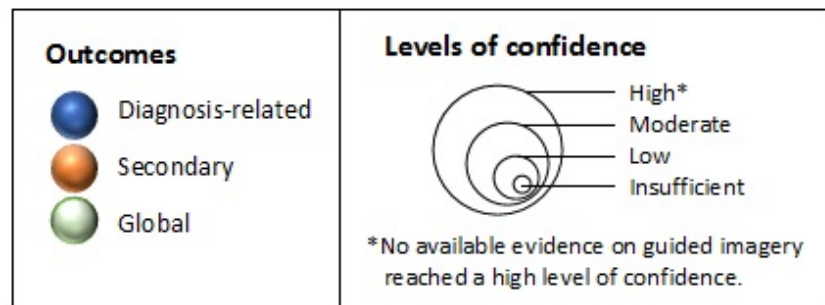
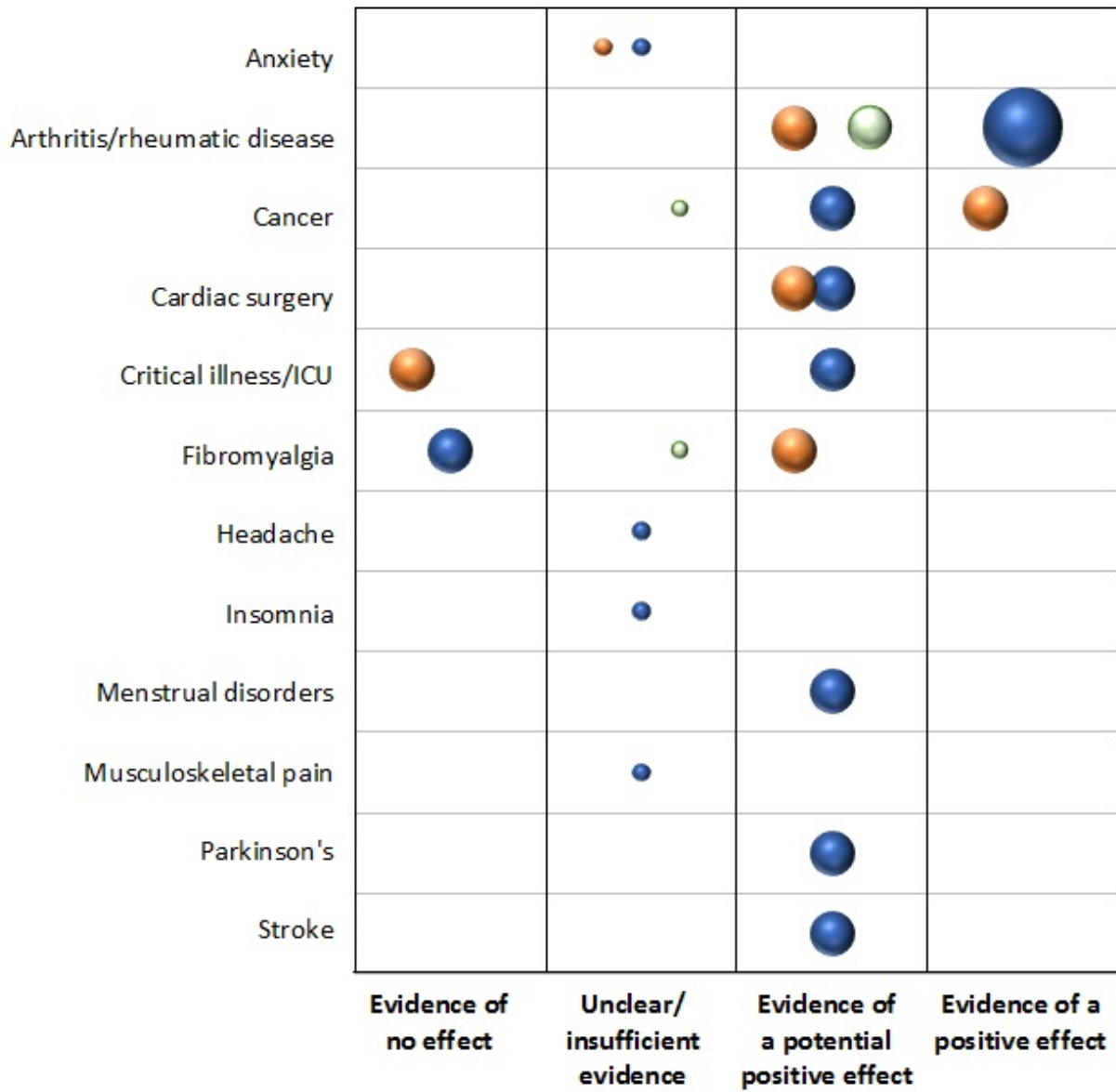
In patients with fibromyalgia,³ while there was evidence of no effect on pain (4 studies, N=224), there were potential positive effects on secondary outcomes including psychological distress and coping with pain. The level of confidence for both outcomes was low.

Potential positive effects on diagnosis-related outcomes were also reported with guided imagery interventions in patients with stroke, Parkinson's disease, and menstrual disorders (low level of confidence; Table 8 in Appendix D). The evidence of effect was unclear or insufficient in systematic reviews of patients with anxiety, headache, insomnia, and musculoskeletal pain.

Adverse effects of guided imagery were not reported in the systematic reviews identified in our search. The evidence on harms of guided imagery is insufficient.

With the exception of moderate confidence in the evidence for diagnosis-related outcomes in arthritis and rheumatic disease, the levels of confidence in the evidence on guided imagery were generally low, owing to heterogeneity among the intervention modalities, high risk of bias, lack of blinding, and limited generalizability in some of the populations studied (Table 5 in Appendix C).

Figure 3. Map of the evidence from systematic reviews of guided imagery interventions by clinical condition, evidence of effectiveness, and level of confidence



KEY QUESTION 2: In which populations has biofeedback been examined, and what is the evidence of effectiveness and harms in each of these populations?

Summary of Findings

We identified 16 systematic reviews examining the effectiveness of biofeedback alone or as an adjunct for a wide range of clinical conditions. There was clear, high-confidence evidence that biofeedback can reduce pain resulting from migraines and tension type headaches,¹³ and that as an adjunct to pelvic floor muscle training (PFMT) it can provide benefit to men experiencing urinary incontinence after a prostatectomy.⁵⁰ There were also positive effects for stroke and fecal incontinence and the confidence in these findings was moderate. We found low-confidence evidence that biofeedback provides no benefit for women experiencing urinary incontinence,⁵¹ secondary or global outcomes for fibromyalgia patients,³¹ or hypertension.³² Overall, findings for other conditions were insufficient to form a conclusion.

Detailed Findings

We identified 16 systematic reviews examining the effectiveness of biofeedback on primary/diagnosis-related outcomes, secondary outcomes, and global outcomes (eg, quality of life). The number of RCTs in the systematic reviews ranged from 1 (knee osteoarthritis)³⁶ to 94 (headache),¹³ and included subjects ranged from 56³⁶ to over 3,500¹³ (Table 3). Biofeedback modalities varied both within and by condition, as did the use of adjunctive interventions (Table 4). We also looked for evidence regarding heart rate variability biofeedback, but found no systematic reviews that met inclusion criteria. Across all reviews, 9 examined only primary diagnosis-related outcomes, 6 examined secondary outcomes, and 6 examined global outcomes (Table 9 in Appendix D).

For patients with migraine or tension-type headaches, there is consistent evidence of benefit in all 3 outcome categories. There was high-confidence evidence that biofeedback is effective for reducing the frequency, duration, and intensity of headache. Evidence of benefit on secondary outcomes such as medication intake, muscle tension, anxiety, and depression had a moderate-level of confidence. There was low-confidence evidence of improved self-efficacy.¹³

For men with urinary incontinence after prostatectomy, there is high-confidence evidence that biofeedback as an adjunct to PFMT can result in both immediate and long-term improvement compared to PFMT alone. There was moderate-confidence evidence that the addition of biofeedback had a positive effect on quality of life.⁵⁰

For patients with stroke, there is moderate-confidence evidence that compared with usual care, the addition of biofeedback is more effective for short-term lower limb activity improvement, such as standing and walking.¹⁴

For patients with fecal incontinence, electrical stimulation with biofeedback is more effective than electrical stimulation alone.³⁰ The level of confidence in this finding is moderate (Figure 4; Table 9 in Appendix D).

We also identified low-confidence evidence of potential benefit in hemodialysis, fibromyalgia, and balance/gait training. In hemodialysis patients with chronic fluid overload or symptomatic intradialytic hypotension (IDH), there were potential benefits in reducing mortality and IDH.³³

Among patients with fibromyalgia, electromyograph (EMG), but not electroencephalograph (EEG), biofeedback has potential benefit for pain, though no effects were observed on quality of life or secondary outcomes.³¹ Finally, wearable sensors may provide better static steady state balance and health-related quality of life outcomes for patients undergoing balance or gait training (Figure 4; Table 9 in Appendix D).¹⁵

Evidence suggests that biofeedback provides no benefit for urinary incontinence in women⁵¹ or for blood pressure control.³² Findings related to all other conditions were insufficient (Figure 4; Table 9 in Appendix D).

For 5 conditions (*ie*, fecal incontinence,³⁰ urinary incontinence in women,⁵¹ dysphagia,²⁹ stroke,⁵³ and Bell's palsy²¹) systematic reviews specifically examined biofeedback as an adjunct to another intervention. Five reviews examined the effectiveness of biofeedback independent of other interventions (*ie*, sleep bruxism,²² chronic idiopathic constipation,²⁶ knee osteoarthritis,³⁶ balance/gait training,¹⁵ and intradialytic hypotension³³). For all other conditions, systematic reviews included studies examining biofeedback with or without another intervention (Table 4).^{13,31,32,37,50}

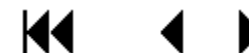
Contributing to the confidence levels for diagnosis-related outcomes were small combined sample sizes, poor study quality, heterogeneity in adjunctive interventions, and inconsistencies across studies included in the systematic reviews. For secondary and global outcomes, sample sizes were all less than 500 (half of those reporting secondary outcomes were less than 100), and study quality was generally poor (Table 6 in Appendix C).

Table 4. Biofeedback techniques used and adjunctive therapies by health condition

Condition	Biofeedback techniques used	Adjunctive therapies
Balance/Gait training ¹⁵	Wearable plantar pressure sensors (sensor which measures the distribution of plantar pressure, usually when standing or moving) IMU (inertial measurement unit: a type of sensor measuring velocity, acceleration, and direction of body movements)	---
Bell's Palsy ²¹	Electromyography (EMG, also called Surface EMG or SEMG) - Sensors placed on the surface of the skin measure muscle tension Biofeedback rehabilitation - "Method of biofeedback rehabilitation (patients tried to keep their eyes open symmetrically during 3 designated mouth movements using a mirror) for 30 min"	With mime therapy. Other therapies varied - facial expression exercises, lip movement without eye closure.
Chronic idiopathic constipation ²⁶	EMG biofeedback Balloon sensory biofeedback - balloon is inserted into the rectum and used to measure amount of pressure exerted by muscles Manometry biofeedback - sensors are used to measure pressure, usually used for urinary and fecal incontinence	---
Dysphagia ²⁹	Surface electromyography, accelerometry, tongue manometry, video endoscopy, respiratory plethysmography, external laryngeal manometry: <u>Accelerometry</u> : "This consists of a small accelerometer being placed just above the thyroid cartilage. It measures the epidermal vibrations caused by the internal sounds and vibrations of the superior/inferior and or anterior/posterior movements of the hyoid and larynx during swallowing. The vibrations are converted into a voltage signal, which the patient can use as visual feedback to facilitate their swallowing therapy" <u>Tongue Manometry</u> : "This intervention consists of using an air-filled pressure bulb which acts as a pneumatic pressure sensor and measures isometric tongue strength. The bulb is placed on the tongue and the participant is instructed to push the tongue against the hard palate. The pressure generated is measured by a manometer and the signal can be displayed graphically on a screen to give patients biofeedback" <u>External Laryngeal Manometry</u> : "an air-filled balloon fixed externally to the cervical region to measure changes in pressure during swallowing" <u>Video Endoscopy</u> : "This involves the insertion of a flexible nasoendoscope to the level of the soft palate so that the pharynx and larynx can be visualized. The timing, safety and efficiency of the swallow can also be visualized and used for biofeedback" <u>Respiratory Inductance Plethysmography</u> : "Nasal airflow is measured by a nasal cannula and respiratory inductance plethysmography measures movements of the ribcage and abdomen."	With swallow therapy
Fecal Incontinence ³⁰	EMG biofeedback, balloon sensory biofeedback	With electrical stimulation
Fibromyalgia ³¹	EMG biofeedback	Varied - PMR



Condition	Biofeedback techniques used	Adjunctive therapies
	<p>EEG – also known as EEG biofeedback or neurofeedback- sensors placed on various points on the scalp measure brain wave activity which is fed back to the patient via a display, and the display is used to teach the patient self-regulation</p> <p>LENS – “a combination of a conventional EEG and sub-threshold photic stimulation in order to change EEG patterns”</p> <p>Sensorimotor Rhythm Training (SMR) – an EEG procedure that aims to facilitate thalamic inhibitory mechanisms”</p>	
Headache ¹³	<p>TEMP biofeedback, TEMP + EMG biofeedback, EMG biofeedback, BVP biofeedback, EEG biofeedback, GSR biofeedback</p> <p>Blood Volume Pulse (BVP) Biofeedback. BVP measures “heart rate based on the volume of blood that passes through tissue in a localized area with each beat (pulse) of the heart”</p>	Varied - relaxation
Hypertension ³²	<p>Indirect biofeedback – trains patient to identify and control any stress response that might lead to increased blood pressure</p> <p>Direct biofeedback – direct feedback of blood pressure on a heartbeat from any blood pressure device</p>	Varied - relaxation, meditation, imagery, inner quality management
Intradialytic hypotension ³³	<p>Biofeedback hemodialysis: BVM with dialysate conductivity control, BVM with plasma conductivity-controlled BVM (relative blood volume monitoring).</p> <p>Biofeedback hemodialysis: “biofeedback dialysis in which the primary input variable for the biofeedback algorithm was relative blood volume and in which dialysate conductivity was manipulated without directly measuring blood-side conductivity (eg, Hemocontrol™, Hospal-Gambro, Quebec, Canada).”</p> <p>BVM with plasma conductivity-controlled “biofeedback dialysis in which plasma conductivity was measured directly (in the blood lines), and served as an input variable in the biofeedback algorithm, along with relative blood volume (eg, Diacontrol™, Hospal-Gambro)”</p>	---
Knee osteoarthritis/Gait retraining ³⁶	Visual, haptic (not specified) – feedback is delivered via visual system or haptic (touch)	---
Labor pain ³⁷	<p>EMG-electromyograph. A biofeedback technique in which sensors measure and feed back muscle tension, skin-conductance (the property of the human body that causes continuous variations in the electrical characteristics of the skin) (WIKIPEDIA)</p> <p>Also called galvanic skin response or electrodermal response – sensors measure the amount of sweat you produce (a measure of stress response) to measure the conductivity of your skin</p>	Varied - relaxation, PMR, Lamaze
Raynaud’s ⁴⁶	<p>Thermal biofeedback-TBF – biofeedback technique which measures skin temperature with the goal to train subjects to control peripheral vasoconstrictor responses and acquire voluntary hand warming skills.</p> <p>Thermal feedback + EMG (biofeedback focused on measurement of skin temperature and muscle tension)</p>	Varied - autogenic training, relaxation
Sleep bruxism ²²	Contingent electrical stimulation – electrical stimulation is delivered to the skin, lip, and masticatory muscles to interrupt the sleep cycle upon detection of grinding, clenching	---

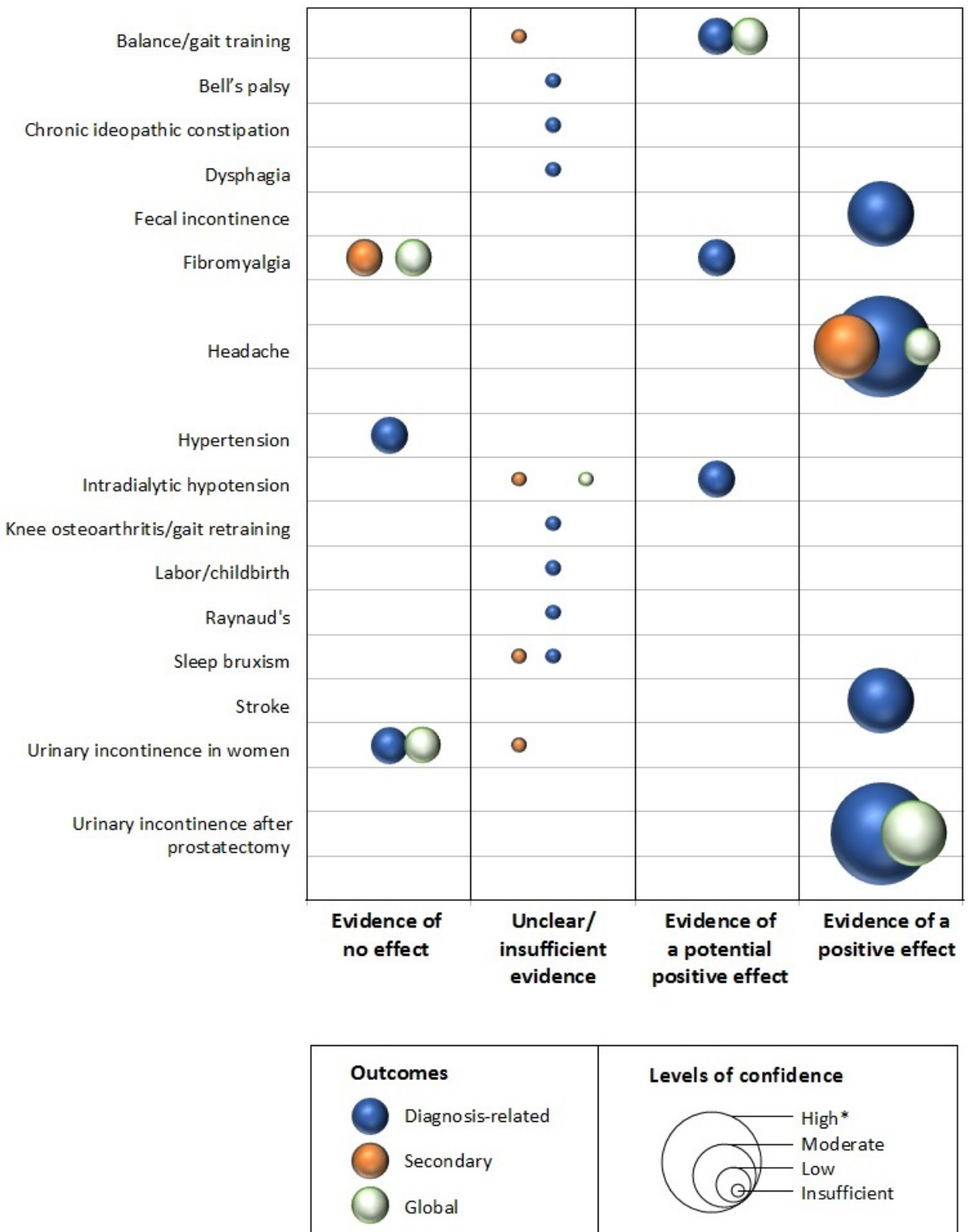


Condition	Biofeedback techniques used	Adjunctive therapies
Stroke ⁵³	Weight distribution from a force platform or sensor, muscle activity from EMG, linear gait parameters from foot sensors, joint angle from a goniometer. <u>Weight distribution from a force platform or sensor</u> – Force platform (or sensor) measures ‘ground reaction forces’ generated by a body in motion or standing and quantifies various parameters including gait, weight distribution, gait, etc. <u>Muscle activity from EMG</u> – as previously defined <u>Linear gait parameters from foot sensors</u> – “parameters of gait patterns which included step length, width symmetry of feet, etc. which were fed back either visually or auditorily and measured when the patient was walking.” <u>Joint angle from a goniometer</u> – used to measure the angle/range of motion in a joint.	With usual therapy including therapist communication
Urinary incontinence (women) ⁵¹	EMG, vaginal and/or anal squeeze pressure, ultrasound	With pelvic floor muscle training
Urinary incontinence after prostatectomy ⁵⁰	Biofeedback-assisted pelvic floor muscle training – trains the patient to strengthen and control the muscle in the pelvic floor (eg, muscles involved in maintaining continence) and to recognize when they are using the wrong muscles. Recordings of muscle tension from sensors on the abdomen and in the vaginal canal are shown to the patient so they can learn to recognize and control muscles tension.	Varied - electrical stimulation

Abbreviations: BVM = blood volume monitoring, BVP=blood volume pulse, EEG = Electroencephalograph, EMG = electromyograph, IMU = inertial measurement units, GSR = galvanic skin response, LENS = low-intensity neurofeedback system, PMR = progressive muscle relaxation, SMR = sensorimotor rhythm, TEMP = peripheral temperature feedback.



Figure 4. Map of the evidence from systematic reviews of biofeedback interventions by clinical condition, evidence of effectiveness, and level of confidence



KEY QUESTION 3: In which populations has hypnosis been examined, and what is the evidence of effectiveness and harms in each of these populations?

Summary of Findings

We identified 14 systematic reviews examining the effectiveness of hypnosis on a wide range of clinical conditions. We found low-confidence evidence that hypnosis is effective for weight loss in obese adults,⁴⁰ for reducing anxiety in patients with cancer,¹⁸ and for symptoms experienced during breast cancer treatment.²⁴ We identified low-confidence evidence that hypnosis provides no benefit for smoking cessation⁴⁸ or schizophrenia.⁴⁷ No effects on secondary and/or global outcomes were observed for labor and childbirth,³⁸ or IBS,³⁵ though the confidence in these findings was low.

Detailed Findings

We identified 14 systematic reviews examining the effectiveness of hypnosis on primary/diagnosis-related outcomes, secondary outcomes, and global outcomes such as quality of life. Hypnosis was generally administered by a professional, and in some cases the intervention also included a self-hypnosis component. For a few conditions, the effectiveness of self-hypnosis alone was examined (*eg*, labor)³⁸ The number of controlled trials in the systematic reviews ranged from 1 (postnatal depression)²⁸ to 20 (cancer anxiety)¹⁸ and the number of included participants ranged from 63²⁸ to just under 3,000 (Table 3).³⁸ Across all reviews, 10 examined only primary diagnosis-related outcomes, 4 examined secondary outcomes, and 2 examined global outcomes (Table 10 in Appendix D).

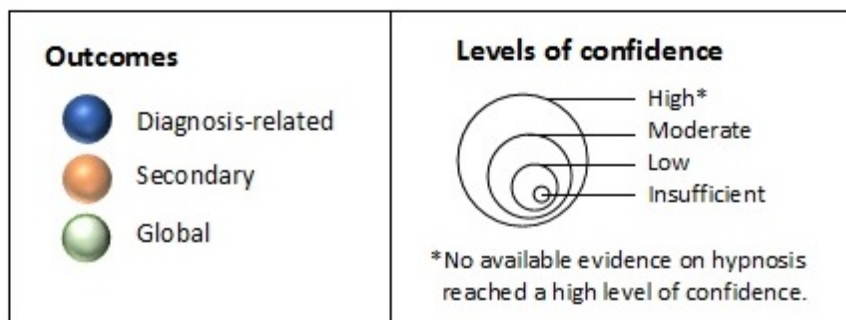
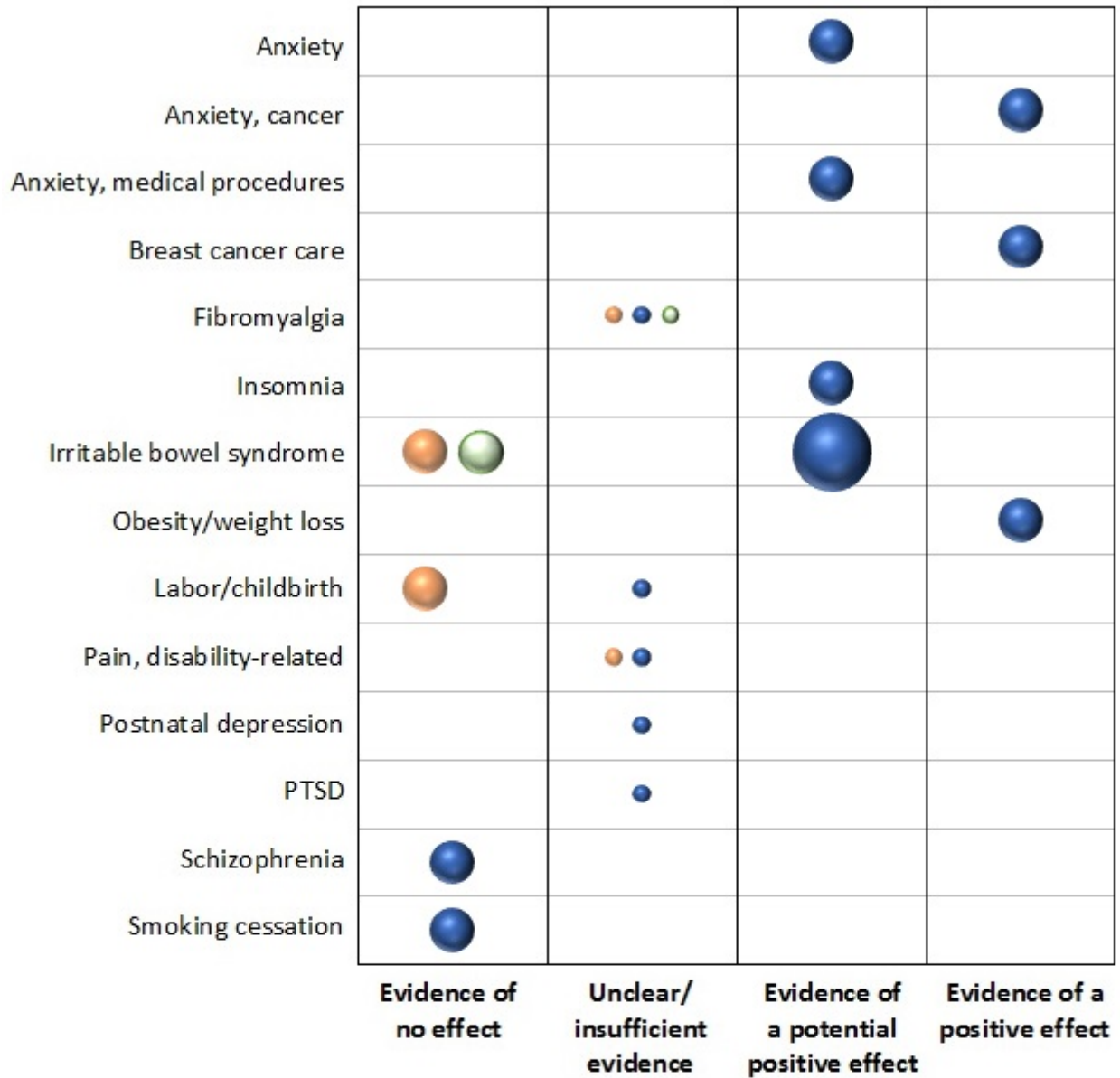
Across conditions, the evidence examining the effectiveness of hypnosis for the treatment of primary/diagnosis-related outcomes depended largely on the condition examined (Figure 5). Although our confidence estimates were low due to methodological concerns about the trials included in the SRs, there is evidence that hypnosis provides benefit over comparator interventions for anxiety related to cancer,¹⁸ breast cancer care (*ie*, pain, distress, fatigue, nausea/vomiting, and hot flashes),²⁴ and for weight loss in obese participants.⁴⁰ Weight loss was significantly greater for those hypnosis interventions that included a self-hypnosis component, and for trials comparing cognitive behavioral therapy (CBT) combined with hypnosis to CBT alone.⁴⁰

Findings from the systematic reviews also suggest with moderate confidence that hypnosis may potentially provide symptom relief and improved overall gastrointestinal functioning for patients with IBS.³⁵ However, findings indicate no effect on secondary outcomes for IBS (*ie*, pain, diarrhea, constipation, and bloating/distension, depression, anxiety), or health-related quality of life.³⁵ In addition, while our confidence ratings were low due to methodological limitations, findings also indicate the potential for hypnosis to provide symptom-related relief for anxiety related to generalized anxiety, phobic disorders, test anxiety,¹⁷ and medical procedures,¹⁹ as well as insomnia.³⁴

We identified limited evidence that hypnosis provides no benefit for smoking cessation,⁴⁸ or for schizophrenia,⁴⁷ nor does it have any effect on a wide range of maternal and infant outcomes during and after labor (Table 10 in Appendix D).³⁸ Findings related to all other conditions were insufficient (Figure 5; Table 10 in Appendix D).

Contributing to the generally low confidence levels for diagnosis-related outcomes were small combined samples sizes, poor study quality, and inconsistencies across studies included in the systematic reviews. For secondary and global outcomes, sample sizes were generally lower, results were inconsistent across studies, and study quality was generally poor (Table 7 in Appendix C). Although not a factor considered in our limited method of rating of confidence, comparison groups even within conditions were heterogeneous, ranging from no intervention to a wide range of active interventions.

Figure 5. Map of the evidence from systematic reviews of hypnosis interventions by clinical condition, evidence of effectiveness, and level of confidence



SUMMARY AND DISCUSSION

These evidence maps provide a broad overview of the evidence base regarding guided imagery, biofeedback, and hypnosis interventions. We systematically searched the literature for systematic reviews and meta-analyses of these interventions, and we included 40 good-quality systematic reviews examining these interventions across a variety of targeted health conditions. We compiled evidence maps to illustrate the reported effects of each intervention in the populations studied. Figure 6 on the following page shows the health conditions for which the interventions that were found to have either a consistently positive effect for any outcome, or consistent evidence of no effect; findings of potential or unclear effectiveness are not shown in Figure 6.

Biofeedback was the best studied intervention both in terms of the absolute size of the literature, and in terms of the overall level of confidence in findings. In particular, there was moderate to high level confidence that biofeedback is likely to be effective for urinary incontinence after prostatectomy, fecal incontinence, balance and gait in stroke patients, and headache. Indeed, the finding that biofeedback may improve global health outcomes in headache (both migraine and tension-type) and for urinary incontinence after prostatectomy (as an adjunct to pelvic floor muscle training) further underscores these as particularly promising areas for intervention.

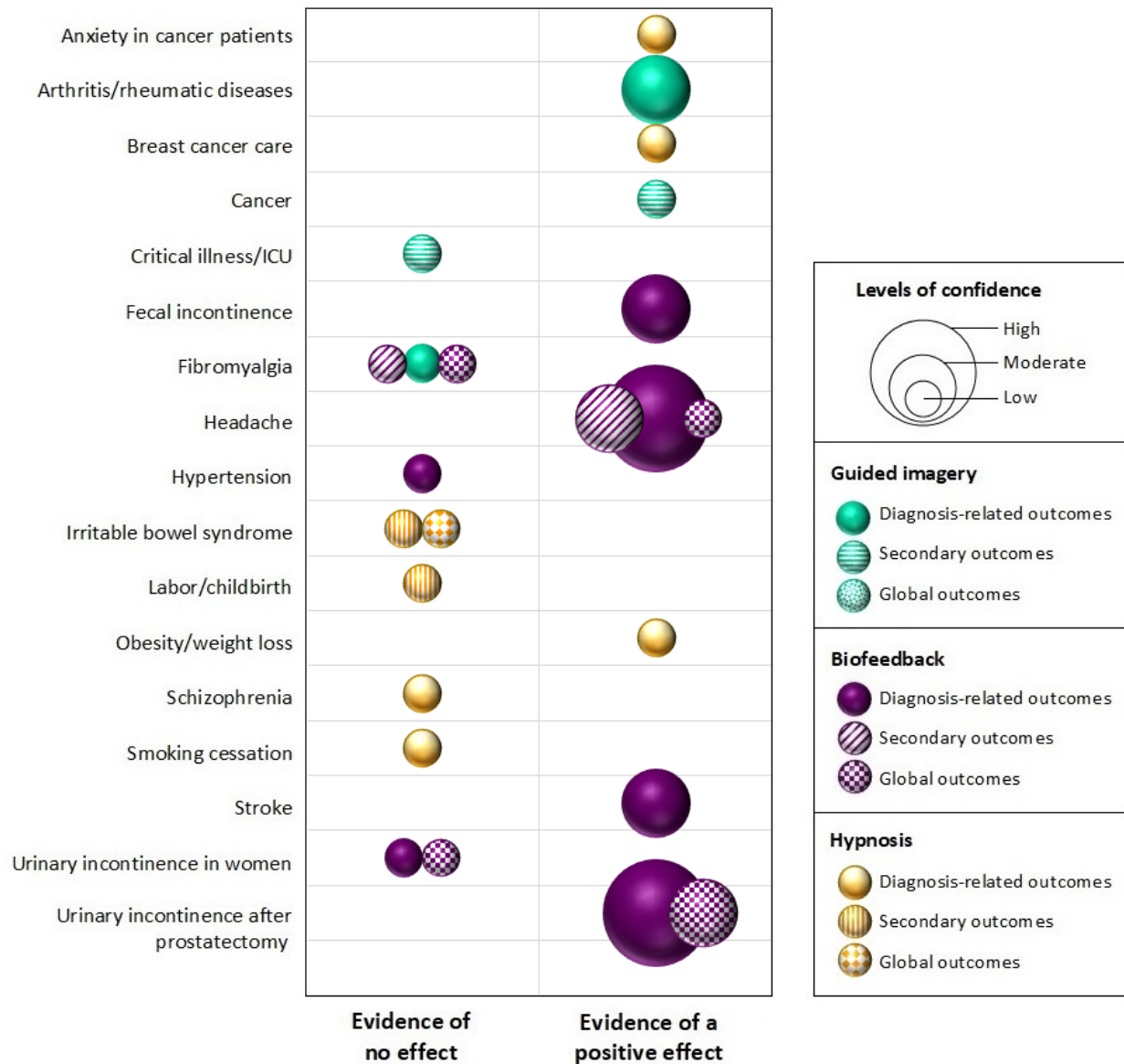
The only other intervention for which there was evidence of effectiveness supported by at least moderate level confidence was guided imagery in the treatment of patients with arthritis or other rheumatic diseases (Figure 6).

The level of confidence for the majority of outcomes for most of the health conditions that were included was low or insufficient, which suggests that further research in these areas is very likely to appreciably change our understanding of the effectiveness of these interventions. The most common reasons the level of confidence was inadequate were a limited number of trials/small combined sample sizes and methodologic limitations in the included RCTs. Of note, the reviews included in this report generally provide very little insight into the impact of these interventions on global outcomes such as quality of life and functional status.

Limitations

Because these evidence maps provide a broad overview of the existing evidence compiled by systematic reviews, they cannot be definitive in determining an absence of evidence. Many conditions for which these therapies have been utilized do not appear on the maps at all due to the lack of quality evidence syntheses. Because we relied on existing systematic reviews and did not perform a comprehensive search for primary trials, it is possible that more recent evidence is available, or that the interventions of interest have been tested in populations not represented in existing systematic reviews. Another potential limitation is that we included systematic reviews that focused specifically on the interventions of interest, and excluded systematic reviews that examined multiple treatments for a particular health condition. We attempted to mitigate potential loss of information by comparing the findings and included trials from more broadly scoped reviews with those of the more narrowly focused systematic reviews that we included. Finally, in regard to biofeedback, the use of systematic reviews meant that in many cases we were not able to distinguish the different types of biofeedback modalities, and were therefore unable to evaluate the utility of specific types of biofeedback. There may be evidence that some types but not others are effective for various conditions, but the evidence map format of this review precluded our ability to elucidate that level of granularity.

Figure 6. Evidence map of the health conditions for which guided imagery, biofeedback, and hypnosis interventions had evidence of a positive effect or evidence of no effect



The authors of the included reviews often noted lack of patient blinding, which is not surprising given the nature of the interventions. The role and necessity of patient blinding in studies of these types of interventions has been debated. There are techniques even for complex nonpharmacologic interventions to blind patients to some degree.⁵⁴ Some argue that lack of patient blinding in trials of non-pharmacologic therapies may considerably exaggerate treatment effects;⁵⁵ in which case, it would be difficult to determine whether and to what extent positive treatment effects – especially for the findings with only low level confidence – were due to an independent effect of treatment, expectancy as a mechanism of change, placebo effect, or a combination of these factors. On the other hand, others have argued that blinding is not only challenging but also potentially counterproductive as expectancy for change is thought to be an integral part of the intervention itself.⁵⁶

The decision about which conditions to implement these interventions in VA is a policy-level one that depends in part on consideration of the evidence regarding benefits and harms, as well as an understanding of the costs of the intervention, and patients' values and preferences. These maps provide only broad "brushstrokes" regarding the potential benefits of these interventions. Evidence maps such as these are not designed to provide definitive conclusions about benefit, and there are several reasons for cautious interpretation: 1) we relied only on systematic reviews and did not search for more recently published trials, 2) we cannot comment on the magnitude of treatment effect, 3) we relied on others' study quality assessments, and 4) our measure of the level of confidence cannot approach the rigor represented by standardized approaches⁵⁷ given the previously listed constraints. One should be particularly circumspect about the "potential for positive effect" findings since these were – by design – weighted toward identifying any potential area of benefit to aid with research prioritization.

Unfortunately, we have very little data from these reviews regarding harms as they were almost uniformly poorly reported. On the other hand, from a clinical and biologic plausibility standpoint, it is unlikely that these 3 interventions are associated with clinically significant harms.

RESEARCH GAPS/FUTURE RESEARCH

As stated above, the maps highlight many potential areas for future research. The interventions and health conditions for which there was evidence of a "potential positive effect" may be one place to start to prioritize research, since these findings may represent mixed findings across multiple outcomes. However, these specific conditions likely underscore potentially fruitful areas of research. Future studies should be designed to allow for patient blinding,⁵⁵ as this was a common and important weakness in much of the literature.

CONCLUSIONS

Of the 3 interventions, biofeedback was the most widely studied, and there was moderate- to high-level confidence that biofeedback is beneficial for urinary incontinence after prostatectomy, fecal incontinence, balance and gait in stroke patients, and headache. There was a moderate level of confidence that guided imagery has positive effects in the treatment of patients with arthritis or other rheumatic diseases. Positive effects were reported with hypnosis on obesity, anxiety in patients with cancer, and symptoms during breast cancer treatment, but the levels of confidence in these findings were low.

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